

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

The comparison of the conventional versus virtual reality training on the functional movement skills in women with primary osteoporosis.

Protocol summary

Study aim

The comparison of the conventional versus virtual reality training on the functional movement skills in women with primary osteoporosis

Design

Clinical trials include control group, conventional training group and exergame group, double blind and randomized trials with blinded postoperative outcome assessment and evaluator

Settings and conduct

Individuals are randomly divided into three groups, before and after the intervention, the motion control indicators will be checked with the help of the Mars software of Kistler force platform and the motion analyser (Vicon) device. The outcome analyst and data analyst are unaware of how the group is intercepted and grouped

Participants/Inclusion and exclusion criteria

تقاضای بیمار برای ادامه ندادن درمان به هر دلیل و شرکت نکردن منظم در برنامه

Intervention groups

1-conventional training group 2-exergame group 3-control group

Main outcome variables

The center of pressure variable, which is obtained in limits of stability, curve tracking, sit to stand test, turning by the Mars software and with the aid of the force plate, and analyzing the torque around the lower limb joints of the dominant foot by the motion analysis camera

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101017004952N7**

Registration date: **2019-04-21, 1398/02/01**

Registration timing: **registered_while_recruiting**

Last update: **2019-04-21, 1398/02/01**

Update count: **0**

Registration date

2019-04-21, 1398/02/01

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

2019-04-21, 1398/02/01

Expected recruitment end date

2020-01-21, 1398/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of the conventional versus virtual reality training on the functional movement skills in women with primary osteoporosis.

Public title

Effect of exercise therapy on quality of functional movement skills in primary osteoporosis.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

BMI: 22-30 kg/m² Have at least one year of menopause
Not attending sports regularly, at least a year before the start of the study (At least 30 minutes a day and 2 to 3 days a week)
Cardiologist and rheumatologist confirm their entry into the power-balance exercise protocol
Eating the same dose of calcium and vitamin D based on the prescription of rheumatologist
According to the WHO criteria, bone mineral density (BMD) pre-entry bone mass for menopausal osteoporotic meninges was 2.5-> Tscore and for non-osteoporotic menopause subjects Tscore > -1.5
There is no history of fractures due to osteoporosis
There is no secondary osteoporosis
Do not suffer from cardiovascular disease and diseases of the joints of the extremities and spine
Do not take medications that affect the level of consciousness, such as sedation
no hormone therapy for at least 6 months

Exclusion criteria:

Patient's request to discontinue treatment for any reason and not to participate in the program regularly.

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

people allocated with simple randomization method via random numbers and divided into three groups:
exergame group, traditional exercise group, control group

Blinding (investigator's opinion)

Double blinded

Blinding description

The outcome assessor and data analyst are biomechanics who are unaware of who is involved in each group. The data is recorded by the machine, without any knowledge of the type of training.

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Committee of Ethics in Biomedical Research of Tarbiat Modares University

Street address

Jalal AleAhmad Ave., Nasr

City

tehran

Province

Tehran

Postal code

1411713116

Approval date

2018-07-21, 1397/04/30

Ethics committee reference number

IR.MODARES.REC.1397.050

Health conditions studied

1

Description of health condition studied

postmenopausal osteoporosis

ICD-10 code

m81.9

ICD-10 code description

osteoporosis, unspecified

Primary outcomes

1

Description

Cop sway velocity and displacement in functional activity
testes, sit to stand, limit of stability, reaching and curve tracking

Timepoint

pre and post intervention

Method of measurement

motion analyser, kistler forceplate and Mars software

Secondary outcomes

1

Description

activity balance - specific questionnaire

Timepoint

pre and post intervention

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention group 1: conventional training group

Category

Rehabilitation

2

Description

Intervention group 2: exergame

Category

Rehabilitation

3

Description

Control group: maintaining physical activity and activity of daily living as same as entrance time.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Tarbiat Modares University

Full name of responsible person

Dr. Giti Torkaman

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2

Recruitment center

Name of recruitment center

Shetab physicaltherapy center

Full name of responsible person

M.K.Rezaee

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No. 1, 2nd boostan Alley, Farahzadi Blvd, Shahrak ghods

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rezaeepthd@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tarbiat Modares University

Full name of responsible person

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Phone

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Email

torkamg@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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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

Person responsible for updating data

Contact

Name of organization / entity

Tarbiat Modares University

Full name of responsible person

M.K.Rezaee

Position

PhD candidate

Latest degree

Master

Other areas of specialty/work

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