Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Designing a 6-week training program with balance boards and examining its effects on posture control, balance, walking speed, fall risk, and quality of life in elderly individuals

Protocol summary

Study aim

The overall objective of the current study is to examine the effects of a 6-week balance training program on static and dynamic balance, walking speed, posture control, fall risk, and quality of life in the elderly.

Design

A clinical trial with intervention and control groups randomized into study groups.

Settings and conduct

To evaluate the effect of balance exercises on balance, postural control, gait speed, risk of falls and quality of life in the elderly, a 6-week training program for the elderly who meet the inclusion criteria in the Mehraban elderly home for 3 days a week and 90 days will be done. After the warm-up, the subjects specifically performe exercises with the researcher on the balance shuttle.

Participants/Inclusion and exclusion criteria

Inclusion criteria Age over 60 years Ability to move independently The satisfaction of the patient and the family to participate in the research Scoring 21 or higher on the Berg Balance Test Exclusion criteria Have a history of cognitive problems, orthopedics, neurology, cardiovascular disease receive help from other persons or device to walk Lower limb fracture in the last 3 months BMI higher than 35

Intervention groups

The present study consisted of two intervention and control groups. The intervention group consisting of male and female, exercising for six weeks, three days a week, 90 minutes per session of balance exercise with an unstable device under the supervision of the researcher (practitioner). The control group also includes male and female with no intervention.

Main outcome variables

Posture control; Balance; Risk of falling; Gait speed Quality of life

General information

Reason for update

In this experimental work, the descriptions related to the quality of life test were incomplete, and the study's blinding method was also updated.

Acronym

IRCT registration information

IRCT registration number: **IRCT20190410043229N1**
Registration date: **2019-11-09, 1398/08/18**
Registration timing: **retrospective**

Last update: **2024-12-15, 1403/09/25**
Update count: **1**

Registration date

2019-11-09, 1398/08/18

Registrant information

Name

Zahra Mohammadian

Name of organization / entity

Faculty of Physical Education and Sports Sciences university of tehran

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Iran (Islamic Republic of)

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zahra.md70@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-29, 1398/06/07

Expected recruitment end date

2019-10-22, 1398/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Designing a 6-week training program with balance boards and examining its effects on posture control, balance, walking speed, fall risk, and quality of life in elderly individuals

Public title

The impact of a balance board training program on posture control, balance, walking speed, fall risk, and quality of life in elderly individuals

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 60 years Ability to move independently The satisfaction of the patient and his/her family to participate in the research Scoring 21 or higher on the Berg Balance Test.

Exclusion criteria:

Have a history of cognitive problems, orthopedics, neurology, cardiovascular disease Receive help from other persons or device to walk Lower limb fracture in the last 3 months BMI higher than 35

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, subjects (female, male) are randomly drawn and divided into two intervention and control groups. Randomization is designed to occur in a manner where group allocation takes place only after the initial stages are completed. Allocation concealment is achieved through the use of computerized coding software. Consequently, random codes are automatically assigned to each participant, and allocation information is encrypted in the system to ensure confidentiality until the final data analysis.

Blinding (investigator's opinion)

Single blinded

Blinding description

In the present study, participants are divided into two research groups through random allocation. The evaluator is also blinded to the allocation of individuals to each intervention and control group.

Placebo

Not used

Assignment

Parallel

Other design features

The present study has two intervention and control groups (both male and female in each group) that has the intervention group with balance training using shuttle balance but the control group is considered without any intervention.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Sport Sciences Research Institute

Street address

No. 3 Fifth Alley, Mir Emad St, Motahhari St., Tehran

City

Tehran

Province

Tehran

Postal code

1587958711

Approval date

2019-03-11, 1397/12/20

Ethics committee reference number

IR.SSRC.REC.1398.026

Health conditions studied

1

Description of health condition studied

Posture control

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Balance

ICD-10 code

ICD-10 code description

3

Description of health condition studied

Gait speed

ICD-10 code

ICD-10 code description

4

Description of health condition studied

Risk of falling

ICD-10 code

ICD-10 code description

5

Description of health condition studied
Quality of life
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Postural control
Timepoint
Before the intervention and 6 weeks after the intervention
Method of measurement
FDM-S pressure distribution device manufactured by ZBIS company

2

Description
Balance
Timepoint
Before the intervention and 6 weeks after the intervention
Method of measurement
Berg scale

3

Description
Gait speed
Timepoint
Before the intervention and 6 weeks after the intervention
Method of measurement
Timed Up and Go Test

4

Description
Risk of fall
Timepoint
Before the intervention and 6 weeks after the intervention
Method of measurement
The falls effiacacy scale-international

5

Description
Quality of life
Timepoint
Before the intervention and 6 weeks after the intervention
Method of measurement
The item short-form health survey (SF-36) questionnaire is used for measurement.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this study, a group consisting of (male, female) receive intervention, the intervention is applied to people using shuttle balance. The present study uses the shuttle balance in the Corrective Movement Laboratory of the Faculty of Physical Education, University of Tehran, manufactured by Pajouhesh Sport today company. People practice the exercises under the supervision of a researcher for 90 minutes per session, 3 times a week for 6 weeks. Subjects warm-up for 15 minutes before starting the exercise. The exercise program lasts 60 minutes. Then they cool down for 15 minutes.
Category
Prevention

2

Description
Control group: The control group also includes (male, female). The people in this group do not receive any intervention.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Mehraban Elderly Home
Full name of responsible person
Dr. Jalil Ghafourian
Street address
Fahimi Street, Mehran, Tehran
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1471864771
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Faculty of Physical Education and Sport Science

Full name of responsible person
Dr. Reza Rajabi
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Faculty of Physical Education and Sport Sciences, between 15th and 16th St., North Kargar st., Tehran, Islamic Republic
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Email
infosport@ut.ac.ir
Web page address
http://sport.ut.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Faculty of Physical Education and Sport Science

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
Faculty of Physical Education and Sports Sciences
Full name of responsible person
zahra mohammadian
Position
Student
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
The data file cannot be published to the article due to its illegal use without the author's permission.
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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
The data from the efficacy results are unavailable but information on its consequences is available.
When the data will become available and for how long
After submitting the results of the articles, it is possible to make the data available.
To whom data/document is available
All people in the community who are interested and need data.
Under which criteria data/document could be used
To confirm that the research is correct and if the researcher himself is present
From where data/document is obtainable
zahra.md70@gmail.com 09304354565
What processes are involved for a request to access data/document
Submit a Request for Need
Comments