

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

The effect of the Whole Body Vibration on the static and dynamic balance indices and Invertor and Evertor muscle torque in Functional Ankle Instability

Protocol summary

Summary

The purpose of this double-blind clinical trial is to investigate the impact of the Whole body Vibration on the static and dynamic balance indices and the invertors and evertors muscle torque in the individuals with functional ankle instability. The patients with the functional ankle instability that the number of whom is determined by a pilot study and meet the inclusion criteria are enrolled in the experimental group and the control group is selected from the individuals with no background of ankle sprain. The patients in the experimental group will be treated by the whole body vibration and the individuals in the control group will receive no treatment. First, the static and dynamic balance as well as the muscle torque in the healthy legs are compared with the legs with functional ankle instability to determine whether these indices in the individuals with the functional ankle instability suggest any differences with those of the individuals in the control group or not. The differences between the individuals in the experimental and control groups being registered, the clinical intervention for the experimental group will commence. The patients in the experimental group will receive clinical intervention and then they will be assessed in terms of the static and dynamic balance indices and invertor and evertor muscles torque.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201011135112N2**

Registration date: **2011-11-22, 1390/09/01**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-11-22, 1390/09/01

Registrant information

Name

Rozita Hedayati

Name of organization / entity

Semnan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 23 1335 4180

Email address

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Recruitment status

Recruitment complete

Funding source

Semnan University of Medical Sciences

Expected recruitment start date

2011-11-22, 1390/09/01

Expected recruitment end date

2012-04-20, 1391/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of the Whole Body Vibration on the static and dynamic balance indices and Invertor and Evertor muscle torque in Functional Ankle Instability

Public title

The effect of the Whole Body Vibration on the balance and ankle muscle power in Functional Ankle Instability

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: At least 1 significant lateral (inversion) sprain of the right ankle, in which the subject was unable to bear weight or was placed on crutches, within the last year, No reported history of fracture to either ankle, At least 1 repeated injury or the perception of ankle instability or "giving way" in the right ankle, No formal or informal rehabilitation of the unstable ankle, No evidence of mechanical instability as assessed by an orthopedic physician using Anterior Drawer and Talar Tilt Tests Exclusion criteria: Pain, Abnormal gait, Mechanical injury to the ligaments, Participants who had not experienced any lower extremity injury in the last 6 months, subjects who were not suffering from a lower extremity injury and had no history of major injury that resulted in severe ligamentous damage, fracture, need for surgery or therapeutic treatment, Visual disorders not to be improved by glasses, vestibular disorders, balance disorders, history of falling, use of drugs that affect postural control system

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size:

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Semnan University of Medical Sciences

Street address

Semnan Rehabilitation University; Damghan Road, 5 km towards Damhan

City

Semnan

Postal code

Approval date

2010-10-26, 1389/08/04

Ethics committee reference number

111318/90

Health conditions studied

1

Description of health condition studied

Functional Ankle Instability

ICD-10 code

S93.4

ICD-10 code description

Sprain and strain of ankle

Primary outcomes

1

Description

Dynamic and static balance

Timepoint

Before and after intervention

Method of measurement

Biodex

2

Description

Invertor and evertor muscles torque

Timepoint

Before and after intervention

Method of measurement

Isokinetic

Secondary outcomes

empty

Intervention groups

1

Description

Control: Control group gives no treatments in this time.

Category

N/A

2

Description

Intervention: Treatment with the Whole Body Vibration for 6 weeks and 3 times a week.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Treatment Centers and Clinics affiliated to the

Semnan University of Medical Science
Full name of responsible person
Street address
City
Semnan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Dr Raheb Ghorbani
Street address
Semnan Rehabilitation University; Damghan Road, 5
km towards Damhan
City
Semnan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Semnan University of Medical Sciences

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
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Full name of responsible person
Dr Rozita Hedayati
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PHD,Head of Physiotherapy Department
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Person responsible for scientific inquiries

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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