Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Jun 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

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Iran (Islamic Republic of)

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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
Age
From **20 years** old to **40 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target 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
City
Tehran
Province
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
Dr Mohsen Mir
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Vice Chancellor for Research and Technology, Sixth floor, University Central Organization, Corner of Ghods Street, Keshavarz Boulevard, Tehran
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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
Tehran University of Medical Sciences

Full name of responsible person
Makan Piri

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Physiotherapy

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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