

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The Effects of Whole Body Vibration on Balance and Muscles Strength in Lower Extremities in Flat Foot individuals, during and after the developing age, after fatigue Conditions.

Protocol summary

Study aim

The purpose of this study is to investigate the effect of Whole body vibration on limb muscle torque following fatigue in subjects with flat foot during and after the growth age.

Design

A concealed, randomized, blinded, sham controlled clinical trial with a parallel group design of 40 patients, will enrolled between April 2019 and September 2019.

Settings and conduct

This study will be carried out at the Neuromuscular Rehabilitation Center of Semnan University of Medical Sciences. After allocation, two groups were randomly assigned into intervention and control groups, a blinded assessor, will evaluate the strength of the dominant lower extremity muscles, pre and post fatigue protocol using isokinetic device. Then, an experienced physiotherapist, intervened the participants via the whole body vibration for the intervention group for 10 sessions. After the intervention, the strength of the lower limb muscles before and after the fatigue condition by evaluator that was blinded to grouping as the beginning of the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Individuals with flat feet aged between 12 and 30 year 2-BMI 20-25 3. Having an index of 6 in foot posture index Exclusion criteria: 1. Neuromuscular, rheumatic diseases, and any disturbances in balance 2-structural flatfoot (with doctor's diagnosis)

Intervention groups

In this study, subjects with flat foot in two age groups including during and after age of growth, will assigned into two intervention and control groups.

Main outcome variables

1. Isokinetic strength of knee flexors and extensors 2. Isokinetic strength of ankle plantar flexors and dorsi-

flexors

General information

Reason for update

Acronym

WBV

IRCT registration information

IRCT registration number: **IRCT20160808029264N4**

Registration date: **2019-03-02, 1397/12/11**

Registration timing: **prospective**

Last update: **2019-10-01, 1398/07/09**

Update count: **2**

Registration date

2019-03-02, 1397/12/11

Registrant information

Name

Rasool Bagheri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3344 1022

Email address

rasool.bagheri@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2019-09-23, 1398/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The Effects of Whole Body Vibration on Balance and Muscles Strength in Lower Extremities in Flat Foot individuals, during and after the developing age, after fatigue Conditions.

Public title
The effect of Whole body vibration on the flat foot

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 1. Individuals with flat feet aged between 12-30 years 2- BMI of 20-25 3- Having an flat foot posture index above 6
Exclusion criteria:
 1-neuromuscular diseases 2. History of any musculoskeletal disorder 3. History of fractures in the limbs and spine 4. History of rheumatic diseases 5. History of mental illness 6. Any drug use 7. Any disturbances in balance 8-Structural flatfoot (with doctor's diagnosis)

Age
From **12 years** old to **30 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Investigator
- Outcome assessor

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Subjects were randomly assigned into two age groups of 12-18 years of age (growth ages) and 20-30 years old (after age of growth), according to inclusion criteria. Then, in each age group, subjects were randomly assigned In both intervention and control groups. So, in general, this study has four groups. After inclusion the study, the subjects will be randomly assigned to each intervention and control group by simple method using a random numbers table.

Blinding (investigator's opinion)
Double blinded

Blinding description
1. The person who evaluates the results of the study will also blind the allocation of the groups. 2. An individual analyzing the results will also blind the allocation of groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Comitee of Semnan University of Medical Sciences

Street address

Basij Blvd, Semnan, Semnan Province.

City

Semnan

Province

Semnan

Postal code

۹۹۹۵۱- ۳۵۱۹۸

Approval date

2019-02-20, 1397/12/01

Ethics committee reference number

IR.SEMUMS.REC.1397.266

Health conditions studied

1

Description of health condition studied

Flat foot

ICD-10 code

M21.4

ICD-10 code description

Flat foot [pes planus] (acquired)

Primary outcomes

1

Description

Isokinetic strength of knee flexors and extensors, ankle plantar and dorsi-flexors

Timepoint

Measurement of the strength before and immediately after 10 sessions of whole body vibration

Method of measurement

Isokinetic power measuring device

2

Description

Static and dynamic balance

Timepoint

Pre and post intervention

Method of measurement

BIODEX instrument

Secondary outcomes

1

Description

Foot posture index (FPI)

Timepoint

Before first session and after the 10th session of whole body vibration

Method of measurement

Foot posture index

Intervention groups

1

Description

Intervention group: Whole body vibration for 10 sessions, 3 sessions per week at 35 Hz, 10 repetitions with 60 seconds, 60 seconds rest between each repetition.

Category

Rehabilitation

2

Description

Control group: Corrective foot exercises for 10 sessions, 3 sessions per week and 30 minutes per session

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Ibn-e-Sina Rehabilitation Clinic

Full name of responsible person

Rasool Bagheri

Street address

Next to Sepah Bank., 17 shahrivar Blvd., Semnan town

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Dr Parviz Kokhaei, Research & Technology Deputy of University

Street address

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99951- 35198

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Email

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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

Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Ali Akbar Pahlavanian

Position

Lecturer

Latest degree

Master

Other areas of specialty/work

Occupational Therapy

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Person responsible for scientific inquiries

Contact

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Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information.

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Title and more details about the data/document

Only part of the data, such as the primary outcome, can
be released.

**When the data will become available and for how
long**

Start the access period 6 months after publishing the
results

To whom data/document is available

I have not decided yet - its release plan is still unknown

Under which criteria data/document could be used

I have not decided yet - its release plan is still unknown

From where data/document is obtainable

I have not decided yet - its release plan is still unknown

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

I have not decided yet - its release plan is still unknown

Comments