

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 2026

### Comparing the effect of exercise therapy with Mckenzie versus Common methods in treatment of patients with Anterior Knee Pain (AKP): A randomized controlled trial.

#### Protocol summary

##### Study aim

The aim of this study is to compare the effect of McKenzie method with common physiotherapy protocol in subjects with anterior knee pain.

##### Design

This study is a randomized clinical trial. Twenty-two patients with anterior knee pain and all of inclusion criteria and without exclusion criteria that they refer to Daron hospital in Shiraz are selected and will be randomly assigned in experiment and control groups. Each participant is assigned a code.

##### Settings and conduct

The treatment program included modality and exercise therapy. Modalities, superficial heat and electrical stimuli will be fixed in both groups from the first to the tenth session. From the third session, each group will be received their exercise therapy program. The location of the study is the physiotherapy center of the Doran hospital in Shiraz.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: The age between 16 to 40 years old; having at least two months pain in front of knee; The pain rate at least 3 cm by virtue of linear Visual Analog Scale ; Positive response to at least 2 items of the Kujala questionnaire. Exclusion criteria: Dissatisfaction of patient in each step of the study; Having a history of real locking of the knee; Having a history of patellar dislocation; Joint inflammation; Active infection; The presence of any abnormalities in knee joint radiography; Ligament injuries; Malignancy; The actual length difference of the limbs; The previous history of physiotherapy for knee; Taking of any tranquilizer medication during the 48 hours before the evaluation; The presence of any abnormalities in the chest, upper and lower extremities;

##### Intervention groups

The treatment program is included 10 sessions of the Hot

pack and the TENS modalities that are fixed in both groups. From the third session, in the experiment group, McKenzie exercises will be given according to the directional preference that is different for each subject and is determined by Mackenzie method. These exercises will be repeated 10 times every 2 hours. Attain and maintain exercises for postural correction and recommends of avoiding contrary directional preference movements, also are in the test group program. In control group strengthening exercise of hip and knee muscles will be done with 50% of the one maximum number of repetitions (ORM) and 20 percent increasing on a daily basis (against gravity and without weights) , as well as strengthening exercises of trunk with Swiss ball. These exercises will be repeated 2 times a day and 10 repetition in each time. Before and after the warm-up and the cool-down exercises are considered.

##### Main outcome variables

Main outcome measure variables are including: score of pain, functional status, strength of quadriceps and hamstring, length of quadriceps and hamstring, knee flexion and extension range of motion and Fear-Avoidance Beliefs score.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150314021459N5**  
Registration date: **2018-02-13, 1396/11/24**  
Registration timing: **retrospective**

Last update: **2018-02-13, 1396/11/24**

Update count: **0**

##### Registration date

2018-02-13, 1396/11/24

##### Registrant information

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Mohammad Akbari

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**Recruitment status**  
**Recruitment complete**

**Funding source**  
Vise research and technology, Iran university of medical  
science,

**Expected recruitment start date**  
2017-07-03, 1396/04/12

**Expected recruitment end date**  
2017-09-03, 1396/06/12

**Actual recruitment start date**  
2017-07-03, 1396/04/12

**Actual recruitment end date**  
2017-10-04, 1396/07/12

**Trial completion date**  
empty

**Scientific title**  
Comparing the effect of exercise therapy with Mckenzie  
versus Common methods in treatment of patients with  
Anterior Knee Pain (AKP): A randomized controlled trial.

**Public title**  
The Effect of McKenzie exercises in treatment of anterior  
knee pain

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Their age is between 16 and 40 years old. Have at least  
two months pain in front of knee. The pain rate is at least  
3 cm by virtue of linear Visual Analog Scale. At least 2 of  
the questionnaire Kujala give a positive response.  
**Exclusion criteria:**  
Dissatisfaction of patient in each step of the study  
Having a history of real locking of the knee Having a  
history of dislocation of the patella. Having the joint  
inflammation. Having active infections The presence of  
any abnormalities in knee joint radiography Having the  
ligament injuries. Having the malignancy. Having the  
actual length difference of the lower extremities. Taking  
of any tranquilizer medication during the 48 hours before  
the evaluation. The presence of any abnormalities in the  
chest, upper and lower extremities. The previous history  
of physiotherapy for knee.

**Age**  
From **16 years** old to **40 years** old

**Gender**  
Both

**Phase**

2-3

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **22**  
Actual sample size reached: **22**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
This randomized study into intervention and control  
groups was conducted by using Random allocation rule.  
A total of 22 individuals were assigned to individual  
randomization units with numbers 1 and 2, including 11  
number 1 for the intervention group, and 11 number 2  
for the control group. They were placed in a draw  
box. Allocation concealment was done by Sequentially  
numbered, sealed, opaque envelopes. Subsequently, the  
envelopes were removed without replacement.

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Iran University of Medical  
Sciences,

##### Street address

Vice chancellor for Research and Technology, Central  
headquarters of Iran university of Medical Sciences,  
between Hemmat and Sheykh fazl ollah High ways,

##### City

Tehran

##### Province

Tehran

##### Postal code

1545913187

#### Approval date

2017-05-22, 1396/03/01

#### Ethics committee reference number

IR.IUMS.REC 1396.041130009

## Health conditions studied

### 1

#### Description of health condition studied

Anterior Knee Pain

#### ICD-10 code

M95, M96,

### **ICD-10 code description**

Other disorders of the musculoskeletal system and connective tissue

### **2**

#### **Description of health condition studied**

anterior knee pain

#### **ICD-10 code**

#### **ICD-10 code description**

### **Primary outcomes**

### **1**

#### **Description**

pain

#### **Timepoint**

At the beginning of the study, 10 days and one month after the start of the study.

#### **Method of measurement**

Linear scale VAS

### **2**

#### **Description**

function

#### **Timepoint**

At the beginning of the study, 10 days and one month after the start of the study.

#### **Method of measurement**

Kujala questionnaire

### **3**

#### **Description**

range of motion of knee

#### **Timepoint**

At the beginning of the study, 10 days and one month after the start of the study.

#### **Method of measurement**

Goniometer

### **Secondary outcomes**

### **1**

#### **Description**

length of the hamstring muscles

#### **Timepoint**

At the beginning of the study, 10 days and one month after the start of the study

#### **Method of measurement**

Clinometer

### **2**

#### **Description**

length of the quadriceps muscle

#### **Timepoint**

At the beginning of the study, 10 days and one month after the start of the study

### **Method of measurement**

Clinometer

### **3**

#### **Description**

Hamstring muscle strenght

#### **Timepoint**

At the beginning of the study, 10 days and one month after the start of the study

#### **Method of measurement**

Hand Dynamometer

### **4**

#### **Description**

Quadriceps muscle strenght

#### **Timepoint**

At the beginning of the study, 10 days and one month after the start of the study

#### **Method of measurement**

Hand Dynamometer

### **5**

#### **Description**

The fear avoidance beliefs

#### **Timepoint**

At the beginning of the study, 10 days and one month after the start of the study

#### **Method of measurement**

FABQ questionnaire

### **Intervention groups**

### **1**

#### **Description**

Intervention2: First the subjects have physiotherapy including hot pack with defined TENS. The place for electrodes are according to acupuncture points. Therapeutic exercise includes strengthening of extensor, abductor, external rotator muscles of hip and flexor and extensors of knee.Exercises starts with warm up (5 min walking) and ended with cool down (hamstring, quadriceps and gastrocnemius stretch, 5 sec hold, 3 times repeat) 1RM is determined without counterweight and untigravity,to the border between fatigue and pain Start with 50% 1RM, daily to ten days. training progreses with 20% 1RM. trunk strengthening exercises performs with swiss ball in three methods (supine with straight knees and feet on ball, supine with bent knees and feet on ball and sitting on ball and raise feet from the floor),holding the position 10 seconds to 2 minutes depending on the individual's tolerance . 2 times a day.

#### **Category**

Rehabilitation

### **Recruitment centers**

## 1

### Recruitment center

**Name of recruitment center**

Shahid Doran Hospital

**Full name of responsible person**

Jaleh Farahmand Farzaneh

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Air Base Shahid Doran. Modarres Blvd.

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Vice chancellor for Research and Technology, Iran University of Medical Sciences,

**Full name of responsible person**

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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**

Vice chancellor for Research and Technology, Iran 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**

Vice research, School of Rehabilitation Sciences, Iran University of Medical Sciences

**Full name of responsible person**

Mojtaba Kamyab

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Ph.D.

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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)**

No - There is not a plan to make this available

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

Excessive conflict

**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