

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

The effect of neuromuscular training with and without cognitive intervention on proprioception, balance, strength and center of pressure displacement in active females at risk of ankle sprain

Protocol summary

Study aim

Determining the effect of neuromuscular training with and without cognitive intervention on balance, strength, proprioception and center of pressure displacement in active females at risk of ankle sprain

Design

The clinical trial has two groups of neuromuscular training with cognitive intervention and neuromuscular without cognitive intervention, with parallel groups, double-blinded, randomized, phase 2 on 44 participants. Randomization is done based on the Random Number Generator software, and they will be assigned to double groups based on the allocation concealment using the SNOSE method.

Settings and conduct

This study will be performed in a double-blinded manner. The tests will be taken in the sport rehabilitation laboratory of Bu Ali Sina University in Hamedan by specialists, then intervention and exercises will take place in the university gym.

Participants/Inclusion and exclusion criteria

Inclusion criteria include: active females at risk of ankle sprain with a normal body mass index of 20-25, age range of 16-30 years, dynamic balance score and a score of 13-15 from the Beck questionnaire and exclusion criteria: a history of ankle sprain injury, fracture, injury or surgery of the lower limb, abnormalities of the lower limb such as: foot flat, genu varum, genu valgum, genu recurvatum, history of vestibular system disorders, the presence of diseases such as diabetes

Intervention groups

Group of neuromuscular training with cognitive intervention: balance, strength, plyometric and agility exercises with cognitive exercises to examine the amount of attention needs of postural control for 8 weeks and three 1-hour sessions every week. Group of neuromuscular training without cognitive intervention:

balance, strength, plyometric and agility exercises for 8 weeks and three 1-hour sessions every week.

Main outcome variables

Balance, Strength, Proprioception, Center of pressure displacement

General information

Reason for update

Editing the original English name of the device that will be used in the laboratory to measure the primary outcome variable of displacement of the center of pressure, adding items related to how to measure the secondary outcome variable of chronic ankle instability, editing the English related to the intervention groups in the protocol abstract.

Acronym

IRCT registration information

IRCT registration number: **IRCT20230619058535N1**
Registration date: **2023-06-26, 1402/04/05**
Registration timing: **prospective**

Last update: **2023-06-28, 1402/04/07**

Update count: **1**

Registration date

2023-06-26, 1402/04/05

Registrant information

Name

Mina Mansouri

Name of organization / entity

Bu-Ali Sina University

Country

Iran (Islamic Republic of)

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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-08-25, 1402/06/03

Expected recruitment end date
2023-09-04, 1402/06/13

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of neuromuscular training with and without cognitive intervention on proprioception, balance, strength and center of pressure displacement in active females at risk of ankle sprain

Public title
The effect of neuromuscular training with and without cognitive intervention on ankle sprain

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Normal body mass index is 20-25 Age range 16-30 years
Obtaining a dynamic balance score Obtaining a score of 13-15 from Beck's questionnaire

Exclusion criteria:

History of ankle sprain injury History of fracture, injury or surgery of the lower limb Abnormalities of the lower limbs include Foot Flat, Genu Varum, Genu Valgum, Genu Recurvatum History of Vestibular System disorders The presence of diseases such as diabetes

Age
From **16 years** old to **30 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **44**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization is done based on the Random Number Generator software, and they will be assigned to double groups based on the allocation concealment using the SNOSE method. The randomization of subjects is done in two steps. First, each subject chooses a number between 1-30 using a lottery, then fifteen random numbers are selected between 1-30 numbers using the Random Number Generator software and according to the generated numbers and the selected numbers, subjects are divided into two groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, outcome assessors (laboratory technicians) are asked to take the desired tests from the clients. These people will be unaware of the purpose of the research, the allocation of study groups and the reason for their presence in the laboratory, and they will only evaluate the variables and record their observations.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Bu Ali Sina Hamadan University

Street address

Bu Ali Sina University, Abu Taleb ST, Modares Quarter, Hamedan

City

Hamedan

Province

Hamedan

Postal code

3869565178

Approval date
2023-04-11, 1402/01/22

Ethics committee reference number
IR.BASU.REC.1402.022

Health conditions studied

1

Description of health condition studied

Ankle sprain

ICD-10 code

S93.4

ICD-10 code description

Sprain of ankle

Primary outcomes

1

Description

Balance

Timepoint

Before the intervention begins, one day after the end of the intervention

Method of measurement

Y balance test, Foot lift test

2

Description

Strength

Timepoint

Before the intervention begins, one day after the end of the intervention

Method of measurement

Dynamometer

3

Description

Proprioception

Timepoint

Before the intervention begins, one day after the end of the intervention

Method of measurement

Electrogoniometer

4

Description

Center of pressure displacement

Timepoint

Before the intervention begins, one day after the end of the intervention

Method of measurement

RS-Scan device

Secondary outcomes

1

Description

Chronic ankle instability (CAI)

Timepoint

Before and after the intervention

Method of measurement

Electrogoniometer, Dynamometer, RS-Scan device, Y balance test, Foot lift test

Intervention groups

1

Description

The neuromuscular training with cognitive intervention, exercises for 8 weeks and three 1-hour sessions each week. Neuromuscular training will include balance, strength, plyometric and agility exercises. Cognitive exercises will be used as an effective strategy for this group to examine the amount of attention needs of pastoral control.

Category

Prevention

2

Description

Intervention group: the neuromuscular training without cognitive intervention, exercises for 8 weeks and three 1-hour sessions each week. Neuromuscular training will

include balance, strength, plyometric and agility exercises.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Hamedan basketball board

Full name of responsible person

Mina Mansouri

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Bu Ali siSina Univerty, Abu Taleb ST, Modares Quarter, Hamedan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The University of Bu Ali Sina

Full name of responsible person

Farzaneh Saki

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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

The University of Bu Ali Sina

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
The University of Bu Ali Sina
Full name of responsible person
Mina Mansouri
Position
Student
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Other areas of specialty/work
Sport rehabilitation
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Person responsible for updating data

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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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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