

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison the effect of transcranial direct current stimulation of primary motor cortex in improving motor learning in high and low activity elderly.

Protocol summary

Study aim

Determine the effect of transcranial direct current stimulation on motor learning of serial reaction time task in high and low activity elderly

Design

This study is a randomized clinical trial with single blind, sham-controlled. All participants are divided to High Activity and Low Activity groups according to their physical activity level. Participants in each of these group are randomly divided to stimulation on primary motor cortex group and sham stimulation group to create four groups.

Settings and conduct

Research population: All elderly living in the elderly homes of Qom. Reaction time and number of error are recorded before the intervention (day 1), immediately after the intervention (day 5), 1 and 10 days after the completion of the intervention.

Participants/Inclusion and exclusion criteria

Healthy and right handed elderly that do not have disability in the upper extremity and memory problems.

Intervention groups

Participants practice 8 blocks of serial reaction time task during 5 consecutive days. Transcranial direct current stimulation is applied during the whole course of the motor training. Stimulation is applied on mentioned areas with 1mA current, 0.16 mA/cm² current density for 20 minutes during 5 consecutive days. In sham stimulation, same current is applied only for the first 30 s and in the remained time, the current is turned off without the awareness of person.

Main outcome variables

Reaction time: Number of errors

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200809048346N1**

Registration date: **2020-11-07, 1399/08/17**

Registration timing: **prospective**

Last update: **2020-11-07, 1399/08/17**

Update count: **0**

Registration date

2020-11-07, 1399/08/17

Registrant information

Name

Razieh Abedi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-12-22, 1400/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of transcranial direct current

stimulation of primary motor cortex in improving motor learning in high and low activity elderly.		Ethics committee of Shahid Beheshti University of Medical Sciences	
Public title	The effect of transcranial direct current stimulation on motor learning in elderly.	Street address	No. 32, Alley. 92, Kashani Ave., Qom City
Purpose	Health service research	City	Qom
Inclusion/Exclusion criteria		Province	Ghous
Inclusion criteria:	Healthy elderly Right-handed	Postal code	3718759573
Exclusion criteria:	History of neurological diseases Visual or auditory conditions Serious memory deficits Musculoskeletal disorders especially in the upper extremity	Approval date	2020-06-28, 1399/04/08
Age	From 65 years old to 90 years old	Ethics committee reference number	IR.SBMU.RETECH.REC.1399.268
Gender	Both	Health conditions studied	
Phase	N/A	1	
Groups that have been masked	Participant	Description of health condition studied	
Sample size	Target sample size: 60	Motor learning	
Randomization (investigator's opinion)	Randomized	ICD-10 code	
Randomization description	In this study, a sample of 60 people, 30 cards for each intervention group were considered and placed inside a sealed envelope that is non-transparent to draw then each patient takes one of the cards randomly and their group is identified and the generated sequence is recorded.	Z50	
Blinding (investigator's opinion)	Single blinded	ICD-10 code description	
Blinding description	Participants are unaware of the allocation of study groups. In sham stimulation, there is a gradual increase in current for only 30 seconds at the beginning of the stimulation, and the rest of the time, the current is interrupted, so that similar to the real stimulation, the person feels initial burning and itching and the person will not notice the lack of flow throughout the stimulation session.	Care involving use of rehabilitation procedures	
Placebo	Used	Primary outcomes	
Assignment	Parallel	1	
Other design features		Description	
Secondary Ids	empty	Reaction time	
Ethics committees		Timepoint	
1		Before and after intervention, 1 and 10 days after intervention	
Ethics committee		Method of measurement	
Name of ethics committee		In millisecond and using Superlab5 software	
		Secondary outcomes	
		1	
		Description	
		Number of errors in each block	
		Timepoint	
		Before and after intervention, 1 and 10 days after intervention	
		Method of measurement	
		Based on the number and using Superlab5 software	
		Intervention groups	
		1	
		Description	
		Intervention group: Transcranial direct current stimulation of primary motor cortex, 1 milliampere current intensity, 0.16 milliampere/square centimeter current density, 20 minutes time of stimulation, Five consecutive days.	
		Category	

Rehabilitation

2

Description

Control group: Transcranial direct current stimulation, Sham stimulation, 1 milliampere current intensity only for the first 30 s, Turned off current for remained 20 minutes time of stimulation, Five consecutive days.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Fayyaz Bakhsh Nursing and Rehabilitation Center

Full name of responsible person

Razieh Abedi

Street address

Shahid Fayyaz Bakhsh Nursing and Rehabilitation Center, Shahid Mahallati Square, Panardeb Khordad Boulevard, Qom City, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.

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Grant name

Grant code / Reference number

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

No

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

DR. Sedigheh Sadat Naimi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Other areas of specialty/work

Physiotherapy

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City

Tehran

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