Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effects of Mobilization with movement technique and knee osteoarthritis conventional physiotherapy on disability, pain and spatiotemporal and kinematic characteristics of gait in individuals with knee osteoarthritis

Protocol summary

Study aim

General aim Investigating the effect of 10 treatment sessions of mulligan technique along with common physiotherapy in the knee joint on disability, pain and kinematic and spatiotemporal characteristics of walking and electromyographic activity of muscles during gait, sit to stand and static balance in people with knee osteoarthritis

Design

Clinical trial with treatment and control group, double-blind, stratified randomization on 38 patients by RANDOM NUMBER GENERATOR

Settings and conduct

First, the participants will be evaluated in the biomechanics laboratory, the subject and the examiner will be blind to the grouping and the examiner will not be present in the treatment process, then the examinees will receive 10 treatment sessions in the hospitals and clinics affiliated to the Iran University of Medical Sciences, then again will be evaluated in the laboratory.

Participants/Inclusion and exclusion criteria

- Age 40 to 70 years -Diagnosis of knee tibiofemoral joint arthrosis based on American College of Rheumatology criteria -Pain intensity (VAS) between 4 and 8 while walking at the time of evaluation - The severity of OA on K-L classification system, 2 and 3 - Ability to walk more than 6 meters -Pain of one-sided of the knee (even if a person has bilateral arthritis, a knee that is painful will be included in the study) - knee pain for more than 3 months

Intervention groups

In the treatment group, the participants will receive the common physiotherapy of knee arthrosis with the Mulligan technique, and in the control group they will receive the common physiotherapy of the knee arthrosis with the Mulligan technique in an artificial form. After 10 sessions of physiotherapy, the intervention group will receive electrical muscle stimulation along with walking for 12 sessions.

Main outcome variables

Disability, spatiotemporal and kinematic characteristics of walking and pain

General information

Reason for update

Completion and termination of sampling and addition of outcome and the second phase of the intervention, which was approved by the ethics committee.

Acronym

IRCT registration information

IRCT registration number: **IRCT20190315043058N2**
Registration date: **2024-01-09, 1402/10/19**
Registration timing: **prospective**

Last update: **2025-12-31, 1404/10/10**
Update count: **1**

Registration date

2024-01-09, 1402/10/19

Registrant information

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2024-01-29, 1402/11/09
Expected recruitment end date
2024-08-30, 1403/06/09
Actual recruitment start date
2024-01-29, 1402/11/09
Actual recruitment end date
2024-10-30, 1403/08/09
Trial completion date
2024-12-29, 1403/10/09

Scientific title
The effects of Mobilization with movement technique and knee osteoarthritis conventional physiotherapy on disability, pain and spatiotemporal and kinematic characteristics of gait in individuals with knee osteoarthritis

Public title
The effects of Mobilization with movement technique and knee osteoarthritis conventional physiotherapy in knee osteoarthritis.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
1) Age 40 to 70 years 2) Diagnosis of knee tibiofemoral joint arthrosis based on the criteria of the American College of Rheumatology (knee pain for at least the last 3 months, joint crepitation and morning stiffness lasting 30 minutes or less) by a specialist physician. 3) Pain intensity based on visual pain scale between 4 and 8 while walking at the time of evaluation 4) The severity of arthritis should be 2 and 3 based on the Kellgren and Lawrence classification system. 5) Ability to walk more than 6 meters 6) One-sided arthritis pain of the tibiofemoral joint of the knee (even if a person has bilateral arthritis, a knee that is painful will be included in the study) 7) Having knee pain for more than 3 months
Exclusion criteria:
1) Any neurological problem that affects a person's walking, such as a stroke 2) Arthritis secondary to trauma or accident or fracture in the joint 3) Any surgery and fracture in any of the lower limbs in the last year 4) Injection of corticosteroid or hyaluronic acid or platelet-rich plasma in the last 6 months 5) Any pain in the upper or lower joints 6) Heart problems with medium and high risk, such as uncontrolled angina or heart infarction in the last month 7) Inflammation and infection in the knee 8) Any prohibition to manual treatments such as severe osteoporosis or unstable joint 9) Cognitive problem 10) Receiving physiotherapy intervention for knee arthritis in the last 12 months 11) Body mass index above 35 12) Using walking aids 13) Smoking 14) Systemic diseases such as rheumatoid arthritis
Age
From **40 years** old to **70 years** old
Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **38**
Actual sample size reached: **38**
Randomization (investigator's opinion)
Randomized
Randomization description
Subjects will be divided into two control and treatment groups by the stratified randomization method, so the two groups will be balanced in terms of gender, and the process of this random division will be such that after creating blocks of 4 in each class (male gender and female) which consist of letters A and B, we will create a random sequence of these blocks using RANDOM NUMBER GENERATOR and the subjects will be placed in two control and treatment groups based on the order of reference by this sequence. The individual generating the randomization sequence will not participate in any other phase of the study.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, the examiner or the person in charge of data collection and the one who evaluates the outcome and the subject or the participant will not know how the groups are divided. The examiner will not be present at the stage of dividing the subjects into treatment and control groups and the rest of the study stages. Also, the treatment that the subjects will receive in both groups will be apparently and look the same. In the treatment group, the subjects will receive preparatory treatments, therapeutic exercises and manual treatments in the form of the Mulligan technique, and in the control group, the subjects will receive preparatory treatments, therapeutic exercises and manual treatments in the form of the Mulligan technique in a simulated form; The method of performing this technique will be in such a way that no force will be applied to the place of handing after correct handing.
Placebo
Used
Assignment
Factorial
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
Iran University of Medical Sciences, Hemet Highway, next to Milad Tower, Tehran
City
Tehran
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Tehran
Postal code
1341853347
Approval date
2023-10-23, 1402/08/01
Ethics committee reference number
IR.IUMS.REC.1402.665

2

Ethics committee
Name of ethics committee
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Iran University of Medical Sciences, Hemet Highway, next to Milad Tower, Tehran
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Approval date
2023-10-29, 1402/08/07
Ethics committee reference number
IR.IUMS.REC.1402.668

Health conditions studied

1

Description of health condition studied
Knee Osteoarthritis
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Disability score in Western Ontario and McMaster Universities Osteoarthritis Index questionnaire
Timepoint
Measurement of Western Ontario and McMaster Universities Osteoarthritis Index questionnaire score at the beginning of the study and after 10 sessions of physiotherapy treatment
Method of measurement
Western Ontario and McMaster Universities Osteoarthritis Index

Secondary outcomes

1

Description
Spatiotemporal and Kinematic characteristics of gait
Timepoint
Measurement of spatio-temporal and kinematic parameters of walking at the beginning of the study and after 10 sessions of physiotherapy treatment
Method of measurement
Vicon Motion Capture System

2

Description
Intensity of pain
Timepoint
Measurement of intensity of pain at the beginning of the study and after 10 sessions of physiotherapy treatment
Method of measurement
Visual Analogue Scale

3

Description
Characteristics of electromyographic activity of muscles during gait, sit to stand and static balance
Timepoint
Measurement of variables at the beginning of the study and after 10 sessions of physiotherapy treatment and after 12 sessions of home-based walking training.
Method of measurement
Kistler force plates and Myon electromyography system

Intervention groups

1

Description
Intervention group: Intervention group: The participants in this group will receive10 treatment sessions during 4 weeks with at least one day between sessions by a therapist who is proficient in the Mulligan technique and regular physical therapy. The treatment in each group lasts for 60 minutes and includes 3 phases of preparation, exercise therapy and manual treatments. The first phase, preparation: in this phase, subjects will receive high-frequency electrical nerve surface stimulation for 20 minutes and infra red for 15 minutes. 4 electrodes are placed inside wet pads around the knee joint (two electrodes on the medial of the knee above and below the joint line and two electrodes on the lateral of the knee above and below the joint line) and will be tightened by the strap. The frequency and pulse duration used will be 110 Hz and 50 microseconds, respectively. The second phase, exercise therapy: The exercise therapy for these people will be in the form of strengthening exercises, stretching exercises, and range of motion exercises. Strengthening exercises include isotonic contraction with the help of varying leg weights of the knee extensor and hip abductor muscles, respectively, in sitting positions on the edge of the bed and lying on the side while the painful knee is elevated, with a frequency of 3 sessions per week according to the

ability of the subject with The intensity of 60% to 80% of 1RM will include 2 to 4 sets of 8 to 15 sets, and between each set we will allocate 30 to 60 seconds of rest time to the subjects. We will use stretching exercises and active range exercises for muscle shortening or reducing the range of motion that disrupts the person's performance. Stretching exercises will be performed for 30 seconds in 3 sets of 10 for the biceps and hamstring muscles, and active and passive range of motion exercises will be performed in the form of movement from fully bent knee to fully straightened knee in 3 sets of 10. will get The third phase, manual treatments: At first, we will perform these exercises while lying on the back with the knees slightly bent. If the subject does not have pain in bending or straightening the knee while lying on the back, we will perform this technique for the subject while standing. gave Also, if after a few treatment sessions, the examiner does not have pain in bending and straightening his knee while lying on his back, we will follow the technique while standing. The treatment process will be like this, lying on the back with a slightly bent knee, we will ask the subject to actively bend and straighten the knee, then after placing hands around the knee joint, the subject's leg will be internally rotated, respectively. We will perform external rotation, internal glide, external glide, anterior glide and posterior glide and at the same time we will ask the subject to move his knee in the same painful direction and if the active movement of the subject that was painful before with any of the rotations or glides It was done without pain, we will use the same rotation or glide to continue the treatment. This technique should be performed without pain or with minimal pain, and if the pain decreases but does not reach zero, the therapist will reach a completely pain-free state by increasing or decreasing the applied pressure or applying additional pressure at the end of the range. This technique will be performed in the first session as a set of 6 and in the following sessions, according to the subject's ability, as 3 to 5 sets of 6 to 10. To perform the technique in a standing position, the subject will place the sole of the foot whose knee is painful on a stool at a height of 30 cm ; Then we will take active knee bending and straightening movements by applying internal and external rotations, internal and external glides, and anterior and posterior glides to the subject's leg. If the rotations do not hurt, we will continue the painful movement with the same rotation or glide for the subject. Secondary intervention description: After completion 10 sessions of the physiotherapy intervention, participants will be re-randomized, such that an equal number of participants from each group will be allocated to the intervention and control groups. In this study, the knee joint with more severe symptoms will be selected for assessment of muscle activation and fitting of the unloader knee brace. In cases where symptom severity is equal in both knees, the dominant knee will be selected. Both groups will use the brace daily for 1 to 8 hours and will perform twelve 30-minute walking sessions over a four-week period. The control group will use the unloader knee brace without electrical stimulation, whereas the NMES group will receive neuromuscular electrical stimulation concurrently with gait during walking. Stimulation intensity will be adjusted based on patient feedback up to the maximum tolerable level, such that painless muscle contractions are elicited, and participants will be encouraged to gradually increase the stimulation intensity. Electrode placement will be instructed by a physiotherapist, and patient adherence will be monitored through weekly follow-ups and adherence forms.

Category

Treatment - Other

2

Description

Control group: Intervention group: Intervention group: The participants in this group will receive10 treatment sessions during 4 weeks with at least one day between sessions by a therapist who is proficient in the Mulligan technique and regular physical therapy. The treatment in each group lasts for 60 minutes and includes 3 phases of preparation, exercise therapy and artificial manual treatments . The first phase, preparation: in this phase, subjects will receive high-frequency electrical nerve surface stimulation for 20 minutes and infra red for 15 minutes. 4 electrodes are placed inside wet pads around the knee joint (two electrodes on the medial of the knee above and below the joint line and two electrodes on the lateral of the knee above and below the joint line) and will be tightened by the strap. The frequency and pulse duration used will be 110 Hz and 50 microseconds, respectively. The second phase, exercise therapy: The exercise therapy for these people will be in the form of strengthening exercises, stretching exercises, and range of motion exercises. Strengthening exercises include isotonic contraction with the help of varying leg weights of the knee extensor and hip abductor muscles, respectively, in sitting positions on the edge of the bed and lying on the side while the painful knee is elevated, with a frequency of 3 sessions per week according to the ability of the subject with The intensity of 60% to 80% of 1RM will include 2 to 4 sets of 8 to 15 sets, and between each set we will allocate 30 to 60 seconds of rest time to the subjects. We will use stretching exercises and active range exercises for muscle shortening or reducing the range of motion that disrupts the person's performance. Stretching exercises will be performed for 30 seconds in 3 sets of 10 for the biceps and hamstring muscles, and active and passive range of motion exercises will be performed in the form of movement from fully bent knee to fully straightened knee in 3 sets of 10.The third phase, manual treatments: after the usual physical therapy exercises, the Mulligan technique will be performed in an artificial way for these patients in such a way that hands will be placed around the joint and the subject will be asked to bend and straighten his knee without applying glide or pressure, and we will perform this operation in 3 to 5 sets of 6 to 10, and we will give the patient a 60-second rest between each set. All the mentioned steps, including the evaluation to find the glide or rotation with pain-free movement, as well as the part of performing the technique for the treatment, for the implementation of this technique in the treatment group, will be done exactly for the control group, and as it was said, the only

difference will be this. It was that the glide or rotation in question will not be done in real way and no force will be applied and it will only be manual.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Firoozgar general Hospital

Full name of responsible person
Hanieh Javan

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Sponsors / Funding sources

1

Sponsor

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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
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Full name of responsible person
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Other areas of specialty/work
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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
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