# 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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**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

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**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
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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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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

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## Person responsible for updating data

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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**