Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Immediate Effects of Blood Flow Restriction Combined with Whole Body Vibration on Balance and Proprioception in Non-professional Athletes with Chronic Ankle Instability

Protocol summary

Study aim

Investigating the immediate effect of blood flow restriction combined with whole body vibration on balance and proprioception of non-professional athletes with chronic ankle instability

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, on 38 patients with sealed envelope method.

Settings and conduct

The samples and the assessor are blinded to the treatment group.

Participants/Inclusion and exclusion criteria

Inclusion criteria 1- Non-professional athlete 2- Age range from 18 to 35 years 3- Male and female gender 4- Having at least one ankle sprain in one of the legs, the first history of the sprain occurred at least one year before the study and was associated with inflammatory symptoms and caused the person to be unable to participate in desired physical activities for at least one day. slow 5- A score less than or equal to 24 in the Cumberland questionnaire 6- Having a history of ankle giving way or recurrent ankle sprain or a feeling of instability in the injured ankle exclusion criteria 7- history of acute injury (including sprained ankle), fracture or lower limb surgery in the last 3 months 8- having any disease (vestibular problem, vision and hearing disorders, etc.) that affects the person's balance 9- history of hypertension, blood clotting disease, peripheral vascular disease, cardiovascular problems or diabetes 10- People with internal prosthesis, acute disc herniation, recent fracture, joint inflammation, recent stroke, having an artificial pacemaker, epilepsy, migraine, peripheral neuropathy, pregnancy and malignancy are excluded from the study.

Intervention groups

1- Blood flow restriction group in combination with whole body vibration 2- Whole body vibration group alone

Main outcome variables

1- Reaching distance in star excursion balance test 2- Number of errors in balance error scoring system 3- Ankle joint repositioning error

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230203057314N1**
Registration date: **2023-06-02, 1402/03/12**
Registration timing: **registered_while_recruiting**

Last update: **2023-06-02, 1402/03/12**
Update count: **0**

Registration date

2023-06-02, 1402/03/12

Registrant information

Name

Anahita Bajalan

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-03, 1402/01/14

Expected recruitment end date

2023-08-21, 1402/05/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Immediate Effects of Blood Flow Restriction Combined with Whole Body Vibration on Balance and Proprioception in Non-professional Athletes with Chronic Ankle Instability

Public title
Immediate Effects of Blood Flow Restriction Combined with Whole Body Vibration in Chronic Ankle Instability
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Non-professional Athlete Age range from 18 to 35 years Male and female gender Having at least one ankle sprain in one of the ankles, the first history of the sprain occurred at least one year before the study and was associated with inflammatory symptoms and caused the person to be unable to participate in desired physical activities for at least one day. A score less than or equal to 24 in the Cumberland questionnaire Having a history of ankle giving way or recurrent ankle sprain or a feeling of instability in the injured ankle
Exclusion criteria:
People who have had an acute injury (including sprained ankle), fracture or lower limb surgery in the last three months. Any disease (vestibular problem, vision and hearing disorders, etc.) that affects a person's balance People who have a history of high blood pressure, blood clotting disease, peripheral vascular disease, cardiovascular problems or diabetes People with internal prosthesis, acute disc herniation, recent fracture, joint inflammation, recent stroke, having an artificial pacemaker, epilepsy, migraine, peripheral neuropathy, pregnancy and malignancy.
Age
From **18 years** old to **35 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **38**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple non-probability randomization is done using the numbered and sealed envelope method. With the help of physiotherapist 1 (evaluator), patients are randomly divided into 2 intervention and control groups through the sealed envelope method. be. For this purpose, 38 envelopes are prepared, which are filled with the numbers 1 and 2 (19 envelopes containing the number 1 and 19 envelopes containing the number 2). The numbers 1 and 2 each separately means entering one of the intervention and control groups, which only physiotherapist 2 (therapist) knows about. Before the patient chooses the envelope, we will change the order of the envelopes several times, and after the patient chooses the envelope, its number is noted on the evaluation sheet.
Blinding (investigator's opinion)
Double blinded
Blinding description
The participants and the evaluating physiotherapist are blinded to the study groups. Both groups of patients receive whole body vibration treatment, and in one group, the cuff around the thigh is filled with air, and in the other group, it is simply closed without filling with air, and the patients do not see any difference between the two groups. The evaluating physiotherapist does not know which treatment group each patient is in, and the assignment of patients to two groups is done by the treating physiotherapist.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committees of School of Nursing and Midwifery & Rehabilitation - Tehran University o
Street address
Faculty of Rehabilitation , corner of Safi Alishah St.,Enqelab St., Tehran town
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Province
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Postal code
11489-65111
Approval date
2023-02-01, 1401/11/12
Ethics committee reference number
IR.TUMS.FNM.REC.1401.162

Health conditions studied

1

Description of health condition studied
chronic ankle sprain
ICD-10 code

M25.373

ICD-10 code description

Other instability, unspecified ankle

Primary outcomes

1

Description

Reaching distance in star excursion balance test

Timepoint

Before the intervention and immediately after the intervention

Method of measurement

tape measure

2

Description

Number of errors in balance error scoring system

Timepoint

Before the intervention and immediately after the intervention

Method of measurement

Balance scoring system

3

Description

Ankle joint repositioning error

Timepoint

Before the intervention and immediately after the intervention

Method of measurement

Using a goniometer and calculating the angle in AutoCAD software

Secondary outcomes

1

Description

Time Score in side hop test

Timepoint

Before the intervention and immediately after the intervention

Method of measurement

digital chronometer

2

Description

Dorsiflexion range of motion

Timepoint

Before the intervention and immediately after the intervention

Method of measurement

goniometer

3

Description

Rate of perceived instability

Timepoint

Before the intervention and immediately after the intervention

Method of measurement

visual analog scale

Intervention groups

1

Description

Intervention group: Blood flow restriction combined with whole body vibration using whole body vibration device and blood flow restriction device for a single treatment session for 6 minutes.

Category

Rehabilitation

2

Description

Control group: Whole body vibration alone

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Rehabilitation, University of Tehran

Full name of responsible person

Dr. Sofia Naqdi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Fatuhi

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6th floor of Research and Technology Vice-Chancellor, Central Organization of the University , corner of Quds St. , Keshavarz Blvd. , Tehran Town

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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
Tehran 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)
Yes - There is a plan to make this available
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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code

Yes - There is 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

All data is potentially shareable after de-identifying individuals

When the data will become available and for how long

2024

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

Students

From where data/document is obtainable

a-bajalan@tums.ac.ir

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

no

Comments