Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 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 2 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
Ḍr. Giti Torkaman
Street address
Jala AleAhmad Ave., Nasr
City
Tehran
Province
Tehran
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
Tehran
Province
Tehran
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
Tehran
Postal code
1411713116
Phone
+98 21 8288 2009
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

Street address

Jalal AleAhmad Ave., Nasr

City

Tehran

Province

Tehran

Postal code

1411713116

Phone

+98 21 8288 4509

Email

torkamg@modares.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tarbiat Modares University

Full name of responsible person

Dr Giti Torkaman

Position

professor

Latest degree

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Other areas of specialty/work

Physiotherapy

Street address

Jalal AleAhmad Ave, Nasr

City

Tehran

Province

Tehran

Postal code

1411713116

Phone

+98 21 8288 0000

Email

torkamg@modares.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Tarbiat Modares University

Full name of responsible person

Mohammad Gilani

Position

PhD candidate

Latest degree

Master

Other areas of specialty/work

Physiotherapy

Street address

Jalal AleAhmad Ave, Nasr

City

Tehran

Province

Tehran

Postal code

1411713116

Phone

+98 21 8288 0000

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