Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)

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+98 21 4413 8605

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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

1

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 Indext 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 Indext 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
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr Majid Safa
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Iran University of Medical Sciences, Next to Milad Tower
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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
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Other areas of specialty/work
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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