Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the Non-thrust Manipulation VS. Muscle Energy Techniques in the Management of Patients with Knee Osteoarthritis: A Randomized Clinical Trial.

Protocol summary

Study aim

To evaluate the effectiveness of manipulation as compared with muscle energy techniques both with supervised exercise and electrical stimulation on pain, range of motion, performance and disability in patients with knee osteoarthritis.

Design

A concealed blinded, randomized, clinical trial with a parallel group design of 42 patients. Sequential numbers using an online randomization website will be used.

Settings and conduct

In patients with knee osteoarthritis (OA), joint mechanics and ineffective muscle working affect performance, and joint alignment. So the present study intends to evaluate the effectiveness of manipulation as compared with muscle energy technique on range of motion and performance of patients with knee OA, who refer to the physiotherapy clinic of the school of rehabilitation. The study will be double blinded (participant, accessor, analyzer) and coding to the evaluation forms will be used for blinding.

Participants/Inclusion and exclusion criteria

Patients with chronic knee Osteoarthritis (OA) (35- 65 years old, Visual Analogue Scale >=30mm, extension lack >10, Grade 2 OA) will be included. Patients with acute pain and inflammation, recent fractures and trauma, prolonged immobilization, severe cardiopulmonary disease, osteoporosis, rheumatoid arthritis, neurological disorders, and hip or knee arthroplasty will be excluded.

Intervention groups

In the group A, will receive manipulation included tibiofemoral distraction, anterior and posterior glide of the tibia on the femur and patellofemoral glide. In the group B, muscle energy technique will be used. Both of the intervention groups received the same supervised exercises and electrical stimulation.

Main outcome variables

Pain intensity at rest and during activity , 6-minute Walking Test, 30 Chair Stand Test, Lack of Knee Extension , Tibio-Femoral Angle, and Western Ontario and McMaster Universities scale.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210214050356N2**
Registration date: **2021-10-17, 1400/07/25**
Registration timing: **prospective**

Last update: **2021-10-17, 1400/07/25**
Update count: **0**

Registration date

2021-10-17, 1400/07/25

Registrant information

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-23, 1400/08/01

Expected recruitment end date

2022-01-21, 1400/11/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the Non-thrust Manipulation VS. Muscle Energy Techniques in the Management of Patients with Knee Osteoarthritis: A Randomized Clinical Trial.

Public title
Comparison of the Manual Therapy and Muscle Contraction in the treatment of Patients with Knee Arthrosis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with knee OA (diagnosed already) Age 35 -65 years Grade 2 Kellgren-Lawrence radiographic confirmed OA Unilateral or bilateral knee OA. Chronic stages of knee pain. Patients who scored 30mm out of 100mm knee pain or greater on the VAS with activity intervention at baseline. Those who consented were able to ambulate at least 30 meters on an even surface with or without a walking device and were able to perform physical exercises with minimal support. WOMAC score above 10. Knee extension lack 10 degrees or more.
Exclusion criteria:
Acute pain and inflammation. Recent fractures. Patients having other major musculoskeletal problems and having with red flag signs and patients with recent history of knee trauma.• Prolonged immobilization. Uncontrolled hypertension. Severe cardiopulmonary disease. Mentally challenged. Severe osteoporosis. Rheumatoid arthritis. Neurological disorders affecting lower limb. Individuals with impaired function such as stroke, neoplastic disorder and hip or knee arthroplasty. Gout or Psedo-gout. Hyper/ hypo-thyroidism.
Age
From **35 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **42**
Randomization (investigator's opinion)
Randomized
Randomization description
After the baseline assessment, the participants will be randomized into one of the two intervention groups using simple randomization procedure. Forty two cards will be collected inside a ball with no clinical involvement in the study to ensure allocation concealment. A computer generated list of random number will be used. Receptionists dispense either non-thrust manipulation or MET according to a computer generated randomization list includes the sequential numbers using an online randomization website (https://www.graphpad.com/quickcalcs/randomize1.cfm). Each number and it's allocate group will be written on a piece of paper and will be concealed in an opaque envelope. The receptionist will inform the treating therapist about patients' allocation according to the selected index card.
Blinding (investigator's opinion)
Double blinded
Blinding description
As mentioned above, the study will be double-blinded. In this way, the participants do not know in which group they are. Another physiotherapist will do the baseline and post-treatment evaluations without knowing which patients belonged to which groups (assessor-blinded).The data analyzer is also unaware of which study group the data belongs to.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences
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Approval date
2021-09-26, 1400/07/04
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1400.728

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 Intensity (at rest)
Timepoint
Before intervention- After the 10th intervention session (last session).
Method of measurement
Visual Analogue Scale

2

Description
Pain Intensity (during activities)
Timepoint
Before intervention- After the 10th intervention session (last session).
Method of measurement
Visual Analogue Scale

3

Description
Knee Extension Lack
Timepoint
Before intervention- After the 10th intervention session (last session).
Method of measurement
Passive Knee Extension Test by using Goniometer.

4

Description
Functional impairment
Timepoint
Before intervention- After the 10th intervention session (last session).
Method of measurement
Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC).

Secondary outcomes

1

Description
Distance Covered
Timepoint
Before intervention- After the 10th intervention session (last session).
Method of measurement
Six Minutes Walking Test (6MWT)

2

Description
Chair Stand Repetition
Timepoint
Before intervention- After the 10th intervention session (last session).
Method of measurement
30 Seconds Chair Stand Test (30CST)

3

Description
Knee Mal-alignment
Timepoint
Before intervention- After the 10th intervention session (last session).
Method of measurement
Tibio-Femoral Angle (TFA) by using Goniometer.

Intervention groups

1

Description
Intervention group: Group A: will receive non-thrust manipulation supplemented with supervised exercises and TENS program at the clinic (three times a week), consisting of 10 sessions of approximately 50 min. Non thrust manipulation included Tibiofemoral Distraction, Anterior glide, Posterior glide of the tibia on the femur with grades II and III will be applied with the knee in slight flexion supported with using a pillow and Patellofemoral Joint glide in all directions based on the observation that in patients with patellofemoral joint osteoarthritis. This will be given for three repetitions of 1 minute each with a 30 second break between each repetition. Each direction will be repeated two times.
Category
Rehabilitation

2

Description
Intervention group: Group B: Contract–relax agonist contract (CRAC) which is one of muscle energy techniques will be used in this study supplemented with supervised exercises and electrical stimulation at the clinic (three times a week), consisting of 10 sessions of approximately 50 min.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
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Sponsors / Funding sources

1

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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
Tehran 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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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
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
Yes - There is 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 unidentified individuals.
When the data will become available and for how long
Access period starts 3 months after the articles are published.
To whom data/document is available
For researchers working in academic, scientific and hospital institutions and clinicians.
Under which criteria data/document could be used
Researchers working in the field of musculoskeletal disorders rehabilitation and manual therapies.
From where data/document is obtainable
Applicants for documentation can contact Dr. Sara Fereydoonnia via email. S-fereydounnia@sina.tums.ac.ir
What processes are involved for a request to access data/document
Once they have the necessary criteria, the information will be provided to them within a month.
Comments