

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 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. 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 7754 6533

##### Email address

a-bajalan@tums.ac.ir

##### 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

**City**

tehran

**Province**

Tehran

**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

**Street address**

Faculty of Rehabilitation ,corner of Safi Alishah St.,Enqelab St., Tehran city

**City**

tehran

**Province**

Tehran

**Postal code**

11489-65111

**Phone**

+98 21 7753 3939

**Email**

rehabilitation@tums.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Fatuhi

**Street address**

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

**City**  
tehran  
**Province**  
Tehran  
**Postal code**  
11489-65111  
**Phone**  
+98 21 8163 3698  
**Email**  
vcr@sina.tums.ac.ir

**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**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Dr nastaran ghotbi  
**Position**  
Associate Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Physiotherapy  
**Street address**  
Faculty of Rehabilitation , corner of Safi Alishah St.,  
Enqelab St. , tehran city  
**City**  
tehran  
**Province**  
Tehran  
**Postal code**  
11489-65111  
**Phone**  
+98 21 7753 4133  
**Email**  
nghotbi@sina.tums.ac.ir

## Person responsible for scientific inquiries

**Contact**  
**Name of organization / entity**  
Tehran University of Medical Sciences

**Full name of responsible person**  
Dr nastaran ghotbi  
**Position**  
Associate Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Physiotherapy  
**Street address**  
Faculty of Rehabilitation , Corner of Safi Alishah St.,  
Enqelab St. , Tehran city  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
11489-65111  
**Phone**  
+98 21 7753 4133  
**Email**  
nghotbi@sina.tums.ac.ir

## Person responsible for updating data

**Contact**  
**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Anahita Bajalan  
**Position**  
Masters student  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Physiotherapy  
**Street address**  
No.50 , Shahid Asqar Amini Alley , Shahid Madani Ave  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1638954113  
**Phone**  
+98 21 7754 6533  
**Fax**  
**Email**  
a-bajalan@tums.ac.ir

## 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**