

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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.

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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 gonio meter

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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