

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The Effect of Hip and Core Stability Exercise on Pain and Disability of Patients with Knee Osteoarthritis

#### Protocol summary

##### Study aim

To determine and comparison the effects of hip, knee and core stability muscles strengthening versus knee muscles strengthening to improve pain and function in patients with (KOA).

##### Design

The sample size determined by referring to similar article and according to the following formula.  $n = 7.78 \times 2(S.D/Chang \text{ in mean})^2$  Using the formula written above and according pain variable as a common variable of the studies, the total subjects obtained as 40 people.

##### Settings and conduct

This study will be conducted in the physiotherapy clinic of the School of Rehabilitation Sciences, Eligible people will be invited to participate in the study by placing notices in the clinics around the venue.

##### Participants/Inclusion and exclusion criteria

People with knee osteoarthritis in grade 2 or 3 of the KL scale, aged 40 to 70 years will be included in the study.

##### Intervention groups

The subjects will be distributed by simple lottery in two control and experiment groups. The program of the control group will be using superficial heat, and electrical stimulation for 20 minutes and strengthening exercises for the knee muscles. Beside the control group protocol, strengthening exercises of the hip and core stability muscles in the lumbar and pelvic region will be added in the experiment group.

##### Main outcome variables

1- WOMAC scale, - visual analog., 3- Knee flexion range (n=0-135), 4- Knee extension range (n=0-135), 5- Quadriceps muscle strength, 6- Hamstring muscle strength, 7-thigh muscle volume, 9-calf muscle volume.

#### General information

##### Reason for update

##### Acronym

نقش فیزیوتراپی در درمان آرتروز زانو

##### IRCT registration information

IRCT registration number: **IRCT20150314021459N7**

Registration date: **2024-07-30, 1403/05/09**

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

Last update: **2024-07-30, 1403/05/09**

Update count: **0**

##### Registration date

2024-07-30, 1403/05/09

##### Registrant information

###### Name

Mohammad Akbari

###### Name of organization / entity

Dept. of Physical therapy, School of Rehabilitation, Iran University of Medical Sciences.

###### Country

Iran (Islamic Republic of)

###### Phone

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###### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-07-20, 1403/04/30

##### Expected recruitment end date

2024-10-29, 1403/08/08

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Effect of Hip and Core Stability Exercise on Pain and

Disability of Patients with Knee Osteoarthritis

### Public title

The effect of core stability and hip joint muscle strengthening on (KOA)

### Purpose

Health service research

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Age 40 -70 years, Both males and females, Patients with grade 1 or 2 (KOA) according KL scale), Chronic stages of knee pain, Unilateral or bilateral (KOA), Patients who scored 3 out of 10 knee pain or greater on the VAS with activity intervention at baseline, WOMAC score above 10,

#### Exclusion criteria:

Acute knee pain and inflammation Recent fractures  
Prolonged immobilization Uncontrolled hypertension  
Severe cardiopulmonary disease Other grades of knee osteoporosis (grade I and IV) Having active rheumatoid arthritis Having any neurological disorders affecting lower limbs

### Age

From **40 years** old to **70 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

- Participant
- Outcome assessor

### Sample size

Target sample size: **40**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Subjects will be distributed in control and test groups by simple lottery, in such a way that people with odd numbers will enter the control group and people with even numbers will enter the test group.

### Blinding (investigator's opinion)

Single blinded

### Blinding description

Subjects will not be informed of the difference in treatment methods. In this way, the subjects of the control and test groups will be treated in a different treatment center with similar facilities.

### Placebo

Not used

### Assignment

Parallel

### Other design features

Does not have.

## Secondary Ids

empty

## Ethics committees

## 1

### Ethics committee

#### Name of ethics committee

Ethics Committee of the Iran University of Medical Sciences

#### Street address

Hemmat High Way, Near the Milad Tower

#### City

Tehran

#### Province

Tehran

#### Postal code

1545913187

### Approval date

2024-05-18, 1403/02/29

### Ethics committee reference number

IR.IUMS.REC.1403.I68

## Health conditions studied

## 1

### Description of health condition studied

Knee arthritis

### ICD-10 code

### ICD-10 code description

Degenerative knee disease

## Primary outcomes

## 1

### Description

Pain

### Timepoint

At the beginning of the study and before the intervention and at the end of 10 treatment sessions.

### Method of measurement

Visual analogue scale (VAS)

## 2

### Description

McMaster Osteoarthritis Index (WOMAC)

### Timepoint

At the beginning of the study and before the intervention and at the end of 10 treatment sessions.

### Method of measurement

Summarizing the answers to key questions

## 3

### Description

Knee Flexion range of motion

### Timepoint

At the beginning of the study and before the intervention and at the end of 10 treatment sessions.

### Method of measurement

By goniometer

#### 4

**Description**

Knee Extension range of motion

**Timepoint**

At the beginning of the study and before the intervention and at the end of 10 treatment sessions.

**Method of measurement**

By gonio meter

#### 5

**Description**

Thigh muscle trophy

**Timepoint**

At the beginning of the study and before the intervention and at the end of 10 treatment sessions.

**Method of measurement**

Tape

### Secondary outcomes

#### 1

**Description**

WOMAC Scale

**Timepoint**

Knee flexion ROM

**Method of measurement**

Knee extension ROM

### Intervention groups

#### 1

**Description**

Control group: application, surface heat, electrical stimulation and knee muscle strengthening

**Category**

Rehabilitation

#### 2

**Description**

Intervention group: application of the program of the control group in addition to strengthening the hip joint muscles and core stability muscles in the back and hip areas

**Category**

Rehabilitation

### Recruitment centers

#### 1

**Recruitment center****Name of recruitment center**

School of Rehabilitation Science, Iran University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Akbari

**Street address**

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### Sponsors / Funding sources

#### 1

**Sponsor****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Reza Falak Md.

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**Grant name**

Not assigned yet

**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

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**

UN agencies and international organizations

**Country of origin****Type of organization providing the funding**

Academic

### Person responsible for general inquiries

**Contact**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Akbari

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

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

Iran University of Medical Sciences

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

Yes - There is a plan to make this available

**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**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

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

After the people cannot be identified, the results of the data will be published through statistical analysis through the publication of articles in reputable journals. For this purpose, the data of the first outcome and also other outcomes will be used.

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

It is hoped that this work will be realized in about a year.

**To whom data/document is available**

Principal researcher and statistical consultant

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

If there is a significant difference between the control and test groups in the study variables. The results will be used to treat people with knee arthritis.

**From where data/document is obtainable**

There is no need to visit in person. Items will be available by searching for articles.

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

Searching for articles about knee arthritis in databases

**Comments**