Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

Effect of balance training combined with transcranial direct current stimulation on preparatory brain activity in patients with chronic ankle instability

Protocol summary

Study aim

Effect of balance training combined with transcranial direct current stimulation on preparatory brain activity in patients with chronic ankle instability

Design

A concealed, randomized, double blinded, sham controlled clinical trial with a parallel group design of 23 patients

Settings and conduct

First, evaluations are performed and then therapeutic interventions in each group are performed 3 days a week for 4 weeks and finally, 48 hours after the last treatment session, re-evaluation Takes place. Individuals will refer to the biomechanics laboratory of the Faculty of Rehabilitation, Tehran University of Medical Sciences for evaluation sessions.

Participants/Inclusion and exclusion criteria

unilateral ankle sprain, feeling of instability, History of inflammation symptoms such as swelling, weakness, pain within the past year, Cumberland Ankle Instability Tool (CAIT) score less than 24, Acquiring a score < 90% in daily living activities and < 80% in sport activities from foot and ankle ability measure (FAAM) questionnaire; evidence of neurological or psychiatric disorders, seizure and epilepsy, had a head injury resulting in a loss of consciousness, history of migraines, History of ankle and lower limb surgery or fracture, pregnant, Have any metallic implants, including intracranial electrodes,surgical clips, shrapnel or pacemaker

Intervention groups

The real group that receives balance exercises with anodal Transcranial Direct Current Stimulation. The control group receives balance exercises and sham flow of transcranial electrical stimulation.

Main outcome variables

Time of Peak Amplitude and peak amplitude of Contingent Negative Variation (CNV) ; Amplitude of Late CNV ; Alpha and beta event-related desynchronization (ERD) ; FAAM questionnaire score ; Star Excursion Balance Test ; CAIT questionnaire scor

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210604051488N1**
Registration date: **2021-06-28, 1400/04/07**
Registration timing: **prospective**

Last update: **2021-06-28, 1400/04/07**
Update count: **0**

Registration date

2021-06-28, 1400/04/07

Registrant information

Name

Zivar Beyraghi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7753 3939

Email address

beyraghi-z@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-06, 1400/04/15

Expected recruitment end date

2022-01-05, 1400/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of balance training combined with transcranial direct current stimulation on preparatory brain activity in patients with chronic ankle instability

Public title

Effect of transcranial direct current stimulation in patients with chronic ankle instability

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The initial unilateral ankle sprain must have occurred at least 12 months prior to study enrollment The most recent injury must have occurred more than 3 months prior to study enrollment Episodes of giving way or feeling of instability in the involved ankle History of inflammation symptoms such as swelling, weakness, pain within the past year Cumberland Ankle Instability Tool (CAIT) score less than 24 Acquiring a score < 90% in daily living activities and < 80% in sport activities from foot and ankle ability measure (FAAM) questionnaire People in the age range of 18 to 35 years

Exclusion criteria:

Evidence of neurological or psychiatric disorders, seizure and epilepsy, had a head injury resulting in a loss of consciousness, history of migraines History of ankle and lower limb surgery or fracture Pregnant Have any metallic implants, including intracranial electrodes,surgical clips, shrapnel or pacemaker

Age

From **18 years** old to **35 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

After the baseline session, subjects were randomly allocated into groups using a balanced block randomization scheme (block size, 4) using a list randomizer from randomization.com.Sealed and coded envelopes used for concealment, which are provided to the participants by the secretary.

Blinding (investigator's opinion)

Double blinded

Blinding description

All participants also blind to the sham and active applications of the a-tDCS and also to the grouping. In the sham group, the stimulator turn off after 30 s of stimulation without the participant's knowledge. The a-tDCS or sham protocol was load into the software for each participant by study staff uninvolved in any other aspects of study. Then the same third party who coded the data into SPSS.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

School of Nursing and Midwifery and School of Rehabilitation - Tehran University of Medical Sciences

Street address

Research and Technology Affairs Department, Room 605, 6th Floor, Tehran University of Medical Sciences Headquarters Building, Intersection of Keshavarz Boulevard and Ghods Street

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2021-04-26, 1400/02/06

Ethics committee reference number

IR.TUMS.FNM.REC.1400.020

Health conditions studied

1

Description of health condition studied

Chronic ankle instability

ICD-10 code

S93.4

ICD-10 code description

Sprain of ankle

Primary outcomes

1

Description

Peak Amplitude of Contingent Negative Variation (CNV) ; CNV is an event-dependent potential that is recorded using the warning-stimulus-response-motor response paradigm. In fact, CNV is a slow negative shift in the electroencephalographic wave amplitude between the two warning stimuli and the response stimulus, which is

calculated by averaging the electroencephalographic wave in the time interval between the warning stimulus and the response stimulus.

Timepoint

In the first evaluation session (before the intervention) and 48 hours after the last treatment session

Method of measurement

Using a 64-channel electroencephalography device(Micromed)

2

Description

Time of Peak Amplitude of CNV; CNV is an event-dependent potential that is recorded using the warning-stimulus-response-motor response paradigm. In fact, CNV is a slow negative shift in the electroencephalographic wave amplitude between the two warning stimuli and the response stimulus, which is calculated by averaging the electroencephalographic wave in the time interval between the warning stimulus and the response stimulus.

Timepoint

In the first evaluation session (before the intervention) and 48 hours after the last treatment session

Method of measurement

Using a 64-channel electroencephalography device(Micromed)

3

Description

Amplitude of Late CNV; CNV is a slow negative shift in the electroencephalographic wave amplitude between the two warning stimuli and the response stimulus, which is calculated by averaging the electroencephalographic wave in the time interval between the warning stimulus and the response stimulus. It has two components, late and early. The early component reflects the perceptual processes and attention, and the late component represents the prediction and preparation of the brain to start moving.

Timepoint

In the first evaluation session (before the intervention) and 48 hours after the last treatment session

Method of measurement

Using a 64-channel electroencephalography device(Micromed)

4

Description

Alpha event-related desynchronization (ERD) ; ERD is actually the frequency reduction in the beta and alpha bands, which begins about 2 to 1.5 seconds before the start of motion. The value of ERD at alpha and beta frequencies expresses the degree of cortical excitability. The larger the beta / alpha ERD, the higher the cortical excitability. In fact, ERD reflects the activity of motor areas along with the weakening of sensory afferents during movement. Alpha and beta band activity demonstrates brain preparation and brain planning.

Timepoint

In the first evaluation session (before the intervention) and 48 hours after the last treatment session

Method of measurement

Using a 64-channel electroencephalography device (Micromed)

5

Description

Beta event-related desynchronization (ERD) ; ERD is actually the frequency reduction in the beta and alpha bands, which begins about 2 to 1.5 seconds before the start of motion. The value of ERD at alpha and beta frequencies expresses the degree of cortical excitability. The larger the beta / alpha ERD, the higher the cortical excitability. In fact, ERD reflects the activity of motor areas along with the weakening of sensory afferents during movement. Alpha and beta band activity demonstrates brain preparation and brain planning.

Timepoint

In the first evaluation session (before the intervention) and 48 hours after the last treatment session

Method of measurement

Using a 64-channel electroencephalography device (Micromed)

Secondary outcomes

1

Description

Star Excursion Balance Test ; This test is used for clinical evaluation. In other words, the maximum range of motion of the person standing on one leg stimulates the opposite leg in the posterolateral, posteromedial, and anterior direction.

Timepoint

In the first evaluation session (before the intervention) and 48 hours after the last treatment session

Method of measurement

Strip Meter

2

Description

The foot and ankle ability measure questionnaire (FAAM) score ; This questionnaire consists of 29 questions that are divided into two parts ADL and Sport, which includes 21 and 8 items, respectively, and 5 answers are considered for each question and its total score is reported as a percentage. The higher percentage show higher performance.

Timepoint

In the first evaluation session (before the intervention) and 48 hours after the last treatment session

Method of measurement

The foot and ankle ability measure questionnaire (FAAM)

3

Description

The Cumberland Ankle Instability Tool's score; This questionnaire consists of 9 questions, the total score of

which is 30, which indicates a high stability in the ankle. The Persian version of the Cumberland Ankle Instability Questionnaire can be used as a reliable tool to diagnose instability and measure changes due to therapeutic interventions in athletes with functional ankle instability.

Timepoint

In the first evaluation session (before the intervention) and 48 hours after the last treatment session

Method of measurement

The Cumberland Ankle Instability Tool

Intervention groups

1

Description

Intervention group: Participants give 4-wk intervention of anodal transcranial direct current stimulation (aTDCS) with balance exercise. The exercises consist of Gastrocnemius and Soleus stretching; strengthening involved Thera-Band resistance Dorsiflexion, Plantar flexion, Inversion, Eversion; Neuromuscular control exercises involved Single-limb stance while kicking and single-limb–stance activities with eyes open and closed and Single-limb stance with ball toss; Progressive Balance Program consist of single-limb hops to stabilization ,hop to stabilization and reach. Exercises have difficulty levels and progress. Anodal transcranial direct current stimulation is applied using Medina Teb Gostar's neurostim 2 device and The skin and scalp assess for irritationor lesions before being cleaned with an alcohol pad. Two 4*4 cm sponge electrodes were saturated with 0.09 NaCl, and rubber electrodes corresponding to the TDCS anode and cathode were placed within the sponges. The anode sponge was placed at the location of Cz, whereas the cathode sponge was placed over the forehead. The stimulator set to provide 1.5 mA over 20 min. At the beginning of the current, we will have a 30-second period of ramping up current to reach the planned maximum intensity, which is considered here at 1.5 Amp. At the end of the current, we will have a 30-second ramping down period, which will gradually reduce the current and the device will turn off.

Category

Rehabilitation

2

Description

Control group: Participants give 4-wk intervention of sham transcranial direct current stimulation (aTDCS) with balance exercise. The exercises consist of Gastrocnemius and Soleus stretching; strengthening involved Thera-Band resistance Dorsiflexion, Plantar flexion, Inversion, Eversion; Neuromuscular control exercises involved Single-limb stance while kicking and single-limb–stance activities with eyes open and closed and Single-limb stance with ball toss; Progressive Balance Program consist of single-limb hops to stabilization ,hop to stabilization and reach. Exercises have difficulty levels and progress. Anodal transcranial direct current stimulation is applied using Medina Teb Gostar's neurostim 2 device and The skin and scalp assess for irritationor lesions before being cleaned with an alcohol pad. Two 4*4 cm sponge electrodes were saturated with 0.09 NaCl, and rubber electrodes corresponding to the TDCS anode and cathode were placed within the sponges. The anode sponge was placed at the location of Cz, whereas the cathode sponge was placed over the forehead. The stimulator set to provide 1.5 mA over 20 min. At the beginning of the current, we will have a 30-second period of ramping up current. the DC stimulator was turned off in 30 s after the initial ramping up of current.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Rehabilitation, Tehran University of Medical Sciences

Full name of responsible person

Zivar beyraghi

Street address

Faculty of Rehabilitation, Corner of Safi Alisha Street, Pich Shemiran, Enghelab square

City

Tehran

Province

Tehran

Postal code

65111-11489

Phone

+98 21 7753 3939

Email

rehabilitation@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Mohammadali Sahraean

Street address

Central University Organization, corner of Quds Street, Keshavarz Boulevard

City

Tehran

Province

Tehran

Postal code

65111-11489

Phone

+98 21 8163 3685

Email

Research@tums.ac.ir

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
Roya Khanmohammadi
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address
Tehran, District 12, Enghelab Street , Pich-E-Shemiran
City
Tehran
Province
Tehran
Postal code
6511111489
Phone
+98 21 7753 4133
Email
Rkhanmohammadi@sina.tums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Roya Khanmohammadi
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address
Tehran, District 12, Enghelab Street , Pich-E-Shemiran
City
Tehran
Province
Tehran
Postal code
6511111489
Phone
+98 21 7753 4133
Email
Rkhanmohammadi@sina.tums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Zivar Beyraghi
Position
Student
Latest degree
Master
Other areas of specialty/work
Physiotherapy
Street address
Tehran, District 12, Enghelab St, Pich-e-Shemiran، Iran
City
Tehran
Province
Tehran
Postal code
65111-11489
Phone
+98 21 7753 3939
Fax
Email
beyraghi-z@razi.tums.ac.ir

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