Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 2026

The study to compare whole body vibration in combination with unstable shoes and whole body vibration lonely on balance, proprioception and ankle muscle strength in patient with chronic ankle instability

Protocol summary

Study aim

To compare the effect of Whole Body Vibration(WBV) together with and without unstable shoes on balance, proprioception and ankle muscle strength in patient with chronic ankle instability

Design

Design:Three arm parallel group randomized trial including a control group. Blinding: The outcome assessor will be blind. Randomization:45 participants will be randomly allocated to the 3 groups via permuted block randomization with block of size5.

Settings and conduct

This study will be done in Rehabilitation Sciences Research Center and Clinic, Shiraz University of Medical Sciences, Shiraz ,Iran on 45 individual with chronic ankle instability.The individuals will be assessed by a blind assessor and allocated randomly into the 3 groups:combination treatment,Whole body vibration and without treatment.They will receive 12 sessions of treatment during 4 weeks and will be followed up after 2 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria:The person with chronic ankle instability;18_55 years old;A history of at least 1 ankle sprain over the past 12 months; feelings of instability or/and recurrent ankle sprain and/or giving way; receiving a score less than 24 on Cumberland Ankle Instability Tool; receiving a score less than 90% on the ADL and less than 80% on Sport domain of the Foot and Ankle Ability Measure .Non-inclusion criteria: A history of any previous surgery on musculoskeletal of the lower extremities; A history of any fracture in lower extremities; potential contraindication of WBV usage; some disease due to balance problem.

Intervention groups

Intervention group 1: combination treatment group (whole body vibration in combination with unstable shoes). Intervention group 2: whole body vibration group (whole body vibration). control group: without treatment.

Main outcome variables

Balance;Function; Ankle joint proprioception (inversion);Ankle strength (invertor/evertor muscles)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151118025105N4**
Registration date: **2019-03-19, 1397/12/28**
Registration timing: **prospective**

Last update: **2019-03-19, 1397/12/28**
Update count: **0**

Registration date

2019-03-19, 1397/12/28

Registrant information

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2019-07-23, 1398/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The study to compare whole body vibration in combination with unstable shoes and whole body vibration lonely on balance, proprioception and ankle muscle strength in patient with chronic ankle instability

Public title

The effect of the combination of whole body vibration and unstable shoes in chronic ankle instability treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

A history of at least 1 ankle sprain at least 12 months prior to the study enrollment, should be associated with inflammatory symptoms (pain, swelling, etc) and created at least 1 interrupted day of desired physical activity. The most recent injury must have occurred more than 3 months prior to study enrollment. A history of the previously injured ankle joint giving way(participants should report at least 2 episodes of giving way in the 6 months prior to study) and/or recurrent sprain(two or more sprains to the same ankle)and/or feelings of instability. Receiving a score less than 24 on Cumberland Ankle Instability Tool (CAIT) Receiving a score less than 90% for daily activity (ADL scale) and less than 80% for sport on Foot and Ankle Ability Measure (FAAM). Unilateral chronic ankle instability Being at the age of 18_55 years

Exclusion criteria:

A history of any previous surgery on musculoskeletal structures (ie, bones, joint structures, nerves) of the lower extremities A history of any fracture in lower extremities Acute injury to musculoskeletal structures of other joints of the lower extremities in the previous 3 months Potential contraindication of Whole Body Vibration usage Some disease due to balance problem (peripheral neuropathy, MS, Parkinson, Migraine, Radiculopathy, middle ear disease)

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted Block Randomization

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the outcome assessor as well as data analyzer will be blinded to the group allocation

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz Rehabilitation Sciences School

Street address

School of Rehabilitation Sciences, Abiverdi 1 Street, Chamran Blvd

City

Shiraz

Province

Fars

Postal code

33669-71947

Approval date

2018-11-21, 1397/08/30

Ethics committee reference number

IR.SUMS.REHAB.REC.1397.005

Health conditions studied

1

Description of health condition studied

Chronic ankle instability

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Balance

Timepoint

Pre and post intervention (after4 weeks) and during follow up (after 6 weeks)

Method of measurement

Star Excursion Balance Test

Secondary outcomes

1

Description
Ankle proprioception (inversion)
Timepoint
Pre and post intervention (after 4 weeks)
Method of measurement
Isokinetic Dynamometer

2

Description
Ankle muscles strength (Invertor and Evertor)
Timepoint
Pre and Post intervention (after 4 weeks)
Method of measurement
Isokinetic Dynamometer

3

Description
Function
Timepoint
Pre and Post intervention (after 4 weeks) and fallow up (after 6 weeks)
Method of measurement
Single Leg Hope Distance Test

Intervention groups

1

Description
Intervention group 1: This group will receive the whole body vibration alone for 12 sessions during a period of 4 weeks . Frequency of the whole body vibration will be increased from 30Hz to 40 Hz and duration will be increased from 35 second to 60 second during 12 session .Each session will contain 3 sets and the rest between each bout of training will be 45 second.
Category
Treatment - Devices

2

Description
Intervention group 2: This group will receive the whole body vibration with the same parameters and duration as the first group while wearing the unstable shoes.
Category
Treatment - Devices

3

Description
Control group: This group will receive no intervention.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Physiotherapy Clinics in Shiraz city
Full name of responsible person
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Sponsors / Funding sources

1

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Web page address
http://research.sums.ac.ir/fa/contact-information/index.html
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 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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available