

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of dry needling and functional joint mobilization with functional joint mobilization only on pain, disability and quality of life in patients with patellofemoral pain syndrome

#### Protocol summary

##### Study aim

Comparing the effects of functional mobilization with functional mobilization and dry needling in relation to pain, disability, quality of life and the effectiveness of treatment in people with patellofemoral joint pain syndrome

##### Design

The present clinical trial will have a control group, with parallel, double-blind, randomized groups on 56 patients. The closed envelope method will be used for randomization.

##### Settings and conduct

Physiotherapy clinic of Ghaem University Hospital

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Aged between 18 and 40 years The diagnosis of this syndrome is based on pain behind the patella or around the patella, which occurs with at least two opposite activities including squatting, climbing stairs, going downstairs, sitting for a long time, and kneeling. Presence of at least one active trigger point. Have at least a score of 3 on the VAS pain scale.  
Exclusion criteria: History of knee surgery Patellar tendinopathy or osteoarthritis Symptoms of pressure on the lumbosacral nerve root History of injection, dry needling treatment of the quadriceps or knee muscles Any knee sports injury such as a meniscus tear or cruciate ligament injury Anticoagulant drugs usage Pregnancy Any structural problem on the lower limb Any peripheral or central neurological damage Diabetes Fear of needles Presence of bilateral femoral patellar pain

##### Intervention groups

Patients are divided into two groups: routine physiotherapy with dry needling and functional mobilization and routine physiotherapy with functional mobilization.

##### Main outcome variables

pain and function

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20221030056342N1**

Registration date: **2023-01-28, 1401/11/08**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-01-28, 1401/11/08**

Update count: **0**

##### Registration date

2023-01-28, 1401/11/08

##### Registrant information

##### Name

Afsaneh Zeinalzadeh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3884 6710

##### Email address

zeinalzadehaf@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-12-01, 1401/09/10

##### Expected recruitment end date

2023-07-21, 1402/04/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Comparison of dry needling and functional joint mobilization with functional joint mobilization only on pain, disability and quality of life in patients with patellofemoral pain syndrome

## Public title

Comparison of dry needling and functional joint mobilization with functional joint mobilization only on pain, disability and quality of life in patients with patellofemoral pain syndrome

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

The age of participants is between 18 and 40 years. The diagnosis of this syndrome is based on the pain behind the Patella or around the patella. Presence of at least one active trigger point. Have at least a score of 3 on the VAS pain scale.

### Exclusion criteria:

History of knee surgery P Patellar tendinopathy or osteoarthritis, any systemic disease Symptoms of pressure on the lumbosacral nerve root If the participants had acupuncture, injection or dry needling treatment of the quadriceps or knee muscles in the last 6 months. knee sports injury such as meniscus tear or cruciate ligament injury If the participants use anticoagulant drugs, or have blood disorders or are pregnant. Any structural problem of the lower limb (such as arthritis or the presence of a prosthesis) Any peripheral or central neurological damage or chronic disease such as diabetes Any Fear of needles resence of bilateral patellofemoral pain syndrome.

## Age

From **18 years** old to **40 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

## Sample size

Target sample size: **56**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Blocked randomization will be done using random block method. Using the Sealedenvelope.com website, a sequence of 28 letters consisting of letters a and b will be placed in opaque, sealed envelopes, respectively. When the patients visit, the envelopes are taken from the collection of envelopes and according to the order determined by the number on the back of the envelopes, the sample allocator (department secretary) after obtaining informed consent, opens the envelope and assigns the patient to the relevant group. The secretary of the department is also unaware of how to code.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

The allocator is the secretary of the physiotherapy department and does not know how to code. Also, the evaluator and statistical analyst are not aware of the way of grouping. Allocation Concealment method: closed, opaque, and sealed envelopes and numbered in order

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Research Ethics Committees of School of Paramedical Sciences and Health School

##### Street address

Khorasan Razavi, Mashhad, Shaheed Fakuri Blvd, between Shahidjovan and Al Shahidi Square, Danesh and Salamat Shahrek

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

91778-97165

#### Approval date

2022-07-30, 1401/05/08

#### Ethics committee reference number

IR.MUMS.FHMPM.REC.1401.088

## Health conditions studied

### 1

#### Description of health condition studied

Patella Femoral Pain Syndrome

#### ICD-10 code

M22.2X

#### ICD-10 code description

Patellofemoral disorders

## Primary outcomes

### 1

#### Description

Pain

#### Timepoint

Visual Analogue scale

#### Method of measurement

In this scale, there is a horizontal line of 10 cm. The left end of this line corresponds to the absence of pain and

the other end corresponds to the most intense pain that a person experiences. The distance between the two ends is calculated in centimeters and is calculated as the pain intensity.

## 2

### **Description**

Performance

### **Timepoint**

Persian version of Kujala questionnaire

### **Method of measurement**

It is used to assess the functional activity of the knee during movements that potentially stress the knee joint. This questionnaire contains 13 items that are completed by the participant. The scoring range of this questionnaire is from zero to one hundred. Higher scores indicate lower levels of disability, and zero means the most severe disability. The Persian version of this questionnaire has been localized and validated for patients with patellofemoral pain syndrome.

## **Secondary outcomes**

## 1

### **Description**

Quality of Life

### **Timepoint**

Before and after of treatment

### **Method of measurement**

Persian questionnaire SF36

## 2

### **Description**

The effectiveness of treatment

### **Timepoint**

Before and after of treatment

### **Method of measurement**

Global Rating Scale

## **Intervention groups**

## 1

### **Description**

Intervention group: At first, they receive conventional physiotherapy. Exercises are applied in 3 sets with 10 repetitions. The cold pack is applied for 15 minutes after the sessions. Physiotherapy takes place for 12 sessions and 3 times a week. Patients will be taught knee and thigh strengthening exercises at home and exercise brochures will be provided to them. In addition to these, neuromuscular electrical stimulation is used for patients, in which the patient contracts his quadriceps muscle simultaneously with the electrical current. Two surface adhesive electrodes are attached to the movement points of the quadriceps: on the vastus medialis and the vastus lateralis. During the application of neuromuscular electrical stimulation, the patient performs two types of movements: 1. Isometric quadriceps strengthening (30

isometric exercises) 2. Then Terminal knee extension from zero to 30 degrees (30 isotonic exercises).

### **Category**

Rehabilitation

## 2

### **Description**

Intervention group: Functional mobilization is the second intervention, which includes movement of the patella and movement of internal rotation of the tibia in relation to the femur, first in a less functional and non-weight bearing state, then in a weight bearing state, while bending and straightening the knee, standing, squatting, and on the stairs.

### **Category**

Rehabilitation

## 3

### **Description**

Intervention group: The third intervention is the use of dry needling for the quadriceps muscles in the trigger pain points that are detected by the physiotherapist during the manual examination.

### **Category**

Rehabilitation

## 4

### **Description**

Control group: At first, they receive conventional physiotherapy. Exercises are applied in 3 sets with 10 repetitions. The cold pack is applied for 15 minutes after the sessions. Physiotherapy takes place for 12 sessions and 3 times a week. Patients will be taught knee and thigh strengthening exercises at home and exercise brochures will be provided to them. In addition to these, neuromuscular electrical stimulation is used for patients, in which the patient contracts his quadriceps muscle simultaneously with the electrical current. Two surface adhesive electrodes are attached to the movement points of the quadriceps: on the vastus medialis and the vastus lateralis. During the application of neuromuscular electrical stimulation, the patient performs two types of movements: 1. Isometric quadriceps strengthening (30 isometric exercises) 2. Then Terminal knee extension from zero to 30 degrees (30 isotonic exercises).

### **Category**

Rehabilitation

## 5

### **Description**

Control group: Functional mobilization is the second intervention, which includes movement of the patella and movement of internal rotation of the tibia in relation to the femur, first in a less functional and non-weight bearing state, then in a weight bearing state, while bending and straightening the knee, standing, squatting, and on the stairs.

### **Category**

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Physical Therapy Clinic of Qaem Hospital

**Full name of responsible person**

Mr. Javad Zarandi

**Street address**

Narjes building, first floor, Physiotherapy Department,  
Qaem Hospital, Nurse Street.

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9176699199

**Phone**

+98 51 3841 1538

**Email**

zarandiMJ1@mums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr. Majid Ghayour Mobarhan

**Street address**

Ghoreshi Building, Doctora Crossroad.

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9919191778

**Phone**

+98 51 3841 1538

**Email**

vcresearch@mums.ac.ir

**Grant name**

Mashhad University of Medical Sciences

**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

**Full name of responsible person**

Zohre Khorshidi

**Position**

MSc Colleague

**Latest degree**

Bachelor

**Other areas of specialty/work**

Physiotherapy

**Street address**

Faculty of Paramedical Sciences, University campus,  
East entrance of Ferdowsi University of Mashhad,  
Azadi Square, Mashhad.

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177948964

**Phone**

+98 51 3869 8719

**Email**

Zohreh.khorshidi7@gmail.com

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Zohreh Khorshidi

**Position**

MSc Colleague

**Latest degree**

Bachelor

**Other areas of specialty/work**

Physiotherapy

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Faculty of Paramedical Sciences, University campus,  
East entrance of Ferdowsi University of Mashhad,  
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Razavi Khorasan

**Postal code**

9177948964

**Phone**

+98 51 3869 8719

**Email**

Zohreh.khorshidi7@gmail.com

## Person responsible for updating data

#### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Zohreh Korshidi

**Position**

MSc Colleague

**Latest degree**

Bachelor

**Other areas of specialty/work**

Physiotherapy

**Street address**

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9177948964

**Phone**

+98 51 3869 8719

**Email**

Zohreh.korshidi7@gmail.com

**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**

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**

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

**Title and more details about the data/document**

All data will be reported in the form of a research article.

Raw data will be delivered to researchers for meta analysis.

**When the data will become available and for how long**

6 months after publication

**To whom data/document is available**

For researchers only

**Under which criteria data/document could be used**

For meta-analysis Only

**From where data/document is obtainable**

zeinalzadehAF@mums.ac.ir

**What processes are involved for a request to access data/document**

The response will be sent 3 within months after considering the researcher's request.

**Comments**