Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

vahidrafieemanesh@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) ≥24 Hospital Anxiety and Depression Scale (HADS- Depression subscale) ≤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 / 5,000Translation resultsThe 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
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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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1417653761
Phone
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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 updating data

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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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