

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of 6-week strength-balance training under virtual reality environment on the co-contraction of lower limb muscles and center of pressure sway during limit of stability, curve tracking and turning in women with primary osteoporosis

#### Protocol summary

##### Study aim

Effect of 6-week strength-balance training under virtual reality environment on the co-contraction of lower limb muscles and center of pressure sway during limit of stability, curve tracking and turning in women with primary osteoporosis

##### Design

Clinical trial with intervention and control groups, parallel group, double-blind, randomized groups using random number table

##### Settings and conduct

The study will be conducted at Tarbiat Modares University's Gait Lab on women with primary osteoporosis. Intervention group will perform 6-weeks of strength-balance training using active video games via the Xbox 360 Kinect. control group will also perform 6 weeks of specific strength-balance training using the pulley and tilt board. In both groups, the effects of training on lower extremity muscle cocontraction and center of pressure sway after treatment will be examined. Individuals in each study groups were not aware of the type of exercise in the other group. The assessor is also blind to the allocation of study groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Women with primary osteoporosis after menopause Age range 48-65 At least one year has passed since the onset of menopause Not participating in regular exercise Obtain the normal score from the Mini mental exam Questionnaire Exclusion criteria: Vision problems A history of osteoporosis fractures Balance problems such as sudden falls Secondary osteoporosis

##### Intervention groups

Intervention group: 6 weeks strength-balance training under virtual reality environment Control group: 6 weeks of dedicated, lightweight strength-balance training using Polley and Tilt Board

#### Main outcome variables

Muscle strength; quality of life and fear of falling score: RMS: Coactivation index: LOS(reaction time): Curve tracking(RMS error):Curve tracking(area): Curve tracking(mean frequency): Curve tracking(peak frequency): Turning (turning sway)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20101017004952N9**  
Registration date: **2019-11-30, 1398/09/09**  
Registration timing: **registered\_while\_recruiting**

Last update: **2019-11-30, 1398/09/09**

Update count: **0**

##### Registration date

2019-11-30, 1398/09/09

##### Registrant information

##### Name

Giti Torkaman

##### Name of organization / entity

Tarbiat Modares University

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8288 4509

##### Email address

torkamg@modares.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

**Expected recruitment start date**

2019-10-22, 1398/07/30

**Expected recruitment end date**

2020-07-21, 1399/04/31

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effect of 6-week strength-balance training under virtual reality environment on the co-contraction of lower limb muscles and center of pressure sway during limit of stability, curve tracking and turning in women with primary osteoporosis

**Public title**

Effect of training under virtual reality environment on the co-contraction of lower limb muscles and center of pressure sway

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

BMI 22-30 kg / m<sup>2</sup> At least one year after menopause  
Not participating in regular exercise  
Not being on hormone therapy for at least the past 6 months  
No musculoskeletal and neurological problems  
Obtain the normal score from the Mini mental state exam  
Age range 48-65

**Exclusion criteria:**

Balance problems such as sudden falls  
A history of osteoporotic fractures  
Vision problems  
Use of walking aids

**Age**

From **48 years** old to **65 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

- Outcome assessor

**Sample size**

Target sample size: **20**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization will be done by an independent person by blocking randomization using sealed, opaque, and stapled envelopes

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Participants in each group are not aware of the other group program. The assessor or data collector is blinded about grouping.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Tarbiat modares university

**Street address**

Jalale ale ahmad., nasr bridge., chamran highway

**City**

Tehran

**Province**

Tehran

**Postal code**

14115-111

**Approval date**

2019-11-04, 1398/08/13

**Ethics committee reference number**

IR.MODARES.REC.1398.151

**Health conditions studied****1****Description of health condition studied**

postmenopausal osteoporosis

**ICD-10 code**

m81.9

**ICD-10 code description**

Postmenopausal osteoporosis

**Primary outcomes****1****Description**

EMG and Co-contracting index of muscles in functional activities

**Timepoint**

The timing of measurements will be before the start of the intervention and after 6 weeks of strength-balance training.

**Method of measurement**

Electromyography system

**2****Description**

CoP sway in functional activities

**Timepoint**

The timing of measurements will be before the start of the intervention and after 6 weeks of strength-balance training.

**Method of measurement**

mars software and force plate

## Secondary outcomes

### 1

#### Description

Quality of Life Score

#### Timepoint

The variables will be measured at baseline and also after 6 weeks of strength-balance training.

#### Method of measurement

Qualeffo-41 Questionnaire, Fall Efficacy Scale Questionnaire

### 2

#### Description

Muscle strength

#### Timepoint

The variables will be measured at baseline and also after 6 weeks of strength-balance training.

#### Method of measurement

Digital hand-held dynamometer

## Intervention groups

### 1

#### Description

Intervention group: 6 weeks of 3 sessions of strength-balance training under virtual reality environments through active video games using the Xbox kinect 360 Console

#### Category

Rehabilitation

### 2

#### Description

Control group: Performing specific, lightweight strength-balance training for 3 days a week for 6 weeks using a pulley and tilt board

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Tarbiat Modares University

##### Full name of responsible person

Dr. Giti Torkaman

##### Street address

Jala AleAhmad Ave., Nasr

##### City

Tehran

##### Province

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##### Postal code

1411713116

##### Phone

+98 21 8288 4509

##### Email

torkamg@modares.ac.ir

### 2

#### Recruitment center

##### Name of recruitment center

Baqiyatallah Al'Azam Hospital

##### Full name of responsible person

Noushin Bayat

##### Street address

Vanak Square, Mulla Sadra Street, after Sheikh Bahayi, Baqiyatallah Al'Azam Hospital

##### City

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##### Postal code

1435915371

##### Phone

+98 21 8805 0436

##### Email

mohammad.gilani@modares.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tarbiat Modares University

##### Full name of responsible person

Yaghoub Fatholahi

##### Street address

Jala AleAhmad Ave., Nasr

##### City

Tehran

##### Province

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##### Postal code

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##### Phone

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##### Fax

+98 21 8800 6544

##### Email

pres@modares.ac.ir

##### Web page address

<http://www.modares.ac.ir>

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Tarbiat Modares 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**  
Tarbiat Modares University  
**Full name of responsible person**  
Dr Giti Torkaman  
**Position**  
professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Physiotherapy  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tarbiat Modares University  
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Mohammad Gilani  
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**Email**  
mohammad.gilani@modares.ac.ir

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is 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

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

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

### Title and more details about the data/document

All data will be shared after confirmation of chief researcher.

### When the data will become available and for how long

6 months after publication

### To whom data/document is available

All researchers

### Under which criteria data/document could be used

For scientific purposes

### From where data/document is obtainable

Dr. Giti Torkaman

### What processes are involved for a request to access data/document

Confirmation of chief researcher

### Comments