Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 comparisn 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= □7.78×2(S.D/Chang 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 آرتوز 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

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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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Maddakaran Aly, Shahnazari Av. Madar Sq. Mirdamad blv,
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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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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