

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of the effect of physiotherapy and physiotherapy with dry needling on pain, Range of motion, physical function, functional performance and the effectiveness of treatment in patients with primary knee osteoarthritis.

#### Protocol summary

##### Study aim

The effect of adding dry needle on trigger points to routine physiotherapy program on pain, range of motion, physical function, functional performance and effectiveness of treatment in patients with primary knee osteoarthritis.

##### Design

Clinical trial with control group, parallel groups, blinded, randomized, on 28 patients.

##### Settings and conduct

People with primary osteoarthritis of the knee after evaluation are randomly divided into two groups: physiotherapy and physiotherapy with dry needling. Individual background information will be recorded. Individuals in both groups receive 12 session of treatment for 4 weeks. The place of intervention: Tehran, Gamino physiotherapy center Blinding: participants and outcome assessors

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Participants aged 40 years or older with knee pain and dysfunction, Diagnosis of primary knee osteoarthritis (Kellgren-Lawrence 1-3), At least one active or latent myofascial trigger point ipsilateral to the painful knee(s), pain of at least 2 on the NRS scale for more than 3 months. Exclusion criteria: Suffering from other conditions that could cause myofascial or neuropathic pain in the lower limb, Previous total replacement, Any other surgical procedure of the lower limbs in the previous 6 months, Myopathy or lumbosacral neuropathy, Physical therapy, acupuncture or other treatments for the painful knee in the last 6 months, Inflammatory joint disease such as rheumatoid arthritis, Serious trauma or systematic disease

##### Intervention groups

Intervention group: Routine physiotherapy and dry needling Control group: Routine physiotherapy

#### Main outcome variables

Pain intensity on the NRS scale; Knee joint range of motion with goniometer; Physical function with WOMAC questionnaire; Functional performance with TUG test; The effectiveness of treatment with GROG scale

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210314050704N1**

Registration date: **2022-04-23, 1401/02/03**

Registration timing: **prospective**

Last update: **2022-04-23, 1401/02/03**

Update count: **0**

##### Registration date

2022-04-23, 1401/02/03

##### Registrant information

##### Name

Mahdie Morshedlou

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 4221 4227

##### Email address

morshedloum981@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-05-05, 1401/02/15

**Expected recruitment end date**

2023-02-19, 1401/11/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the effect of physiotherapy and physiotherapy with dry needling on pain, Range of motion, physical function, functional performance and the effectiveness of treatment in patients with primary knee osteoarthritis.

**Public title**

The effect of dry needling on knee osteoarthritis

**Purpose**

Treatment

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

Participants aged 40 years or older with knee pain and uni- or bilateral dysfunction Diagnosis of primary knee osteoarthritis based on clinical and radiographic findings (Kellgren-Lawrence 1-3) At least one active or one latent myofascial trigger point elicited by palpation ipsilateral to the painful knee(s) Pain of at least 2 on the NRS scale for more than 3 months

**Exclusion criteria:**

Suffering from other conditions that could cause myofascial or neuropathic pain in the lower limb, such as lumbar radiculopathy, saphenous nerve entrapment, or paresthetica meralgia Previous total replacement of the same knee or both knees Any other surgical procedure of the lower limbs in the previous six months Medical record for myopathy or lumbo-sacral neuropathy physical therapy, acupuncture or other treatments for the painful knee in the last 6 months Inflammatory joint disease such as rheumatoid arthritis Serious trauma or systematic disease

**Age**

From **40 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **28**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Block randomization using closed envelopes so that the number of samples, gender and unilateral or bilateral osteoarthritis are equal in two groups. The 4-volume random block allocation method will be used. All possible 4 permutations will be listed in two groups (permutations 1 to 6 are as follows) A is the intervention group and B is

the control group: 1-AABB 2-ABAB 3-BAAB 4-BABA 5-BBAA 6-ABBA Then, from a random number table with a random starting point, 6 numbers between 1 and 6 will be randomly selected (either using software or randomaize.com). For example, if the 6 random numbers obtained are 3 5 4 3 4 6 , It will mean that the first four people similar to block 3, the second four people similar to block 5 and ... will be allocated.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

This study will be performed in a double-blind manner and the blinding includes a physiotherapist who performs the pre- and post-treatment evaluation in addition to the person who analyzes the data.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics committee of Mashhad University of Medical Sciences

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Faculty of Paramedical Sciences, Mashhad University of Medical Sciences, Azadi Sq

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Razavi Khorasan

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9177948964

**Approval date**

2022-03-05, 1400/12/14

**Ethics committee reference number**

IR.MUMS.FHMPM.REC.1401.002

**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 intensity in Numeric Rating Scale index

### **Timepoint**

Before and after the intervention

### **Method of measurement**

Numeric Rating Scale index

## **Secondary outcomes**

## 1

### **Description**

Knee joint range of motion

### **Timepoint**

Before and after the intervention

### **Method of measurement**

Goniometer

## 2

### **Description**

physical function

### **Timepoint**

Before and after the intervention

### **Method of measurement**

Western Ontario and McMaster Universities Osteoarthritis Index questionnaire

## 3

### **Description**

Functional performance

### **Timepoint**

Before and after the intervention

### **Method of measurement**

Timed Up and Go test

## 4

### **Description**

The effectiveness of treatment

### **Timepoint**

After the intervention

### **Method of measurement**

Global Rating of Change scale

## **Intervention groups**

## 1

### **Description**

Intervention group: Physiotherapy with dry needling. Participants in this group receive 12 sessions (3 times a week) of routine physiotherapy (Electrotherapy, manual therapy and exercise therapy) with dry needling at the trigger points of the muscles around the knee and hip.

### **Category**

Rehabilitation

## 2

### **Description**

Control group: Routine physiotherapy. Participants in this group receive 12 sessions (3 times a week) of routine physiotherapy (Electrotherapy, manual therapy and exercise therapy).

### **Category**

Rehabilitation

## **Recruitment centers**

## 1

### **Recruitment center**

#### **Name of recruitment center**

Gamino physiotherapy center

#### **Full name of responsible person**

Mona Nowrouzi

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No. 10, Ashkan building, Baghdarnia Ave, East Farjam Blvd, Tehranpars

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## **Sponsors / Funding sources**

## 1

### **Sponsor**

#### **Name of organization / entity**

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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**

Mashhad 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**  
Mashhad University of Medical Sciences  
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## Person responsible for scientific inquiries

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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