

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Comparison of the effectiveness of transcranial electrical stimulation of the prefrontal, primary motor cortex and cerebellum on the dual-task cost of parameters of gait in older adults

Protocol summary

Study aim

Comparison of the effectiveness of transcranial electrical stimulation of the prefrontal, primary motor cortex and cerebellum on the dual-task cost of parameters of gait in older adults

Design

Randomized, single-blind clinical trial on 19 subjects

Settings and conduct

People are invited to study through invitations posted in physiotherapy clinics, clinics, hospitals, nursing centers, as well as invitations published in cyberspace. The samples will be selected as simple non-probability sampling, voluntary and based on entry and exit criteria. Volunteers receive three real stimulations and one sham stimulation in four sessions with an interval of one week in the laboratory of Tehran University of Medical Sciences. Before and after the application of transcranial electric current, the evaluation parameters are recorded in single task and double task mode.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Healthy older adults Exclusion criteria : Older adults with orthopedic and neurologic problems

Intervention groups

The first intervention group: transcranial electrical stimulation of the prefrontal region The second intervention group: transcranial electrical stimulation of the primary motor cortex area The third intervention group: transcranial electrical stimulation of the cerebellum The fourth intervention group: Unreal transcranial electrical stimulation

Main outcome variables

-Dual-Task Cost of step time -Dual-Task Cost of step time variability -Dual-Task Cost of step length -Dual-Task Cost of step length variability -Dual-Task Cost of gait velocity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220718055490N1**

Registration date: **2022-10-01, 1401/07/09**

Registration timing: **registered_while_recruiting**

Last update: **2022-10-01, 1401/07/09**

Update count: **0**

Registration date

2022-10-01, 1401/07/09

Registrant information

Name

vahid Rafiee Manesh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 3375 9083

Email address

vahidrafeemanesh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-23, 1401/05/01

Expected recruitment end date

2023-01-20, 1401/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of transcranial electrical stimulation of the prefrontal, primary motor cortex and cerebellum on the dual-task cost of parameters of gait in older adults

Public title

Comparison of the effectiveness of transcranial electrical stimulation on the dual-task cost of parameters of gait in older adults

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age more than 65 Berg Balance Scale (BBS) >40 Mini-Mental State Exam (MMSE) \geq 24 Hospital Anxiety and Depression Scale (HADS- Depression subscale) \leq 7 Ability of reading and writing ability of walking without aids in 10 meters No history of CNS and PNS problems No history of orthopedic problem in recent 6 months No history of falling in recent 6 months No scalp scratch No sensory impairment no history of epilepsy no metal implant in cranium No skin infection No pacemaker or electronic implants

Exclusion criteria:

Use narcotics or pain killers 24 hours before Severe activity 24 hours before Unusual physical or mental exhaustion Unwilling to do or continue

Age

From **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Based on the three locations of real stimulation and one sham stimulation that is planned in this study, we assign one of the letters of the alphabet (A, B, C, D) to each stimulation, and people are randomly assigned in 4 sequences (BDC, BCAD, CDBA and DACB) are divided according to the brain stimulation area and it is determined what type of stimulation should be done in each session. Before the start of the first session, a sealed and numbered envelope is used in which the type of stimulation sequence is placed. It is provided by the secretary to the participants. As a result, the participants are blinded to the type of stimulation that is applied. However, according to the study design and the type of stimulation that is applied by the therapist, it is not possible for the therapists and the evaluator to be blind.

Placebo

Used

Assignment

Parallel

Other design features

All people participating in the study will receive three types of real stimulation and one non-real stimulation alternately with different sequences, and the aim is to compare the interventions.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

2th Floor, No. 31, Mohammadi St, Ghayoori St, Ray, Tehran

City

Tehran

Province

Tehran

Postal code

1857814959

Approval date

2022-08-07, 1401/05/16

Ethics committee reference number

IR.TUMS.FNM.REC.1400.193

Health conditions studied

1

Description of health condition studied

Dual task cost in older adults

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Dual task cost

Timepoint

Assessment of Dual task cost before and after TDCS in every session

Method of measurement

Inertial sensor

Secondary outcomes

1

Description

Assessment of balance and fall risk

Timepoint

After completing the study

Method of measurement

Berg Balance Scale Questionnaire

Intervention groups

1

Description

The first intervention group: a session of transcranial electrical stimulation of the prefrontal area using the Star stim device manufactured by the company (Starstim, Neuroelectrics, Barcelona, Spain) with an intensity of 2 mA and for 20 minutes.

Category

Rehabilitation

2

Description

205 / 5,000 Translation results The second intervention group: a session of transcranial electrical stimulation of the primary motor cortex using the Star stim device manufactured by the company (Starstim, Neuroelectrics, Barcelona, Spain) with an intensity of 2 mA and for 20 minutes.

Category

Rehabilitation

3

Description

The third intervention group: a session of transcranial electrical stimulation of the cerebellum using the Star stim device manufactured by the company (Starstim, Neuroelectrics, Barcelona, Spain) with an intensity of 2 mA and for 20 minutes.

Category

Rehabilitation

4

Description

Control group: a non-real transcranial electrical stimulation session in one of the prefrontal areas, primary motor cortex or cerebellum using the Star stim device manufactured by the company (Starstim, Neuroelectrics, Barcelona, Spain) with an intensity of 2 mA and for 20 minutes

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Laleh Park

Full name of responsible person

Vahid Rafiei Manesh

Street address

2th Floor, No. 31, Mohammadi St., Ghayoori St., Ray, Tehran

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vahidrafieemanesh@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotouhi

Street address

6th floor, Central Organization of the University, corner of Quds St., Keshavarz Blvd.

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Tehran

Postal code

1417653761

Phone

+98 21 8163 3685

Email

vcr@tums.ac.ir

Web page address

<https://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

Vahid Rafiei Manesh

Position

Msc. Student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

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Position

Msc. student

Latest degree

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Other areas of specialty/work

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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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Position

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Latest degree

Bachelor

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

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Title and more details about the data/document

after making volunteers unknowable, all data will be shareable.

When the data will become available and for how long

beginning of availability period from 2023

To whom data/document is available

data will be available for all researchers

Under which criteria data/document could be used

no other conditions needed

From where data/document is obtainable

Vahid Rafiei Manesh 0098 9123147196

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

after receiving sms he can get data in one week

Comments

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