

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The combination effect of vestibular rehabilitation and transcranial direct current stimulation (tDCS) in the treatment of elderly patients with peripheral vertigo

Protocol summary

Study aim

The aim of this study was to investigate the combined effect of vestibular rehabilitation and transcranial direct current stimulation (tDCS) in comparison with vestibular rehabilitation alone on improving the balance symptoms of the elderly with peripheral vertigo.

Design

This is a randomized clinical trial that patients with peripheral vertigo (age over 65 years) will be randomly assigned to intervention groups 1 and intervention 2.

Settings and conduct

Place: Imam Khomeini Hospital, Ahvaz Transcranial Direct Current Stimulation (tDCS) will be applied via two electrodes using 2mA intensity and 20-minutes duration. The anode and cathode electrodes were placed over the right (T4) and left (T3) auditory cortex sites. All patients undergo vestibular rehabilitation treatment (VRT) using the EPLEY approach. Dizziness Handicap Inventory (DHI) questionnaire: This questionnaire is designed to assess the effect of balance problems on the emotional, functional and physical dimensions of the patient's life with imbalance. The score of the questionnaire is between zero and 100, with higher values indicating more disability. VRT and tDCS Stimulation will be applied on 5 weekdays during a TWO-week period (10 sessions) and DHI results will be compared at pre-intervention, 1-week post-intervention and 2-week post-intervention time-points.

Participants/Inclusion and exclusion criteria

Inclusion criteria: chronic peripheral vertigo; age: 65-80 yr Exclusion criteria: history of cervical problem, psychiatric disorders, and epileptic seizures and brain trauma

Intervention groups

1- Group with Vestibular rehabilitation + tDCS therapy (VRT+tDCS) 1- Group only with Vestibular rehabilitation therapy (VRT)

Main outcome variables

Balance problems (emotional, functional and physical dimensions)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200820048467N1**

Registration date: **2020-11-23, 1399/09/03**

Registration timing: **registered_while_recruiting**

Last update: **2020-11-23, 1399/09/03**

Update count: **0**

Registration date

2020-11-23, 1399/09/03

Registrant information

Name

Arash Bayat

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3374 3506

Email address

arashbayat2004@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-21, 1399/07/30

Expected recruitment end date

2021-03-09, 1399/12/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The combination effect of vestibular rehabilitation and transcranial direct current stimulation (tDCS) in the treatment of elderly patients with peripheral vertigo

Public title

The effect of transcranial direct current stimulation on vertigo

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Chronic peripheral vertigo

Exclusion criteria:

History of brain/head trauma History of neck problem
History of psychiatric disorders History of epileptic seizures

AgeFrom **65 years** old to **80 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **36****Randomization (investigator's opinion)**

Randomized

Randomization description

Random assignment of patients to intervention and control groups by lot. For this purpose, we prepare two sheets and write "Intervention 1" on one and "Intervention 2" on the other. Then, with each patient's visit, one of the sheets is randomly chosen and the patient is assigned to intervention group 1 or intervention 2.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Ahvaz Jundishapur University of

Medical Sciences

Street address

Department of Audiology, Rehabilitation School,
Ahvaz Jundishapur University of Medical Sciences,
Golstan Area, Ahvaz

City

Ahvaz

Province

Khouzestan

Postal code

61375-33133

Approval date

2020-07-04, 1399/04/14

Ethics committee reference number

IR.AJUMS.REC.1399.327

Health conditions studied**1****Description of health condition studied**

Peripheral vertigo

ICD-10 code

H81.39

ICD-10 code description

Other peripheral vertigo

Primary outcomes**1****Description**

Balance problems (emotional, functional and physical dimensions)

Timepoint

The therapy session will be applied on 5 weekdays during a TWO-week period (10 sessions)

Method of measurement

DHI questionnaire scoring (Total scores + 3 emotional, physical and functional DHI sub-components)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group 1: Group who received vestibular rehabilitation therapy in combination with direct-current electrical stimulation (VRT + tDCS). tDCS stimulation (2mA intensity, OASIS instrument) and VRT (EPLEY method) exercises are conducted 5 times a week for 2 weeks (10 sessions in total).

Category

Rehabilitation

2**Description**

Intervention group II: Group who received only vestibular rehabilitation therapy (VRT). Vestibular rehabilitation sessions are performed using EPLEY method 5 times a week for 2 weeks (10 sessions in total).

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital, Ahvaz

Full name of responsible person

Arash bayat

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Department of ENT, Imam Khomeini Hospital, Ahvaz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

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Research Deputy, Ahvaz Jundishapur University of Medical Sciences, Golstan Area, Ahvaz

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Grant name

Grant code / Reference number

HRC-9912

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Arash Bayat

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Audiology

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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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

Yes - There is 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

All statistical files and questionnaires are accessible
(names are coded)

When the data will become available and for how long

After publication to

To whom data/document is available

Researchers in the field of vestibular rehabilitation

Under which criteria data/document could be used

For research and treatment purposes

From where data/document is obtainable

Hearing research center, Ahvaz Jundishapur University of Medical Sciences

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

1- Send your request to Ahvaz Jundishapur University of Medical Sciences, AFTER APPROVAL 2- Hearing research center

Comments