

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effects of adding dry needling technique to Mulligan's mobilization with movement technique along with exercise therapy on pain, range of motion, disability and balance in patients with knee osteoarthritis

#### Protocol summary

##### Study aim

Determining the effect of adding dry needling technique to Mulligan's mobilization with movement technique along with exercise therapy on pain, range of motion, disability and balance in patients with knee osteoarthritis

##### Design

A randomized, double blind, sham controlled clinical trial with a parallel group design of 48 patients. Random allocation method is Permuted Block Randomization.

##### Settings and conduct

location: official centers of bushehr university of medical science. for group 1, mulligan's mobilization with movement technique with exercise therapy with dry needling is applied on patients. for group 2, these treatments are all applied while dry needling is sham. blinding: patient, researcher, therapist, outcomes assessor, data analyzer.

##### Participants/Inclusion and exclusion criteria

Inclusion: age 45 to 70; knee osteoarthritis with at least one active trigger point; knee pain more than 3 in visual Analogue Scale (VAS) and disability more than 25 in Western Ontario and McMaster Universities Arthritis Index (WOMAC) scale; at least 10 degrees loss in knee flexion range of motion. Exclusion: knee replacement surgery; neurologic disease; Rheumatoid Arthritis; steroid and analgesic injection in last 3 month in knee; fibromyalgia; inflammation or infection; pregnancy; diabetes; epilepsy; needle phobia; any trigger points treatment in last 3 month; vascular disease; fracture; physiotherapy in last 3 month for knee joint.

##### Intervention groups

Group 1: mulligan's mobilization with movement technique with exercise therapy with dry needling & 2: all above treatments but sham dry needling.

##### Main outcome variables

Pain; range of motion; disability; number of active trigger points in muscles around knee; local pain assessment in

active trigger points; functional mobility; balance.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20221026056300N1**

Registration date: **2022-11-12, 1401/08/21**

Registration timing: **prospective**

Last update: **2022-11-12, 1401/08/21**

Update count: **0**

##### Registration date

2022-11-12, 1401/08/21

##### Registrant information

##### Name

Maryam Eshghi Vasoukolaei

##### Name of organization / entity

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Iran (Islamic Republic of)

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-11-21, 1401/08/30

##### Expected recruitment end date

2023-01-19, 1401/10/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

The effects of adding dry needling technique to Mulligan's mobilization with movement technique along with exercise therapy on pain, range of motion, disability and balance in patients with knee osteoarthritis

**Public title**

The effects of adding dry needling technique to manual therapy in treatment of patients with knee osteoarthritis

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age between 45 - 70, Unilateral or bilateral knee pain and dysfunction, in bilateral knee pain, the knee with more pain will be cured, Knee osteoarthritis with grade 2 and 3 Kellgren & Lawrence, At least one active trigger point in muscles around knee that refer pain, Knee pain more than 3 in VAS scale, Ability to walk for 6 meters and more, Disability more than 25 in WOMAC scale, At least 10 degrees loss in knee flexion range of motion.

**Exclusion criteria:**

Neuropathic pain in lower limb, Knee replacement surgery, Surgery in other parts of lower limb in last 6 month. Radicular pain in knee, Neurologic diseases, Rheumatoid Arthritis, Steroid and analgesic injection in last 3 month in knee, Fibromyalgia syndrome, Patellar tendinopathy, Inflammation or active infection signs in knee, Pregnancy, Diabetes, Epilepsy, Immune system diseases like AIDS, Cancer, Hepatitis, Phobia of needle in dry needling technique, Any treatment for trigger points in considering muscles in last 3 month, Vascular disease associated with unusual bleeding, Treatment with Anticoagulants, Pain in lower limb associated with low back pain, Fracture or any other orthopedic problem in involved lower limb, Musculoskeletal disorders in other joints in lower limb (except osteoarthritis) Physiotherapy sessions in last 3 month for knee joint.

**Age**From **45 years** old to **70 years** old**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**Target sample size: **48****Randomization (investigator's opinion)**

Randomized

**Randomization description**

Random allocation method in this study is Permuted Block Randomization. A represents the person who receives mulligan's mobilization with movement

technique along with exercise therapy with dry needling technique and B represents the person who receives mulligan's mobilization with movement technique along with exercise therapy with sham dry needling technique. This method runs with considering 4 blocks that the number of all possible 4 permutations equals 6. (4 permutations blocks consist of: ABAB ,ABBA ,BAAB ,BABA ,AABB ,BBAA) We assign a number to each mode. Using Random Numbers Table, a list with 48 persons will be produced.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study, main student doing initial assessment based on inclusion and exclusion criteria and treatments in patients. assistant student collecting data from patients and analyzing them. Allocation base on Permuted Block Randomization and for blinding in patients, sham dry needling applied in that way that the patient can't realize that it is not real.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

This study is added value study.it means that dry needling technique is added to mulligan's mobilization with movement technique.one group receives Mulligan's mobilization with movement technique along with exercise therapy with dry needling technique and another group receives Mulligan's mobilization with movement technique along with exercise with sham dry needling technique.

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of shiraz university of medical sciences

**Street address**

Seventh floor, Central building of Shiraz university of medical sciences, Zand ave., Shiraz

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7134814336

**Approval date**

2022-10-19, 1401/07/27

**Ethics committee reference number**

IR.SUMS.REHAB.REC.1401.036

## Health conditions studied

### 1

#### Description of health condition studied

Knee Osteoarthritis

#### ICD-10 code

M17

#### ICD-10 code description

Osteoarthritis of knee

## Primary outcomes

### 1

#### Description

Pain

#### Timepoint

Before treatment, After treatment, 4 weeks after treatment

#### Method of measurement

Visual Analogue Scale

### 2

#### Description

Knee Range of Motion

#### Timepoint

Before treatment, After treatment, 4 weeks after treatment

#### Method of measurement

Goniometer

### 3

#### Description

Disability

#### Timepoint

Before treatment, After treatment, 4 weeks after treatment

#### Method of measurement

Western Ontario and McMaster Universities Osteoarthritis Index questionnaire

### 4

#### Description

Number of active trigger points in muscles around knee

#### Timepoint

Before treatment, After treatment, 4 weeks after treatment

#### Method of measurement

Counting active trigger points

### 5

#### Description

Local pain of trigger points in muscles around knee

#### Timepoint

Before treatment, After treatment, 4 weeks after treatment

#### Method of measurement

Visual Analogue Scale

## Secondary outcomes

### 1

#### Description

Functional mobility

#### Timepoint

Before treatment, After treatment, 4 weeks after treatment

#### Method of measurement

Timed Up and Go test

### 2

#### Description

Balance

#### Timepoint

Before treatment, After treatment, 4 weeks after treatment

#### Method of measurement

Modified STAR Excursion Balance Test (mSEBT)

## Intervention groups

### 1

#### Description

Intervention group: Mulligan's mobilization with movement technique along with exercise therapy with dry needling technique

#### Category

Rehabilitation

### 2

#### Description

Intervention group: Mulligan's mobilization with movement technique along with exercise therapy with sham dry needling technique

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Bushehr University of Medical Sciences

##### Full name of responsible person

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## Sponsors / Funding sources

### 1

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**Name of organization / entity**  
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**Full name of responsible person**  
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<https://research.sums.ac.ir>

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Shiraz 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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## Person responsible for updating data

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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