

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Country

Iran (Islamic Republic of)

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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-generat-or-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 valuator (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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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