

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effects of exercise therapy plus Quadriceps , Gluteus Medius and Quadratus Lumborum self-myofascial-release on pain , function and balance in patients with patellofemoral pain through telerehabilitation

#### Protocol summary

##### Study aim

The aim of this study is to investigate the effects of exercise therapy plus Quadriceps , Gluteus Medius and Quadratus Lumborum self-myofascial-release on pain , function and balance in patients with patellofemoral pain (PFP)through telerehabilitation

##### Design

A randomized clinical trial with controlled, paralleled groups, single blind with a sample size of 60 people

##### Settings and conduct

Patients with PFP who refer to clinics affiliated to Shiraz University of Medical science will be divided into 2 groups randomly. The assessor will unaware of grouping patients and their allocation.

##### Participants/Inclusion and exclusion criteria

Patients with PFP that the onset of pain is more than1 month and they report 30 from 100 on the pain Visual Analogue Scale(VAS) in the last week also they have at least one trigger point in ipsilateral Gluteus Medius, Contralateral Quadratus Lumborum and Quadriceps and they are able to use internet properly are included in this study. Exclusion criteria including history of lower extremity injury and surgery, infections, neurologic and systemic diseases

##### Intervention groups

Intervention group: Patients with PFP will receive videos including exercise program and self-myofascial release techniques weekly for 4 weeks .They perform exercise 3 times a week and self-myofascial release techniques twice a week. In order to ensure that participants do exercise and techniques correctly, video calls will make. Control group: They are the same as intervention group, but they do not perform self-myofascial release techniques. On assessment day, everyone receives pamphlet.

##### Main outcome variables

Pain, function and balance

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220628055300N1**

Registration date: **2022-07-27, 1401/05/05**

Registration timing: **prospective**

Last update: **2022-07-27, 1401/05/05**

Update count: **0**

##### Registration date

2022-07-27, 1401/05/05

##### Registrant information

##### Name

Safoora Akhavan Hariri

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3627 1551

##### Email address

safoora.physio@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-08-23, 1401/06/01

##### Expected recruitment end date

2023-01-20, 1401/10/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

The effects of exercise therapy plus Quadriceps , Gluteus Medius and Quadratus Lumborum self-myofascial-release on pain , function and balance in patients with patellofemoral pain through telerehabilitation

**Public title**

The effects of exercise therapy plus Quadriceps , Gluteus Medius and Quadratus Lumborum self-myofascial-release in patellofemoral pain through telerehabilitation

**Purpose**

Treatment

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

People between the ages of 18 and 45 (both sexes). The onset of pain is more than 1 month which is aggravated by at least two of these activities prolonged sitting, squatting , kneeling ,running ,upstairs and downstairs ,jumping and landing also pain is at least 30 from 100 on visual analogue scale during activities. Unilateral anterior knee pain, prepatellar or retro patellar pain that person reports at least 30 from 100 on pain visual analogue scale in the last week. If the pain is bilateral, the side with more pain is considered. Positive Clarke's sign Kujala questionnaire score is less than 85 The presence of trigger points in Gluteus Medius muscle of the affected side, Quadratus Lumborum on the opposite side and at least one part of the Quadriceps muscle. People have ability to use the Internet and virtual communication.

**Exclusion criteria:**

History of back, hip, ankle or other anatomical knee structures injury in previous 6 months History of lower limb trauma in recent 6 months History of knee surgery History of lower limb surgery Meniscus or knee ligaments injury Patellar tendinopathy History of patellar dislocation History of knee intra-articular injection in last 3 months Systemic or local infections Referral pain from lumbar region Writing and speaking inability Systemic diseases such as Rheumatoid Arthritis and other inflammatory joint diseases Neurological disease such as Multiple Sclerosis, history of stroke and any other nervous system problem Person has received physiotherapy due to his problem since 6 months ago. Sever lower limb deformity People who are suffering from cancer or history of chemotherapy

**Age**

From **18 years** old to **45 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Outcome assessor

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Using of randomization software,60 numbers are dedicated to each case and the program defines 15 blocks of 4, 2 of which are allocated to exercise therapy

plus Quadriceps , Gluteus Medius and Quadratus Lumborum self-myofascial-release through telerehabilitation group and the other 2 people are placed in exercise therapy through telerehabilitation group.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

The person who evaluates the patients is completely unaware of grouping patients and their allocation.

**Placebo**

Not used

**Assignment**

Parallel

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

empty

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

Ethics committee in Research, Shiraz Faculty of Rehabilitation Sciences

**Street address**

Abiverdi1 Street, Chamran Blvd

**City**

Shiraz

**Province**

Fars

**Postal code**

33669-71947

**Approval date**

2022-07-03, 1401/04/12

**Ethics committee reference number**

IR.SUMS.REHAB.REC.1401.016

**Health conditions studied****1****Description of health condition studied**

Patellofemoral pain

**ICD-10 code**

M25.56

**ICD-10 code description**

Pain in knee

**Primary outcomes****1****Description**

Pain

**Timepoint**

Before treatment, immediately after the last treatment session and two weeks after the end of the treatment

**Method of measurement**

Visual Analogue Scale

## 2

### **Description**

Pressure pain Threshold

### **Timepoint**

Before treatment and immediately after the last treatment session

### **Method of measurement**

Algometer

## 3

### **Description**

Function

### **Timepoint**

Before treatment, immediately after the last treatment session and two weeks after the end of the treatment

### **Method of measurement**

KUJALA questionnaire

## 4

### **Description**

Lower extremity function

### **Timepoint**

Before treatment, immediately after the last treatment session and two weeks after the end of the treatment

### **Method of measurement**

Lower Extremity Functional Scale

## 5

### **Description**

Balance

### **Timepoint**

Before treatment, immediately after the last treatment session and two weeks after the end of the treatment

### **Method of measurement**

Modified Star Excursion Balance Test

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: exercise therapy with Quadriceps, Gluteus Medius, Quadratus Lumborum self-myofascial release through telerehabilitation in patients with patellofemoral pain. On assessment day, they are given pamphlet including exercises and pictures related to them and advice about changing their poor habits such as avoiding sitting for a long time and sitting on a short chair then they will be received videos including exercise program and self-myofascial release every week for four weeks also video calls are made to them every week to ensure the correct way of doing the exercises .These people are asked to do exercises 3 times a week and

before starting, use a cold pack on their knees for 20 minutes. Also, these people do self-myofascial release techniques on 2 of the 3 days.

#### **Category**

Rehabilitation

### 2

#### **Description**

Control group: exercise therapy through telerehabilitation in patients with patellofemoral pain. Pamphlet, exercise therapy program, exercises frequency, exercises video and video call for this group is the same as intervention group. They just do not perform self-myofascial release techniques.

#### **Category**

Rehabilitation

## **Recruitment centers**

### 1

#### **Recruitment center**

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

Shiraz School of Rehabilitation

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

Sara Abolahrari-Shirazi

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## **Sponsors / Funding sources**

### 1

#### **Sponsor**

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

Shiraz University of Medical Sciences

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

Younes Ghasemi

##### **Street address**

Research vice-chancell, Central Building of Shiraz University of Medical Science, Opposite Palestine Street, Zand Street

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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**

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**

Shiraz University of Medical Sciences

**Full name of responsible person**

Sara Abolahrari-Shirazi

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

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## Person responsible for updating data

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**Full name of responsible person**

Safoora Akhavan Hariri

**Position**

M.Sc. Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no further information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available