Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of eight- weeks of body balance exercises on posture control, balance, lower limb muscle strength and proprioception of knee and ankle joints in elderly women with knee osteoarthritis

Protocol summary

Study aim
Determining the effect of eight weeks of air balance exercises on the variables of posture control, balance, muscle strength of the lower limbs and proprioception of the knee and ankle joints in elderly women with knee osteoarthritis.

Design
Clinical trial with control group, with parallel group, single blinded, randomized

Settings and conduct
The tests will be carried out by the specialists at the Sport Rehabilitation Laboratory, and then interventions and exercises will take place in the gym. And participants will be randomly assigned to intervention and control groups based on allocation concealment using the SNOSE method. This study will be conducted in a blind way so that the outcome assessors will not know about the allocation of the study groups and the reason for their presence in this study.

Participants/Inclusion and exclusion criteria
Inclusion criteria included elderly women with knee osteoarthritis, not having any history of knee, no injection of intra-articular steroid in the last six months, having pain in the last three months, and non-entry criteria: In regular exercise activities during the research, cardio-respiratory disorders and neurological diseases, History of fracture or surgery of lower limb joints.

Intervention groups
The intervention group will be received body balance exercises that include breathing, stretching, balance and strength exercises for 8 weeks and 3 sessions of one-hour each week. To do the exercises, tools will be used that help the mobility of soft tissue. Control group without intervention

Main outcome variables
posture control, balance, muscle strength and proprioception of knee joint

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230101057015N1**
Registration date: **2023-04-15, 1402/01/26**
Registration timing: **retrospective**

Last update: **2023-04-15, 1402/01/26**
Update count: **0**

Registration date
2023-04-15, 1402/01/26

Registrant information

Name
Parvin Safarpour

Name of organization / entity
The University of Bu Ali Sina

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-03-31, 1402/01/11

Expected recruitment end date
2023-04-10, 1402/01/21

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The effect of eight- weeks of body balance exercises on posture control, balance, lower limb muscle strength and proprioception of knee and ankle joints in elderly women with knee osteoarthritis

Public title
The effect of body balance exercises on knee osteoarthritis of elderly women

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Elderly women with knee osteoarthritis Not having any history of knee No injection of intra-articular steroid in the last six months Having pain in the last three months

Exclusion criteria:
Participate in regular exercises activities Cardio-respiratory disorders and neurological diseases History of fracture or surgery of lower limb joints

Age
From **60 years** old to **80 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization is based on the Random Number Generator software version 1.1 and uses the SNOSE method to assign double groups based on allocation concealment. The randomization of subjects was done in two stages. First, each of the subjects chooses a number between 1-30 using a lottery, then fifteen random numbers are selected between the numbers 1-30 using the Random number generator software, and according to the generated numbers, the chosen numbers of subjects are divided into two groups. Random Number Generator is a simple software for generating random numbers between two specified numbers. To use this software, it is enough to determine the smallest and largest number as well as the wanted number of random numbers and click on the Generate integer button to generate random numbers corresponding to the number and in the specified interval. The software can be downloaded from the following site: http://fa.softoware.org/apps/get-random-number-generator-66296-for-windows.html. To allocation concealment, the closed-sequence envelope method with random allocation (SNOSE) will be used. An accident is recorded on a card and the cards are placed inside the named cleaners in order. In order to maintain random randomness, the numbering on the external surface is done in the same way. Finally, the lids of the letter envelopes are pasted and placed inside the boxes, respectively. At the beginning of the registration of the participants, according to the order of the participants and the conditions of the study, one of them is a special test book or letter.

Blinding (investigator's opinion)
Single blinded

Blinding description
In the study, the outcome valuators (laboratory technicians) will be asked to take the desired tests from the participants. These people will be unaware of the purpose of the research, the allocation of study group, and the reason for their presence in the laboratory, and they only evaluate the variables and record their observations.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Bu Ali Sina University

Street address
Bu Ali Sina University, Abu Talib St, Modares Qods, Hamadan

City
Hamedan

Province
Hamadan

Postal code
3869565178

Approval date
2022-03-08, 1400/12/17

Ethics committee reference number
IR.BASU.REC.1401.022

Health conditions studied

1

Description of health condition studied
knee osteoarthritis

ICD-10 code
M17.9

ICD-10 code description
Osteoarthritis of knee, unspecified

Primary outcomes

1

Description

posture control

Timepoint

Before the intervention begins, one day after the end of the intervention

Method of measurement

Time Up & Go test

2

Description

Balance

Timepoint

Before the intervention begins, one day after the end of the intervention

Method of measurement

Functional reach test

3

Description

Lower limb muscle strength

Timepoint

Before the intervention begins, one day after the end of the intervention

Method of measurement

Dynamometer

4

Description

proprioception of knee and ankle joints

Timepoint

Before the intervention begins, one day after the end of the intervention

Method of measurement

Photography and reconstruction and evaluation of error rate

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:Body balance exercises will be for 8 weeks and 3 sessions of one-hour each week. The body balance protocol includes breathing, stretching, balance and strength exercises.To do the exercises, tools that help the mobility of soft tissue will be used.

Category

Rehabilitation

2

Description

Control group: No Intervention

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

General Welfare Department

Full name of responsible person

Syed Razagh Manafi

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Fadaeiyan Islam st, Besat st, zanjan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bu Ali Sina University

Full name of responsible person

Farzane Saki

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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

Bu Ali Sina University

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
Bu Ali Sina University

Full name of responsible person
Parvin Safarpour

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Sport Rehabilitation

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Person responsible for updating data

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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
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be 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