Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effects of combined and dual-task training on brain electrical activity, proprioception and balance in athletes with chronic ankle instability: A randomized controlled clinical trial

Protocol summary

Study aim

Comparison of the effectiveness of combined and dual-task exercises on brain electrical activity, proprioception, and balance in athletes with chronic ankle instability.

Design

The present study is a randomized controlled clinical trial that includes a statistical population of male and women athletes (18-25 years old) with chronic ankle instability.

Settings and conduct

Men and women with chronic ankle instability who refer to orthopedic and physiotherapy clinics in Hamadan will be recruited. Eligible participants will be enrolled in the study and randomly allocated to the intervention and control groups using block randomization. This study will be conducted as a single-blind trial, in which the assessor will be blinded to group allocation.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Athletes with chronic ankle instability, Cumberland Ankle Instability Tool (CAIT) score ≤ 24. Exclusion criteria prior to randomization: History of anterior cruciate ligament (ACL) injury

Intervention groups

Intervention group 1: Participants will undergo separate neuromuscular and cognitive training for 8 weeks, 3 sessions per week, 60 minutes per session. Neuromuscular training includes balance exercises (eyes open/closed), balance board exercises, and high-knee walking, while cognitive training consists of isolated mental tasks (e.g., reversing four-digit numbers). Intervention group 2: Participants will undergo dual-task training for 8 weeks, 3 sessions per week, using the same neuromuscular exercises performed simultaneously with cognitive tasks, such as backward counting during balance exercises. Control group: The control group will receive no rehabilitation intervention during the 8-week period.

Main outcome variables

Electrical activity of the brain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251221068402N1**
Registration date: **2026-02-06, 1404/11/17**
Registration timing: **registered_while_recruiting**

Last update: **2026-02-06, 1404/11/17**
Update count: **0**

Registration date

2026-02-06, 1404/11/17

Registrant information

Name

Masoud Azizian

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-01-26, 1404/11/06

Expected recruitment end date

2026-03-03, 1404/12/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effects of combined and dual-task training on brain electrical activity, proprioception and balance in athletes with chronic ankle instability: A randomized controlled clinical trial

Public title
The effect of combined exercises on the electrical brain activity of athletes with chronic ankle instability.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
No history of knee ligament or meniscus injury, which will be verified by subjects completing a medical history form No history of fractures or surgery on lower limb joints. No history of neurological or vestibular system disorders. History of at least one ankle sprain in the past 12 months prior to study entry that resulted in a cessation of physical activity for at least one day The person has had the feeling of emptying at least twice in the past 6 months. Score less than 24 on the Cumberland Ankle Instability Questionnaire.

Exclusion criteria:
People with anterior cruciate ligament tears. Athletes with chronic ankle instability who are under 18 and over 25 years of age. Positive anterior ankle abduction test.

Age
From **18 years** old to **25 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **66**

Randomization (investigator's opinion)
Randomized

Randomization description
After confirming eligibility criteria and obtaining written informed consent, participants will be randomly allocated in a 1:1:1 ratio to one of the three study groups. The randomization sequence will be generated by an independent individual who is not involved in participant recruitment, assessment, intervention, or data analysis, using Random Allocation Software (RAS) and a variable block randomization method with block sizes of 3 and 6 to prevent predictability of the allocation sequence. Allocation codes for each participant will be placed sequentially into opaque, light-proof, sealed, and consecutively numbered envelopes (SNOSE). After a participant is definitively enrolled in the study, the corresponding envelope will be opened in sequence and the assigned group will be revealed. Accordingly, group assignment will remain concealed from researchers and outcome assessors until the moment of allocation, thereby minimizing selection bias.

Blinding (investigator's opinion)
Single blinded

Blinding description
The evaluation of the participants will be performed by a physiotherapist who is blinded to group allocation.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Bu Ali Sina University Ethics Committee

Street address
Bu-Ali Sina University, Shahid Mostafa Ahmadi Roshan Street, Hamedan

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Approval date
2025-10-05, 1404/07/13

Ethics committee reference number
IR.BASU.REC.1404.032

Health conditions studied

1

Description of health condition studied
chronic ankle instability

ICD-10 code
M25.373

ICD-10 code description
Other instability, unspecified ankle

Primary outcomes

1

Description
brain electrical activity.

Timepoint
Before and after the 8-week intervention

Method of measurement
Using the Medina Teb Electroencephalography device, the electrical activity of the brain is measured in a state of single-leg balance.

Secondary outcomes

1

Description
Quality of life
Timepoint
Before and after the 8-week intervention
Method of measurement
The Short Form Health Survey (SF-36)

2

Description
Static balance
Timepoint
Before and after the 8-week intervention
Method of measurement
Using a single-leg Zabris foot pressure device manufactured in the United States.

3

Description
Functional disability
Timepoint
Before and after the 8-week intervention
Method of measurement
Oswestry Questionnaire

4

Description
proprioception
Timepoint
Before and after the 8-week intervention
Method of measurement
Electrogoniametr

Intervention groups

1

Description
Intervention group 1:Participants in intervention group 1 will receive a combined training program consisting of neuromuscular and cognitive exercises performed separately. The program will be implemented over 8 weeks, with three sessions per week, each lasting 60 minutes (24 sessions in total).Each session will comprise two main components. The neuromuscular component, designed to improve postural control, balance, coordination, and strengthening of the lower-limb muscles—particularly the ankle, will include balance exercises such as single-leg stance on a stable surface, single-leg stance on a balance board, toe walking, and the runner's knee exercise. All balance exercises will be performed under both eyes-open and eyes-closed conditions to increase sensorimotor challenge. In addition, ankle strengthening exercises will be incorporated to enhance muscular strength and motor control.The cognitive component will consist of mental and cognitive tasks performed separately from the neuromuscular rehabilitation program, such as backward counting of four-digit numbers, aimed at engaging attention, working memory, and cognitive processing. To comply with the principle of progressive overload, the intensity and/or complexity of the exercises will be increased progressively, with progression applied during weeks 2, 4, and 6.
Category
Rehabilitation

2

Description
Intervention group 2 received a dual task/task training program in which neuromuscular exercises and cognitive exercises were performed simultaneously to increase cognitive load and simultaneously engage the neuromuscular and musculoskeletal systems. This intervention was conducted for 8 weeks, with sessions held 3 times a week for 30 minutes each (24 sessions in total). The content of neuromuscular exercises mainly included balance exercises performed in the form of single-leg standing, tiptoe walking, and static and dynamic balance exercises. To increase the sensorimotor challenge, these exercises were performed in both eyes open and eyes closed modes. Simultaneously with the balance exercises, the cognitive task was performed in the form of counting back four digits to increase cognitive load during motor activity. During the course, the difficulty of the exercises was gradually adjusted by changing the visual conditions (eyes open/closed), increasing the duration of maintaining balance positions, or increasing the complexity of the cognitive task. To perform the exercises, a safe training space was used, and if necessary, simple balance tools such as a balance board were used, and all sessions were carried out according to a specific program and in compliance with safety principles.
Category
Rehabilitation

3

Description
Control group: Athletes went about their daily activities and did not do any rehabilitation.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Bu-Ali Sina University
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
Vice President for Research, Bu-Ali Sina University, Hamadan
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

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Latest degree

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Other areas of specialty/work

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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

Not applicable

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

Not applicable

Title and more details about the data/document

The files containing data measured by the assessors will be shared, if needed, after the completion of the study.

When the data will become available and for how long

The sharing period will begin one year following the publication of the study results and related articles.

To whom data/document is available

Researchers and researchers whose field of work is similar to the present research and are employed in universities

Under which criteria data/document could be used

The data of the present study will be provided to other researchers only for comparison with future studies and the use of data and their analysis is not allowed.

From where data/document is obtainable

Email adress m.azizian@phe.basu.ac.ir Phone number: 00989188157747

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

A full description of the research should be provided and the details of the use of the data should be fully described.

Comments