

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Investigating the effect of knee unloader brace compared to graded motor imagery on pain, function, range of motion, position sense, quality of life and and pain persistence in patients with knee osteoarthritis

Protocol summary

Study aim

Investigating the effect of knee unloader brace compared to graded motor imagery(GMI) on pain, function, range of motion, position sense, quality of life and and pain persistence in patients with knee osteoarthritis

Design

This is an unblinded randomized study on 24 patients with unilateral knee osteoarthritis over a 6-week period.

Settings and conduct

Calling patients and After reviewing the inclusion criteria and their satisfaction, they will enter the study from Shafa Yahyaian Orthopedic Hospital in Tehran and will be randomly assigned to the intervention and control groups. The study is not blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Knee osteoarthritis grade 2 and 3 , Age range 40 years to 65 years. Exclusion criteria: Previous knee surgery experience

Intervention groups

1. Intervention group: combined treatment of graded motor imagery (GMI) and knee Unloader brace(KUB) It is a combination of two methods, described below, and is performed for six weeks. 2. Intervention group: (GMI) (control group) (GMI) is a treatment program that aims to sequentially activate the premotor and primary motor cortex through three stages: lateral recognition, explicit motor imagery, and mirror therapy. It is performed over a six-week period. 3 Intervention group: (KUB) (control group) After being manufactured, this knee brace is worn on the patient's knee for six weeks.

Main outcome variables

Pain, function, range of motion, position sense, quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250822066950N1**

Registration date: **2025-10-10, 1404/07/18**

Registration timing: **registered_while_recruiting**

Last update: **2025-10-10, 1404/07/18**

Update count: **0**

Registration date

2025-10-10, 1404/07/18

Registrant information

Name

Seyede Gelare Razavi khorasani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4413 8605

Email address

razavi.ge@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-09-06, 1404/06/15

Expected recruitment end date

2025-11-21, 1404/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of knee unloader brace compared

to graded motor imagery on pain, function, range of motion, position sense, quality of life and and pain persistence in patients with knee osteoarthritis	
Public title	Comparative study of the effect of knee brace and GMI on knee osteoarthritis
Purpose	Supportive
Inclusion/Exclusion criteria	
Inclusion criteria:	Knee osteoarthritis grade 2 and 3 according to the Kellgren-Lawrence grading system Age range 40 years to 65 years (middle age) based on the new age range division
Exclusion criteria:	previous experience with knee surgery
Age	From 40 years old to 65 years old
Gender	Both
Phase	N/A
Groups that have been masked	No information
Sample size	Target sample size: 24
Randomization (investigator's opinion)	Randomized
Randomization description	In this study, 24 people will be enrolled and randomly assigned to one of three groups (each group has eight members). We will write the name and number of each person and put them in a box. Before drawing the names from the box, we will decide that the first eight people whose names are drawn from the box will be assigned to the combined therapy intervention group. The second eight will be assigned to the knee brace control group, and the last eight will be assigned to the Graded motor imagery control group. Thus, a lottery is held and the groups are filled in order. Then, the patients will be contacted and the interventions will begin.
Blinding (investigator's opinion)	Not blinded
Blinding description	
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	Ethics Committee of Iran University of Medical

Sciences
Street address
Central Building, Iran University of Medical Sciences, Next to Milad Tower, Tehran
City
Tehran
Province
Tehran
Postal code
1449614535
Approval date
2025-05-13, 1404/02/23
Ethics committee reference number
IR.IUMS.REC.1404.152

Health conditions studied

1

Description of health condition studied

Knee osteoarthritis

ICD-10 code

M17.1

ICD-10 code description

Unilateral primary osteoarthritis of knee

Primary outcomes

1

Description

Pain

Timepoint

Before the intervention, immediately after the end of the last intervention, one month after the end of the last intervention

Method of measurement

Visual Analog Scale Questionnaire and Western Ontario and McMaster Universities Arthritis Index Questionnaire

2

Description

Function

Timepoint

Before the intervention, immediately after the end of the last intervention

Method of measurement

Western Ontario and McMaster Universities Arthritis Index Questionnaire

3

Description

Range of motion

Timepoint

Before the intervention, immediately after the end of the last intervention

Method of measurement

Goniometer

4

Description

Quality of life

Timepoint

Before the intervention, immediately after the end of the last intervention

Method of measurement

SF36 Questionnaire

5

Description

Position sense

Timepoint

Before the intervention, immediately after the end of the last intervention

Method of measurement

Manual Situational Awareness Assessment Test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The group received a combination of Graded motor imagery(GMI) and a knee Unloader brace. Graded motor imagery is a treatment program that aims to sequentially activate the premotor and primary motor cortex through three stages: lateral recognition, explicit motor imagery, and mirror therapy. This method was identified as a therapeutic approach to address pain and functional issues in patients with chronic complex regional pain syndrome, but has since been used for other complex pain and movement disorders. In the present study, this method was implemented in people with knee osteoarthritis. It includes three stages of lateral recognition (weeks 1 and 2), imagined movements of the affected limb (weeks 3 and 4), and mirror therapy (weeks 5 and 6), which are carried out for 6 weeks. In the lateral diagnosis stage, the patient is shown a bank of limb images twice a day, and the patient must determine whether the limb is left or right in less than two seconds and practice this for 15 minutes daily. In the second stage, the patient must imagine performing movements such as walking and running, etc., twice a day, for 15 minutes each time. In the third stage, knee strengthening exercises are performed by the patient's healthy leg in front of a mirror, and the injured leg is hidden behind the mirror. This is also done for ten minutes a day for two weeks. This method is done by myself, and the implementation of this method is not exclusive to a particular company or institution, and according to articles, the method has validity and reliability. During these six weeks, knee brace treatment will also be used simultaneously. A knee unloader brace is a type of knee brace that can provide stability, support, and pain relief from knee osteoarthritis, which mainly affects only one side of the knee joint. This

unloader brace is designed to transfer or reduce the load from one side of the joint to the other. In other words, a unloader brace does what its name suggests, transferring stress from the injured side of the joint to the healthy side. Wearing a unloader brace may provide enough comfort to improve mobility and reduce pain during rest. In the present study, a brace with a structure based on an aluminum joint located on the inside of the knee is used by thermoplastic shells, one of which is placed on the thigh and the other on the shin, which are placed on the individual's leg by straps and a cross-shaped elastic strap creates a tensioning effect to transfer the load and reduce it to the opposite side. This brace is made for the individual by accurately measuring the height of the leg, the location of the knee axis, and the circumference of the thigh and knee and is worn on the knee for six weeks. It is also important to note that the knee brace is made for each person based on their body shape and the principles of design and construction, which is made, tested and fitted on the patient's body by an orthotist (myself), and no specific company or manufacturer makes it and it is personalized. The knee brace is worn full-time for 6 weeks.

Category

Rehabilitation

2

Description

Control group 1: Group with Graded motor imagery treatment Graded motor imagery is a treatment program that aims to sequentially activate the premotor and primary motor cortex through three phases: lateral recognition, explicit motor imagery, and mirror therapy. This method was identified as a therapeutic approach to address pain and functional issues in patients with chronic complex regional pain syndrome, but has since been used for other complex pain and movement disorders. In the present study, this method was implemented in people with knee osteoarthritis. It includes three phases of lateral recognition (weeks 1 and 2), imagined movements of the affected limb (weeks 3 and 4), and mirror therapy (weeks 5 and 6), which are carried out for 6 weeks. In the lateral diagnosis stage, the patient is shown a bank of limb images twice a day, and the patient must determine whether the limb is left or right in less than two seconds and practice this for 15 minutes daily. In the second stage, the patient must imagine performing movements such as walking and running, etc., twice a day, for 15 minutes each time. In the third stage, knee strengthening exercises are performed by the patient's healthy leg in front of a mirror, and the injured leg is hidden behind the mirror. This is also done for ten minutes a day for two weeks. This method is done by myself, and the implementation of this method is not exclusive to a particular company or institution, and according to articles, the method has validity and reliability.

Category

Rehabilitation

3

Description

Control group 2: Group with treatment of Unloader knee brace An unloader knee brace is a type of brace that can provide stability, support, and pain relief from osteoarthritis of the knee, which typically affects only one side of the knee joint. The brace is designed to transfer or reduce the load from one side of the joint to the other. In other words, An unloader knee brace does exactly what its name suggests, it transfers stress from the affected side of the joint to the healthier side. The use of a knee brace may provide sufficient comfort to improve mobility and reduce pain during rest. In the present study, a load-reducing knee brace with a structure based on an aluminum joint located on the inside of the knee and supported by thermoplastic shells, one of which is located on the thigh and the other on the shin, is used. The shells are placed on the individual's leg with straps and a cross-shaped elastic strap creates a tensioning effect to transfer the load and reduce it to the opposite side. This knee brace is made for the individual by accurately measuring the height of the leg, the location of the knee axis and the circumference of the thigh and knee And it is worn on the knee for six weeks. It is also important to note that the knee brace is made for each person based on their body shape and the principles of design and construction, which is made, tested and fitted on the patient's body by an orthotist (myself), and no specific company or manufacturer makes it and it is personalized. The knee brace is worn full-time for 6 weeks.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafa Yahyaian Hospital

Full name of responsible person

Seyede Gelare Razavi Khorasani

Street address

Next to the Islamic Consultative Assembly,
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shafa.iums@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr Majid Safa

Street address

Iran University of Medical Sciences, Next to Milad
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Web page address

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

Seyede Gelare Razavi Khorasani

Position

PHD condidate

Latest degree

Master

Other areas of specialty/work

Orthotics & Prosthetics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Title and more details about the data/document

All data is potentially shareable after de-identifying individuals.

When the data will become available and for how long

Access period begins one year after results are published.

To whom data/document is available

For researchers only

Under which criteria data/document could be used

In order to advance science and contribute to similar research

From where data/document is obtainable

gelarerazavii@gmail.com

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

The researcher should explain their research intentions and methods to the aforementioned email.

Comments