

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Effects of a progressive balance training program with and without medial wedge on postural control of patients with chronic ankle instability

Protocol summary

Study aim

Effects of a progressive balance training program (PBTP) with and without medial wedge on postural control of patients with chronic ankle instability (CAI)

Design

Clinical trial with control group, single-blind, randomized by block method, on 24 patients

Settings and conduct

Faculty of Rehabilitation of Tehran University of Medical Sciences, 24 patients with CAI, after examining the inclusion and exclusion criteria, were randomly divided into two groups of intervention and control and underwent 12 sessions of therapeutic intervention every other day for 4 weeks. Evaluation is done before the intervention, after the end of each 3 sessions of the intervention and after 12 sessions of the intervention

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with CAI; 20- 40 yrs, Normal range of motion in trunk and lower extremity joints, Patient has a history of at least one lateral ankle sprain, The initial sprain must have occurred at least 12 months prior to study enrollment, The patient has experienced frequent ankle joint giving way, CAIT: score of ≤ 25 , FAAM: activities of daily living subscale $<90\%$, sport subscale $<80\%$ Exclusion criteria: Mechanical ankle instability, Flat foot and any structural deformity in lower limb or spine, Cardio-pulmonary disease, head trauma, numbness of the limbs, dizziness and headache, The subject has received an ankle rehabilitation program in the last 6 weeks, History of the visual, hearing and somatosensory problem, History of lower extremity injury or lower-extremity surgery

Intervention groups

The intervention group receives PBTP with insole with 4 degree medial wedge at rear foot and The control group received PBTP alone.

Main outcome variables

Static postural control, Dynamic postural control, Symmetry limb index, Duration of maintenance in the single-leg squat test

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220212054006N1**

Registration date: **2022-03-26, 1401/01/06**

Registration timing: **prospective**

Last update: **2022-03-26, 1401/01/06**

Update count: **0**

Registration date

2022-03-26, 1401/01/06

Registrant information

Name

Makan Piri

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 26 3332 1098

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mpiri@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-21, 1401/02/01

Expected recruitment end date

2023-04-21, 1402/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of a progressive balance training program with and without medial wedge on postural control of patients with chronic ankle instability

Public title

Effects of a progressive balance training program with and without medial wedge on chronic ankle instability

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with chronic ankle instability; 20- 40 yrs. Normal range of motion in trunk and lower extremity joints Patient has a history of at least one lateral ankle sprain was associated with inflammatory symptoms like pain or swelling and created at least one day interruption of physical activity The initial sprain must have occurred at least 12 months prior to study enrollment The patient has experienced frequent ankle joint giving way (at least twice in the 6 months prior to this study) Cumberland Ankle Instability Tool: score of ≤ 25 Foot and Ankle Ability Measure: activities of daily living subscale $<90\%$, sport subscale $<80\%$

Exclusion criteria:

Mechanical ankle instability Flat foot and any structural deformity in lower limb or spine (Medium and severe flat foot are exclude from the study) Cardio-pulmonary disease, head trauma, numbness of the limbs, dizziness and headache The subject has received an ankle rehabilitation program in the last 6 weeks History of the visual, hearing and somatosensory problem can affect the balance History of lower extremity injury or lower-extremity surgery

AgeFrom **20 years** old to **40 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample sizeTarget sample size: **24****Randomization (investigator's opinion)**

Randomized

Randomization description

Randomization will be done using random allocation software based on random blocking method with a size of 4 blocks and a 1: 1 allocation ratio

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the outcome assessor is blind, as he or she does not know how subjects are assigned to the groups and what treatment intervention each group receives.

Placebo

Not used

Assignment

Parallel

Other design features

This study has a progressive balance training program protocol with and without medial wedge for patients with chronic ankle instability

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

Street address

Department of Physiotherapy, School of Rehabilitation, Pich Shemiran, Enghelab St, Tehran

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Tehran

Postal code

1148965111

Approval date

2022-03-14, 1400/12/23

Ethics committee reference number

IR.TUMS.FNM.REC.1400.236

Health conditions studied**1****Description of health condition studied**

chronic ankle instability

ICD-10 code

M25.37

ICD-10 code description

Other instability, ankle and foot

Primary outcomes**1****Description**

Static postural control by measuring the center of pressure parameters

Timepoint

Before the intervention, after the end of 3 sessions of the intervention, after the end of the 12 sessions of the intervention

Method of measurement

Force plate and insert in formula

2

Description

Dynamic postural control by measuring the reaching distance in the Y balance test

Timepoint

Before the intervention, after the completion of 12 intervention sessions

Method of measurement

Tape and insert in the formula

3

Description

Symmetry limb index

Timepoint

Before the intervention, after the completion of 12 intervention sessions

Method of measurement

Tape and insert in the formula

4

Description

Duration of maintenance in the single-leg squat test

Timepoint

Before the intervention, after the completion of 12 intervention sessions

Method of measurement

Stopwatch

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group receives progressive balance training with insole with 4 degree medial wedge at rear foot for twelve sessions every other day for four weeks (3 sessions of intervention per week). The insole used in this research is semi-rigid. The superficial layer of insole is made of artificial leather with a thickness of one millimeter, the bottom layer of insole is made of cow leather with a thickness of three millimeter and the medial wedge is made of hard plastic (polyethylene).

Category

Rehabilitation

2

Description

Control group: The control group received progressive balance training for twelve sessions every other day for four weeks (3 intervention sessions per week).

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Physiotherapy Clinic, School of Rehabilitation, Tehran University of Medical Sciences

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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)

Undecided - It is not yet known if there will be a plan to
make this available

Study Protocol

No - There is not 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

Yes - There is 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

Data can be shared after people are not identified

When the data will become available and for how long

Access period starts 6 months after the results are
published

To whom data/document is available

Anyone interested can access the data

Under which criteria data/document could be used

The use of data is permitted provided the source is cited
if the information is used elsewhere

From where data/document is obtainable

Makan Piri, makanpiri77@gmail.com

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

All they have to do is send email and they will receive

the information within a month

Comments