Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jun 2026

Changes in Corticomotor Excitability of the Peroneal Muscles in People with Functional Ankle Instability Received Dynamic Balance Exercise: A Randomized Clinical Trial

Protocol summary

Study aim
Determination of motor cortex excitability changes following dynamic balance exercises

Design
A controlled, parallel-group, single-blind, randomized clinical trial of 38 patients. Permutation block randomization is used.

Settings and conduct
Study will be conducted at the Neuromuscular Rehabilitation Research Center of Semnan University of Medical Sciences, people with functional ankle instability randomly allocated in control and treatment groups. the evaluator will be blinded to allocation.

Participants/Inclusion and exclusion criteria
inclusion criteria: at least once unilateral ankle sprain with grade II in last 1-3 years at least twice giving way in injured ankle in last 6 months score ≤ 24 in CAIT questionnaire 20-60 years old exclusion criteria: Ankle joint laxity Moderate to severe pain and swelling in ankle severe limitation in ankle range of motion surgery or fracture in lower limbs neurovascular and musculoskeletal disorders in lower limbs taking any medicine in last 2 weeks before the study physical therapy in last 6 months before the study systemic diseases or rheumatological disorders Balance and vestibular disorder brain surgery and head trauma migraine and seizures metal or electric implant in body psychiatric disorders Pregnancy or breastfeeding

Intervention groups
Balance exercises on the involved leg in each session will be include two statics (3 sets of 30 seconds) and four dynamics (3 sets of 6 repetitions for posterior-anterior and medial-lateral tilts, 1 set of 10 repetitions for clockwise and counterclockwise rotations). Instability of static will be decrease from 11 and 7 in first week to 6 and 2 in sixth week, and in dynamic from 7 to 2. the control group will not receive balance exercises.

Main outcome variables
Cumberland ankle instability tools questionnaire score; motor evoked potential in rest and active state; cortical silence period

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20221218056847N1**
Registration date: **2023-01-10, 1401/10/20**
Registration timing: **prospective**

Last update: **2023-01-10, 1401/10/20**
Update count: **0**

Registration date
2023-01-10, 1401/10/20

Registrant information
Name
mahdis purzolfi
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
2023-03-21, 1402/01/01
Expected recruitment end date
2023-06-22, 1402/04/01
Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Changes in Corticomotor Excitability of the Peroneal Muscles in People with Functional Ankle Instability Received Dynamic Balance Exercise: A Randomized Clinical Trial

Public title

effect of balance training on excitability of brain motor cortex

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

at least once unilateral ankle sprain with grade II in last one to three years, which is followed by symptoms of pain, swelling and temporary loss of function. giving way a in the injured ankle, at least 2 times in the last 6 months less than 24 score in the CAIT questionnaire 20 - 60 years old

Exclusion criteria:

ankle joint laxity Moderate to severe pain and swelling in the ankle Severe limitation of ankle range of motion surgery or fracture in the lower limbs neurovascular and musculoskeletal disorders in the lower limbs taking any medicine in last 2 weeks Participation in physical therapy in last 6 months systemic diseases or rheumatological disorders Balance and vestibular disorder brain surgery and head trauma of migraine and seizures metal or electric implant in body psychiatric disorders Pregnancy or breastfeeding

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **38**

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted block randomization method will be used for randomization. In this regard, blocks of four with numbers 1 to 6 will be used as follows: (in each block, a means the intervention group and b means the control group): 1-aabb 2-abba 3-abab 4-baba 5-baab 6-bbaa After choosing numbers one to six from the table of random numbers (numbers 0 and 7 to 9 are not taken into account), the block associated with each number is determined and the eligible people are enrolled in the study from left to right in each block and will be assigned in one of a or b group. The numbers will be selected nine times and the first 36 people will be grouped in this way, and the last two people will be entered into the group by assigning a coin. Participants, therapists, and evaluators will be unaware of the grouping. To implement the generated random sequence, the method of hiding the box or coded cans is used. In this method, the cans will be numbered based on a random sequence, and inside the boxes, the desired intervention will be given to the therapist with a sheet on which the random allocation is written, with the condition that the boxes are completely sealed and the therapist will assign patients to intervention and control groups based on the order of arrival.

Blinding (investigator's opinion)

Single blinded

Blinding description

A physiotherapist will be in charge of the treatment process of the intervention group, and another physiotherapist will evaluate the desired variables. Therefore, the future study will be a single-blind study.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Semnan University Of Medical Sciences and Health Services

Street address

Basij Blvd, Semnan University of Medical Sciences

City

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Province

Semnan

Postal code

3514799442

Approval date

2022-12-26, 1401/10/05

Ethics committee reference number

IR.SEMUMS.REC.1401.249

Health conditions studied

1

Description of health condition studied

functional ankle instability

ICD-10 code

S93.4

ICD-10 code description

Sprain of ankle

Primary outcomes

1

Description
motor evoked potential (MEP)
Timepoint
Before and After the Intervention
Method of measurement
Transcranial Magnetic Stimulation and surface EMG

2

Description
cortical silence period (CSP)
Timepoint
before and after treatment
Method of measurement
Transcranial Magnetic Stimulation and surface EMG

Secondary outcomes

1

Description
self-reported functional ankle instability
Timepoint
before and after treatment
Method of measurement
cumberland ankle instability tools questionnaire

Intervention groups

1

Description
Intervention group: The treatment in the interventiongroup (19 people) will include 18 session (6 weeks, 3 days per week, every other day) of static and dynamic balance exercises with biodex balance system. Balance exercises on the involved leg in each session will be include two statics (3 sets of 30 seconds) and four dynamics (3 sets of 6 repetitions for posterior-anterior and medial-lateral tilts, 1 set of 10 repetitions for clockwise and counterclockwise rotations). Instability of static exercises will be decrease from 11 and 7 in the first week to 6 and 2 in the sixth week, and in dynamic exercises from 7 to 2 (decreasing one degree per week).
Category
Treatment - Devices

2

Description
Control group: no therapeutic action is considered for this group and this group will be evaluated and compared with the intervention group at the beginning and end of the study in terms of motor cortex excitability.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Neuromuscular Rehabilitation Research Center of Semnan University of Medical Sciences
Full name of responsible person
Mahdis Purzolfi Khansari
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Semnan 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
Semnan University of Medical Sciences

Full name of responsible person
Mahdis Purzolfi Khansari

Position
master student

Latest degree
Bachelor

Other areas of specialty/work
Physiotherapy

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no more information.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available