

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparison of the Effectiveness of Knee and Hip\_ Knee muscle Strengthening Exercises on Single Leg Squat and Step Decent Kinematics in Individuals with Patellofemoral Pain

#### Protocol summary

##### Study aim

To determine the effect of knee and hip muscle strengthening on lower limb kinematics in Females with Patellofemoral Pain

##### Design

This is a double-blinded RCT with parallel design in which 50 females with PFP will randomly be assigned to 2 groups of the case (1) and control (2). Balanced randomization technique and sealed envelope will be used for group assignment.

##### Settings and conduct

Group 1 and 2 will perform the knee plus knee, and the knee strengthening and stretching exercises, respectively. Patients will receive 4 weeks of treatment, 3 times a week. A motion analysis system will record kinematic data while patients perform a single-legged squat and stair descent. A dynamometer will measure the maximal isometric strength of knee and hip muscles. Joint kinematics and muscle strength will be assessed 2-3 days before and after interventions. The assessor and data analyst will be blinded to group allocation.

##### Participants/Inclusion and exclusion criteria

Females with a history of anterior/retro patellar pain with a severity of at least 30 on a 100 mm Visual Analogue Scale in two daily activities of ascending and descending stairs, kneeling, squatting, and long sitting in the last 2 months will be entered to the study Females with a history of patellar dislocation, patellofemoral joint surgery, meniscal and ligament injury, Osgood-Schlatter Syndrome, Positive Apprehension Test, knee tendinitis will be excluded.

##### Intervention groups

Participants will randomly be allocated to the hip and knee strengthening (group 1) and knee strengthening groups (group 2 or control group). Group 1 and 2 will receive 12 sessions of physiotherapy focusing on hip plus knee muscles (group 1), and knee muscles (group 2)

strengthening exercises.

##### Main outcome variables

The hip, knee joint flexion, abduction, and internal rotation. The hip and knee muscles strength.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20140705018362N4**

Registration date: **2018-11-09, 1397/08/18**

Registration timing: **retrospective**

Last update: **2018-11-09, 1397/08/18**

Update count: **0**

##### Registration date

2018-11-09, 1397/08/18

##### Registrant information

##### Name

Fateme Esfandiarpour

##### Name of organization / entity

School of Rehabilitation Sciences, Ahvaz Jundishapur University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-07-23, 1397/05/01

##### Expected recruitment end date

2018-10-21, 1397/07/29  
**Actual recruitment start date**  
2018-07-22, 1397/04/31  
**Actual recruitment end date**  
2018-10-11, 1397/07/19  
**Trial completion date**  
2019-02-03, 1397/11/14

### Scientific title

Comparison of the Effectiveness of Knee and Hip\_ Knee muscle Strengthening Exercises on Single Leg Squat and Step Decent Kinematics in Individuals with Patellofemoral Pain

### Public title

Effects of Muscle strengthening on Motion Characteristics in Patellofemoral Pain

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Females with PFP in the age range of 18-45 Reporting Anterior Knee Pain a minimum pain intensity of 30 based on a 100-mm visual analogue scale A history of Knee Pain in the last 2 months Anterior Knee pain in at least 2 daily activities of ascending and descending stairs, squatting, kneeling, long sitting pain on palpation of the medial and/or lateral facet of patella

#### Exclusion criteria:

Ligament instability Signs or symptoms of meniscal injury or any intra-articular disorder more than trace knee effusion Neural system involvmen that leading to walking disorder Osgood's\_ Schlatter syndrome positive Apprehension Test excessive foot pronation, excessive knee valgus/varus Hip pain, sacroiliac pain, back pain patella, iliotibial band and pes anserinus tendonitis A history of Patellar dislocation

### Age

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

### Gender

Female

### Phase

N/A

### Groups that have been masked

- Outcome assessor
- Data analyser

### Sample size

Target sample size: **70**

Actual sample size reached: **50**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Balanced- Randomization technique will be used to allocate patients to the intervention groups. A person who has no role in the study will allocate the participants to the treatment groups. The Taves technique will be used to balance the groups with respect to demographic variables.

### Blinding (investigator's opinion)

Double blinded

### Blinding description

The assessor and data analyst will be blinded to group allocation of the participants.

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

The Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

##### Street address

Central Office, University Campus, Golestan

##### City

Ahvaz

##### Province

Khouzestan

##### Postal code

۶۱۳۵۷-۱۵۷۹۴

#### Approval date

2018-06-09, 1397/03/19

#### Ethics committee reference number

IR . AJUMS . REC . ۱۳۹۷. ۳۸

## Health conditions studied

### 1

#### Description of health condition studied

Patellofemoral Pain

#### ICD-10 code

M22.4

#### ICD-10 code description

Chondromalacia patellae

## Primary outcomes

### 1

#### Description

Maximal Isometric strength of Quadriceps muscles

#### Timepoint

Before and after treatment

#### Method of measurement

A fixed dynamometer

### 2

#### Description

Maximal Isometric strength of hamstring muscles

#### Timepoint

Before and after treatment

#### Method of measurement

a fixed dynamometer

### 3

#### **Description**

Maximal isometric strength of Hip external rotators and Abductor Muscles

#### **Timepoint**

Before and after treatment

#### **Method of measurement**

a fixed dynamometer

### 4

#### **Description**

Knee flexion angle

#### **Timepoint**

Before and after treatment

#### **Method of measurement**

Motion Analysis System

### 5

#### **Description**

Hip flexion angle

#### **Timepoint**

before and after treatment

#### **Method of measurement**

Motion Analysis system

### 6

#### **Description**

Hip internal/external rotation angle

#### **Timepoint**

before and after treatment

#### **Method of measurement**

Motion analysis system

### 7

#### **Description**

Hip Abduction/adduction angle

#### **Timepoint**

before and after treatment

#### **Method of measurement**

Motion analysis system

### 8

#### **Description**

Knee abduction/adduction angle

#### **Timepoint**

before and after treatment

#### **Method of measurement**

Motion analysis system

## **Secondary outcomes**

### 1

#### **Description**

Pain intensity

### **Timepoint**

Before and after treatment

### **Method of measurement**

Visual Analog scale

### 2

#### **Description**

Function

#### **Timepoint**

Before and after treatment

#### **Method of measurement**

Kujala Questionnaire and the step-down test

## **Intervention groups**

### 1

#### **Description**

Group 1: Individuals in this group will perform the hip abductor and external rotator muscle strengthening exercises in addition to knee muscles strengthening and stretching. Each individual will receive 12 sessions of treatment with the frequency of 3 sessions per week for 45 minutes in each session. Each week, the amount of resistive load will be adjusted to 70% of the 1-repetition maximum. For exercise with the elastic band, the resistance will be adjusted to the maximum resistance each individual can use to complete 10 repetitions of the exercise with no pain. Stretching for the muscles interest consists of three trials of a 30-second stretch, assisted by the therapist.

#### **Category**

Rehabilitation

### 2

#### **Description**

Treatment for group 1 includes the knee muscles strengthening and stretching exercises. Each individual will receive 12 sessions of treatment with the frequency of 3 sessions per week for 45 minutes in each session. Each week, the amount of resistive load will be adjusted to 70% of the 1-repetition maximum. For exercise with the elastic band, the resistance will be adjusted to the maximum resistance each individual can use to complete 10 repetitions of the exercise with no pain. Stretching for the muscles interest consists of three trials of a 30-second stretch, assisted by the therapist.

#### **Category**

Rehabilitation

## **Recruitment centers**

### 1

#### **Recruitment center**

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

Musculoskeletal Rehabilitation Clinics of School of Rehabilitation Sciences, Ahvaz Jundishapur Unive

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

Fateme Esfandiarpour

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Mohammad Badvi

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The Office of Vice Chancellor for Research  
Development and Technology, University Campus,  
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**Grant name**

IR . AJUMS . REC

**Grant code / Reference number**

1397.380

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

Yes

**Title of funding source**

Ahvaz 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**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Mahsa Keshavarz

**Position**

MSc Student in Physical Therapy

**Latest degree**

Bachelor

**Other areas of specialty/work**

Physiotherapy

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**Position**

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**Latest degree**

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**Other areas of specialty/work**

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**Person responsible for updating data****Contact****Name of organization / entity**

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**Full name of responsible person**

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**Position**

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**Other areas of specialty/work**

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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