Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect of Eight Weeks Land-Based Exercise on Static and Dynamic Stability of Elderly Women with Knee Osteoarthritis During Walking

Protocol summary

Study aim
Increasing the quality of life and reducing the risk of falling, as well as reducing costs related to people with Knee osteoarthritis

Design
The current clinical trial study has intervention and control groups with a parallel design, where 30 women with Knee OA were divided into two groups using a simple randomization method with the help of sealed envelopes.

Settings and conduct
The research is based on pre-test and post-test and is conducted at the Musculoskeletal Disorders Research Center of Isfahan Medical Sciences, Faculty of Rehabilitation. There is no blinding.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Individuals with knee osteoarthritis severity of grade 2 or 3 are determined based on the Kellgren-Lawrence scale through radiography. Self-reported knee osteoarthritis has been officially documented, detailing symptoms such as pain in the past month and morning stiffness. Exclusion criteria: heart disease or uncontrolled blood pressure, uncontrolled diabetes, any neurological disease such as epilepsy, dizziness, stroke or Parkinson's disease, joint injection in the last three months, traumatic surgery of the lower limbs, any injury, recent knee arthroplasty, lower limb arthroplasty, hip and ankle arthritis, as well as other joint diseases other than knee arthritis, participation in any physiotherapy or hydrotherapy treatment in the past three months, use of medical equipment to help walking As with crutches, the worsening of the patient's symptoms during treatment sessions is the patient's failure to complete exercise sessions.

Intervention groups
In the training group, Muscle release, muscle stretching and strength training will be done for eight weeks. In the control group, people will not do any exercise for eight weeks.

Main outcome variables
Encouraging people to exercise, increasing the quality of life, increasing awareness of knee osteoarthritis

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231120060118N1**
Registration date: **2024-04-19, 1403/01/31**
Registration timing: **retrospective**

Last update: **2024-04-19, 1403/01/31**
Update count: **0**

Registration date
2024-04-19, 1403/01/31

Registrant information

Name
Piunik Hovsepian
Name of organization / entity
University of Kashan
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-06-22, 1402/04/01

Expected recruitment end date
2023-07-01, 1402/04/10

Actual recruitment start date

2023-07-20, 1402/04/29

Actual recruitment end date

2023-07-25, 1402/05/03

Trial completion date

2023-11-10, 1402/08/19

Scientific title

The Effect of Eight Weeks Land-Based Exercise on Static and Dynamic Stability of Elderly Women with Knee Osteoarthritis During Walking

Public title

Effect of Exercise on Static and Dynamic Stability of Patients with Knee Osteoarthritis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Individuals with knee osteoarthritis severity of grade 2 or 3 are determined based on the Kellgren-Lawrence scale through radiography. Self-reported knee osteoarthritis has been officially documented, detailing symptoms such as pain in the past month and morning stiffness.

Exclusion criteria:

Heart disease or uncontrolled blood pressure Uncontrolled diabetes Any neurological disease such as epilepsy, vertigo, stroke or Parkinson's disease Joint injection in the last three months Traumatic surgery of the lower limb Any recent knee injury Lower limb arthroplasty Having arthritis of the hip and ankle joints, as well as other joint diseases other than knee osteoarthritis Participating in any physiotherapy or hydrotherapy treatment in the past three months Use of medical equipment to assist in walking such as a cane Failure to complete training sessions by the subject

Age

From **57 years** old to **70 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Actual sample size reached: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

A simple randomization method was used for randomization. For this purpose, a number of sealed opaque envelopes were considered. In this method, mail envelopes with the name of one of the intervention and control groups were registered to the number of subjects, and after merging the envelopes, the subject chose an envelope and its allocation was recorded. In order to hide the random sequence, sealed and waxed opaque envelopes with random sequence were used. After creating a random sequence based on the sample size, a number of envelopes with non-transparent envelopes (in order to make the contents of the envelopes unclear) were prepared and each of the random sequences created was recorded on a card and the cards were placed inside the envelopes in order. In order to preserve the random sequence, the outer surface of the envelopes was numbered in the same order. Finally, the lid of the letter envelopes was glued and placed in a box in order.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in Kashan University Research

Street address

Qotb-e Ravandi Blvd

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Province

Isfehan

Postal code

8731753153

Approval date

2023-05-31, 1402/03/10

Ethics committee reference number

IR.KASHANU.REC.1402.002

Health conditions studied

1

Description of health condition studied

Knee Osteoarthritis

ICD-10 code

M17

ICD-10 code description

Osteoarthritis of knee

Primary outcomes

1

Description

Static balance

Timepoint

The pre-test, the eight-week training period and the post-test are taken at the end

Method of measurement

Kistler 9260 AA force plate was used to measure static balance.

2

Description
Gait balance
Timepoint
The pre-test, the eight-week training period and the post-test are taken at the end
Method of measurement
Qualisys Track Manager (QTM) movement analysis system (manufactured by QTM Company, USA) including 7 cameras was used to measure walking balance. The cameras and power plate were set to work simultaneously.

Secondary outcomes

1

Description
Stride Length
Timepoint
Pre-test and post-test
Method of measurement
Qualisys Track Manager (QTM) motion analysis system (manufactured by QTM Company, USA) including 7 cameras was used to measure walking variables.

2

Description
Step Width
Timepoint
Pre-test and post-test
Method of measurement
Qualisys Track Manager (QTM) motion analysis system (manufactured by QTM Company, USA) including 7 cameras was used to measure walking variables.

3

Description
Step Length
Timepoint
Pre-test and post-test
Method of measurement
Qualisys Track Manager (QTM) motion analysis system (manufactured by QTM Company, USA) including 7 cameras was used to measure walking variables.

4

Description
Cadence
Timepoint
Pre-test and post-test
Method of measurement
Qualisys Track Manager (QTM) motion analysis system (manufactured by QTM Company, USA) including 7 cameras was used to measure walking variables.

Intervention groups

1

Description
A group of 12 people with knee osteoarthritis who do exercise training for 8 weeks and 3 sessions per week.The duration of the exercise is 45 to 60 minutes. Training includes muscle release which was done using foam roll and tennis ball.These exercises were performed in 1 to 3 sets and for a maximum of one minute in the hamstrings, quadriceps, gastrocnemius and soleus muscles, thigh adductors, iliotibial band, plantar fascia, pectoral, rhomboid, trapezius and trunk extensors. In the second stage, the lower muscles, which included the hamstrings, gastrocnemius and soleus, and iliotibial band, were stretched for 20 to 60 seconds for 1 to 4 sets Then, in the last stage, strength exercises were prescribed for the subjects according to their individual fitness. In this stage, isometric and isotonic exercises were performed in 1 to 3 sets. Isometric exercise 4 seconds up and rest 2 to 10 seconds and isotonic exercise 10 to 12 repetitions were performed. The strength exercises for these people included the contraction of the core muscles, modified lateral plank, hip abduction with external rotation,bridge with ball (isometric/isotonic), knee extension (isometric/isotonic), squat to the wall and seated calf raise.This training group of 12 people were tested at the beginning and at the end of 8 weeks.
Category
Other

2

Description
A group of 12 people with knee osteoarthritis who do not do any Exercise activities for 8 weeks.A weekly report was prepared from these people and this report included the daily activities and lifestyle of these people during the week. This control group of 12 people were tested at the beginning and at the end of 8 weeks.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
University of Kashan
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Sponsors / Funding sources

1

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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

University of Kashan

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

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Full name of responsible person

Piunik Hovsepian

Position

Master's Degree Student

Latest degree

Master

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
Some data will be given to researchers after de-identification

When the data will become available and for how long
Start access 12 months print

To whom data/document is available
The data is given to academics and students in the field of sports science

Under which criteria data/document could be used
If their field of work is relatively similar to the present study

From where data/document is obtainable
To receive data, you can send a message to hpiunik@yahoo.com.

What processes are involved for a request to access data/document
Applicants must be professors or students in the field of biomechanics or sports physiology, and their request will be reviewed for one to two weeks, and if the requested data is among the data that can be published and no article has been published with that data recently. It will be available to them.

Comments