Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the effects of whole body vibration alone and in combination with unstable shoes on the balance of healthy older adults

Protocol summary

Summary

The aim of this study is to compare the effects of whole body vibration while wearing unstable shoes and standard shoes on balance of elderly over 65. Older people are included if they gain a score of 25-35 (out of 40) in Fullerton Advance Balance scale and can walk independently for a distance of 20 meters. Elderly people with severe diabetes, kidney stones or bladder disorder ; noticeable and unmodified audio or visual content and elderly who have received balance training in the last 3 months will not be studied. A convenience sample of 60 people over 65 years will be recruited from Jahandidegan Older Comminuty Center in Shiraz, Iran. The participants will be randomly divided into two groups of 30 people. The first group whole body vibration and simple shoes and the second group will receive whole body vibration and unstable shoes.The total study lasts 4 weeks. With a frequency of three times a week and each session is 5 sets. Intervention and rest time per set, respectively first and second in two weeks, 30 seconds -1 minute, and minutes will be 1 min -1. Four weeks after the end of treatment, we will follow up and re-examine the outcome meadures. Selected frequency and amplitude for system is 30 Hz and 4 mm . Outcome measures are : balance ability measured by Fullerton Advance Balance Scale, Gait Speed and fear of falling measured by Fall Efficacy Scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015111825105N1**
Registration date: **2016-03-04, 1394/12/14**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-03-04, 1394/12/14

Registrant information

Name
Sobhan Sobhani
Name of organization / entity
Shiraz University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 71136271551
Email address
sobhanis@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Scineces

Expected recruitment start date

2016-05-01, 1395/02/12

Expected recruitment end date

2016-10-01, 1395/07/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of whole body vibration alone and in combination with unstable shoes on the balance of healthy older adults

Public title

Comparison of the effects of whole body vibration alone and in combination with unstable shoes on the balance of healthy older adults

Purpose

Treatment

Inclusion/Exclusion criteria
inclusion criteria: people older than 65 ؛ receiving the point between 25-35 from FAB scale ؛ ability of walking 20 meters independently ؛ receiving the point over 6 (from 15) in geriatric depression scale ؛ receiving the point lesser than 23(from 30) in mini mental state test ؛ able to maintain semi squat position for at least one minute exclusion criteria : elderly has been suffering from severe DM , kidney and bladder stone ؛ significant and not treated visual and vestibular impairments ؛ sever musculoskeletal , cardiovascular and neurological disorders ؛ elderly were receiving balance training in past three months ؛ fracture ؛ osteoprosis ؛ severe osteoarthritis ؛ taking sedative drugs

Age
From **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shiraz University of Medical Sciences

Street address
Central Building of Shiraz University of Medical Sciences, Zand avenue -shiraz

City
Shiraz

Postal code
1978-71345

Approval date
2016-01-24, 1394/11/04

Ethics committee reference number
IR.SUMS.REC.1394.192

Health conditions studied

1

Description of health condition studied
balance impairment

ICD-10 code
Not Specif

ICD-10 code description
Not Specified

Primary outcomes

1

Description
Fullerton Advance Balance scale(FAB)

Timepoint
Pre and post intervention

Method of measurement
Rating on balance scale

Secondary outcomes

1

Description
Gait Speed

Timepoint
Pre and post intervention

Method of measurement
10 meter walking test

2

Description
Added at 2016-11-19: Fear of Falling

Timepoint
Added at 2016-11-19: pre-post intervention

Method of measurement
Added at 2016-11-19: Fall Efficacy Scale

Intervention groups

1

Description
The intervention group will receive simultaneously the Whole Body Vibration and unstable shoes; Duration of intervention will be for 4 weeks with a frequency of three times per week. Each session contains 5 bouts of treatment (whole body vibration while wearing unstable shoes), with hold and rest periods. The hold-rest ratio will be 30-60 seconds, and 60-60 seconds in the first two weeks and second two weeks respectively. The frequency and amplitude of the applied whole body vibration will be 30 Hz and 3 mm .

Category
Treatment - Devices

2

Description
The control group will receive simultaneously the Whole

Body Vibration and standard shoes, similar in color and brand to unstable shoes; Duration of intervention will be for 4 weeks with a frequency of three times per week. Each session contains 5 bouts of treatment (whole body vibration while wearing unstable shoes), with hold and rest periods. The hold-rest ratio will be 30-60 seconds, and 60-60 seconds in the first two weeks and second two weeks respectively. The frequency and amplitude of the applied whole body vibration will be 30 Hz and 3 mm.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Jahandidegan older community center

Full name of responsible person

Sobhan Sobhani

Street address

School of Rehabilitation Sciences , Abiverdi1 avenue , Chamran Blvd

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Science

Full name of responsible person

Dr. Seyed Basir Hashemi

Street address

Vice-Chancellor for Research, Shiraz University of Medical Sciences, Zand Blvd., Shiraz, Iran Postal Code

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz University of Medical Science

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences, School of Rehabilitation Sciences

Full name of responsible person

Dr. Sobhan Sobhani

Position

Assistant Professor, PT, PhD

Other areas of specialty/work

Street address

School of Rehabilitation Sciences , Abiverdi1 avenue , Chamran Blvd

City

Shiraz

Postal code

Phone

+98 71 3627 1551

Fax

+98 71 3627 2495

Email

sobhan132@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences, School of Rehabilitation Sciences

Full name of responsible person

Dr. Sobhan Sobhani

Position

Assistant Professor, PT, PhD

Other areas of specialty/work

Street address

Chamran Blvd. Abiverdi1 avenue, School of Rehabilitation Sciences

City

Shiraz

Postal code

Phone

+98 71 3627 1551

Fax

+98 71 3627 2495

Email

sobhan132@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences, School of Rehabilitation Sciences

Full name of responsible person

Dr. Sobhan Sobhani

Position

Assistant Professor, PT, PhD

Other areas of specialty/work

Street address
Chamran Blvd. Abiverdi1 avenue, School of Rehabilitation Scienc
City
shiraz
Postal code
Phone
+98 71 3627 1551
Fax
+98 71 3627 2495
Email
sobhan132@gmail.com
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty