

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 ≥ 30 mm, extension lack $>10^\circ$, 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

Name

Sara Fereydounnia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7752 8468

Email address

s-fereydounnia@sina.tums.ac.ir

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.

AgeFrom **35 years** old to **65 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample sizeTarget 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

Street address

Vice Chancellor for Research, 6th Floor, Central University Organization, Corner of Ghods St, Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1417653761

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

Name of recruitment center

Tehran University of Medical Sciences

Full name of responsible person

Sara Fereydounnia

Street address

corner of Ghods Street, Boulevard

City

Tehran

Province
Tehran
Postal code
۱۴۱۷۶۵۳۷۶۱
Phone
+98 21 7752 8468
Email
s-fereydounnia@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Akbar Fotouhi
Street address
Vice Chancellor for Research and Technology, sixth floor, Central University Organization, corner of Quds Street, Keshavarz Boulevard
City
Tehran
Province
Tehran
Postal code
۱۴۱۷۶۵۳۷۶۱
Phone
+98 21 8163 3639
Email
research@tums.ac.ir

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
Tehran University of Medical Sciences
Full name of responsible person
Sara Fereydounnia
Position
Assistant Professor
Latest degree
Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

School of Rehabilitation, Piche- Shemiran, Enghelab Street

City

Tehran

Province

Tehran

Postal code

1148965111

Phone

+98 21 7752 8468

Fax

Email

S-fereydounnia@sina.tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Azadeh Shadmehr
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address
School of Rehabilitation, Piche- Shemiran, Enghelab Street
City
Tehran
Province
Tehran
Postal code
1148965111
Phone
+98 21 7752 8468
Fax
Email
Shadmehr@tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Sara Fereydounnia
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address
School of Rehabilitation, Piche- Shemiran, Enghelab Street

City
Tehran
Province
Tehran
Postal code
1148965111
Phone
+98 21 7752 8468
Fax
Email
S-fereydounnia@sina.tums.ac.ir

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 Fereydounnia 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