

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### The effect of hip and knee muscles strength exercises in the water with or without use of kinesiotapes) as instant and long term (in improvement of pain, dynamic performance, Disability and the balance in women patients Patellofemoral pain syndrome

#### Protocol summary

##### Study aim

The main purpose of this study was to study the effect of strengthening exercises in the thigh and knee muscles in water with and without Kinesiotape (on an on-going and long-term basis) on pain, motor function, disability, balance and quality of life in women with PFPS.

##### Design

In this study, 45 women with this Patellofemoral pain syndrome were randomly assigned into three groups without kinesiotape (15) and water therapy with kinesiotape (15 patients) and water therapy kinesiotape was permanent (15 people)

##### Settings and conduct

The present study is a semi-experimental research based on the research design, the method of selecting the subjects, the measurement tools and the intervention, and the research design was pre-test and post-test on the three experimental groups, which for 8 weeks were as (Three sessions a week) conducted the exercises with the appropriate mentor's guidance.

##### Participants/Inclusion and exclusion criteria

Including Entry Requirements:Diagnosis and confirmation of the presence of patellofemoral pain syndrome by a specialist Positive Clark's test and Patellar Apprehension Womens aged 18 to 45 years Not participating in other sports activities Exclusion criteria: Diseases like osteoarthritis, joint diseases Having an artificial joints in the leg Performing knee surgery in the past Use of pain medications for knee pain in the present Affected by diseases that affect the variables of balance such as: Having no proper vision or any visual impairment, having an internal ear venereal disease

##### Intervention groups

three groups without kinesiotape (15) and water therapy with kinesiotape (15 patients) and water therapy kinesiotape was permanent (15 people)

##### Main outcome variables

Reduced pain, increased motor function, decreased disability, increased stagnation in the form of static and dynamic, increased quality of life

#### General information

##### Reason for update

##### Acronym

PFPS

##### IRCT registration information

IRCT registration number: **IRCT20171205037757N1**

Registration date: **2018-01-17, 1396/10/27**

Registration timing: **retrospective**

Last update: **2018-01-17, 1396/10/27**

Update count: **0**

##### Registration date

2018-01-17, 1396/10/27

##### Registrant information

##### Name

Marzieh Mokhtari Karchegani

##### Name of organization / entity

The University of tehran

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3775 8601

##### Email address

mokhtari.marzieh.1371@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2016-11-05, 1395/08/15  
**Expected recruitment end date**  
2017-01-29, 1395/11/10  
**Actual recruitment start date**  
2016-11-05, 1395/08/15  
**Actual recruitment end date**  
2017-01-10, 1395/10/21  
**Trial completion date**  
empty

#### Scientific title

The effect of hip and knee muscles strength exercises in the water with or without use of kinesiotapes) as instant and long term (in improvement of pain, dynamic performance, Disability and the balance in women patients Patellofemoral pain syndrome

#### Public title

Water therapy to improve patellofemoral pain syndrome

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Diagnosis and confirmation of the presence of patellofemoral pain syndrome by a specialist Positive Clark's test and Patellar Apprehension Womens aged 18 to 45 years Not participating in other sports activities

##### Exclusion criteria:

Diseases like osteoarthritis, joint diseases Having an artificial joints in the leg Performing knee surgery in the past Use of pain medications for knee pain in the present Affected by diseases that affect the variables of balance such as: Having no proper vision or any visual impairment, having an internal ear venereal disease

#### Age

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

#### Gender

Female

#### Phase

2

#### Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

#### Sample size

Target sample size: **45**

#### Randomization (investigator's opinion)

N/A

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

The researcher has by no means interfered in test neither in pre-test before exercise or post-test after exercise as the tests were given by individuals who had no clue about the plan.the participants were not alert of test application as well and just acted to instruction.The person who analyzed the data did not know about the study and generally looked at the data.

#### Placebo

Not used  
**Assignment**  
Parallel  
**Other design features**  
Use kinesiotape the water

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Hamedan University of Medical Sciences

##### Street address

Pajohesh Intersection ., Mahdiah Street

##### City

Hamedan

##### Province

Hamadan

##### Postal code

65178

#### Approval date

2017-01-14, 1395/10/25

#### Ethics committee reference number

IR.UMSHA.REC.1395.468

## Health conditions studied

### 1

#### Description of health condition studied

Patellofemoral pain syndrome

#### ICD-10 code

M00-M99

#### ICD-10 code description

Diseases of the musculoskeletal system and connective tissue

## Primary outcomes

### 1

#### Description

The amount of Visual pain

#### Timepoint

At the beginning of the study before the intervention and 60 days after the exercises

#### Method of measurement

Use the Visual Analogue Scale ruler

### 2

#### Description

The amount of pain

#### Timepoint

At the beginning of the study before the intervention and 60 days after the exercises

### **Method of measurement**

Using the McGill Pain Questionnaire

### **3**

#### **Description**

Motor function

#### **Timepoint**

At the beginning of the study before the intervention and 60 days after the exercises

#### **Method of measurement**

Use the Kujala questionnaire

### **4**

#### **Description**

Disability

#### **Timepoint**

At the beginning of the study before the intervention and 60 days after the exercises

#### **Method of measurement**

Van Kurf et al. Disability questionnaire

### **5**

#### **Description**

Dynamic balance

#### **Timepoint**

At the beginning of the study before the intervention and 60 days after the exercises

#### **Method of measurement**

Biodegrade System balance

### **6**

#### **Description**

Static balance

#### **Timepoint**

At the beginning of the study before the intervention and 60 days after the exercises

#### **Method of measurement**

Biodegrade System balance

### **7**

#### **Description**

Quality of Life

#### **Timepoint**

At the beginning of the study before the intervention and 60 days after the exercises

#### **Method of measurement**

Sherbourne SF36 Questionnaire

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

First Intervention group: water therapy without

kinesiotape (n=15), A two-month-long therapeutic exercise without the use of a kinesiotape

#### **Category**

Rehabilitation

### **2**

#### **Description**

Second Intervention group: water therapy with temporary kinesiotaping (n=15), A two-month-long therapeutic exercise using short-term kinesiotap

#### **Category**

Rehabilitation

### **3**

#### **Description**

Third Intervention group: water therapy with permanent kinesiotaping (n=15), A two-month-long exercise therapy using long-term kinesiotap

#### **Category**

Rehabilitation

## **Recruitment centers**

### **1**

#### **Recruitment center**

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

Besat Hospital

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

Maryam Bashiri

##### **Street address**

Besat Hospital, Motahari BlvdDi, strict 2, Hamedan

##### **City**

Hamedan

##### **Province**

Hamadan

##### **Postal code**

8174784986

##### **Phone**

+98 81 3264 0020

##### **Fax**

+98 81 3265 1515

##### **Email**

Besat@umsha.ac.ir

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

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

The University of Bu-Ali Sina

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

Ali Yalfani

##### **Street address**

University of Bu-Ali Sina, Pajohesh Intersection ., Mahdieh Street

##### **City**

Hamedan

##### **Province**

Hamadan  
**Postal code**  
65178-38695  
**Phone**  
+98 81 3838 1422  
**Fax**  
**Email**  
Ali\_Yalfani@Yahoo.com  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
The University of Bu-Ali Sina  
**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**  
The University of Bu-Ali Sina  
**Full name of responsible person**  
Marzieh Mokhtari Karchegani  
**Position**  
Masters Student  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Corrective Exercises and Sport Injuries  
**Street address**  
No.76, Deadend Ershad., Nastoh Street.  
**City**  
Esfahan  
**Province**  
Isfahan  
**Postal code**  
8174784986  
**Phone**  
+98 31 3775 8601  
**Email**  
Mokhtari.Marzieh.1371@Gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
The University of Bu-Ali Sina  
**Full name of responsible person**  
Marzieh Mokhtari Karchegani  
**Position**

Masters Student  
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8174784986  
**Phone**  
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**Email**  
Mokhtari.Marzieh.1371@Gmail.com  
**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**  
The University of Bu-Ali Sina  
**Full name of responsible person**  
Marzieh Mokhtari Karchegani  
**Position**  
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**Email**  
Mokhtari.Marzieh.1371@Gmail.com  
**Web page address**

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

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**

No - There is not a plan to make this available

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

Data and documentation can be shared, but with unidentifiable individuals and private information for subjects

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

Starting data access 1 year after printing results

**To whom data/document is available**

Researchers in this field are allowed to act for documentation

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

Only the type of analysis that can be done in the research can be redefined

**From where data/document is obtainable**

mokhtari.marzieh.1371@gmail.com

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

When the applicant submits a document for his / her work area in relation to the subject matter of the thesis, and if the request is reasonable and the commitment not to misuse the data of this research, the data will be sent to him within 1 week of work.

**Comments**