

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Evaluation of sub-sensory vibration on balance control in elderly subjects

Protocol summary

Study aim

the aim of this study is to investigate effect of sub threshold vibration on balance control of elderly and subjects with reduced foot sensation

Design

this study is a clinical trial with cross over and double blinded design,

Settings and conduct

the place of performing this study is Djavad Mowafaghian Research Center, Sharif university. All participants are blind to balance condition tests. The investigator and the outcome assessor are also blind and the order of the tests is determined by the computer program. On the other hand, data is coded and another person analyze data who will not be aware of coding .

Participants/Inclusion and exclusion criteria

participant inclusion criteria including: older subject of above 60 years that have history of one falling in 6 month ago or subjects that postural instability was probed by disability in doing single leg stance correctly for 5 second or more. Also, subjects must walk at least 10 meter without any assistive. subjects must score 7 or above from AMT(Abbreviated Mental Test) and score up 2 from clock drawing test. if subjects have heart and pulmonary disease will exclude from study. Any history of lower limb surgery or orthopedic disease , having visual or vestibule deficit and also using some drugs that may interfere balance are considered exclusion criteria. if subject have body mass index 30 or above will not include in this study.

Intervention groups

intervention is orthopedic shoe when vibration is on and second group is orthopedic shoe without vibration mechanism, after that with cross over design, the first group will receive orthopedic shoe and second group will receive orthopedic shoe with vibration on.

Main outcome variables

main outcome variable are: postural stability variable including center of pressure magnitude, velocity and phase plane portrait secondary outcomes: Timed Up and

Go (TUG) and Berg Balance Test

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170422033568N1**

Registration date: **2018-04-30, 1397/02/10**

Registration timing: **registered_while_recruiting**

Last update: **2018-04-30, 1397/02/10**

Update count: **0**

Registration date

2018-04-30, 1397/02/10

Registrant information

Name

atefeh aboutorabi

Name of organization / entity

university of social welfare and rehabilitation sciences

Country

Iran (Islamic Republic of)

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at.aboutorabi@uswr.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-21, 1397/02/01

Expected recruitment end date

2018-05-22, 1397/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of sub-sensory vibration on balance control in elderly subjects

Public title

effect of vibration on balance of elderly

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

elderly above 60 years history of one falling in 6 month ago or disability in doing single leg stance test for 5 second Can walk about 10 m without no assistive AMT (Abbreviated Mental Test) score 7 & above score up to 2 for Clock Drawing test

Exclusion criteria:

having Heart and pulmonary diseases Peripheral neuropathy or Diabetic Visual & vestibular deficiency BMI 30 and above lower Limb surgery, Contraction, amputation Alzheimer Dizziness

Age

From **60 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **12**

Actual sample size reached: **12**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

1- all participant were blinded to performing postural stability tests (because of applying sub sensory vibration, participants were not aware in conditions vibration on or off) 2- investigator was blind to test conditions (order of different condition was completely random and determined by computer software, so outcome assessor was blinded to test and vibration on/off 3- data was coded for every condition and subjects. so another person analyzed data.

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of University of Social Welfare and Rehabilitation Sciences

Street address

kodakyar Ave., Daneshjo Blvd.,Evin

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1985713834

Approval date

2015-09-02, 1394/06/11

Ethics committee reference number

IR.USWR.REC.1394.67

Health conditions studied

1

Description of health condition studied

falling, elderly, aging, older, balance, vibration, stochastic resonance

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

the primary outcome is balance that is measured via center of pressure displacement and velocity via force plate

Timepoint

outcome is measured immediately after intervention

Method of measurement

the primary outcome "center of pressure variable" is measured by force plate in biomechanic lab and secondary outcomes including Timed Up and Go and Berg Balance Test was recorded by therapist

Secondary outcomes

1

Description

secondary outcomes are Timed Up and GO test (TUG) and Berg Balance Test

Timepoint

these secondary outcome record 3 times after intervention immediately

Method of measurement

secondary outcomes records by checklist of TUG and Berg Balance Test by therapist

Intervention groups

1

Description

the first Intervention group: orthopedic shoe with vibration mechanism

Category

Treatment - Devices

2

Description

Second intervention: orthopedic shoe/ or orthopedic shoe without vibration mechanism

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Djavad Mowafaghian Research Center, Sharif University of Technology

Full name of responsible person

Atefeh Aboutorabi

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No.11, Khark Street, Enghelab Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Amir Massoud Arab

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

University of social welfare and rehabilitation sciences

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

University of social welfare and rehabilitation sciences

Full name of responsible person

Atefeh Aboutorabi

Position

researcher

Latest degree

Ph.D.

Other areas of specialty/work

Rehabilitation management

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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

No - There is not 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

Yes - There is a plan to make this available

Title and more details about the data/document

data collected for the primary outcome measure will be shared

When the data will become available and for how long

data can be shared 6 months after publication

To whom data/document is available

data will be available for people working in academic institutions or reserchers

Under which criteria data/document could be used

data will be available for people who working on secondary studies such as systematic review or meta-analysis

From where data/document is obtainable

applicants can be get through via

Email:at.aboutorabi@uswr.ac.ir

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

after publication of results of study, with receiving email from academic person or researcher, data is sent

Comments