

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 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 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/cm<sup>2</sup> 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)

##### Phone

+98 25 3294 1553

##### Email address

raziehabedi28@sbmu.ac.ir

##### 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.

### Public title

The effect of transcranial direct current stimulation on motor learning in elderly.

### Purpose

Health service research

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Healthy elderly Right-handed

#### Exclusion criteria:

History of neurological diseases Visual or auditory conditions Serious memory deficits Musculoskeletal disorders especially in the upper extremity

### Age

From **65 years** old to **90 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

- Participant

### Sample size

Target sample size: **60**

### Randomization (investigator's opinion)

Randomized

### 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.

### Blinding (investigator's opinion)

Single blinded

### 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.

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

### Street address

No. 32, Alley. 92, Kashani Ave., Qom City

### City

Qom

### Province

Ghous

### Postal code

3718759573

### Approval date

2020-06-28, 1399/04/08

### Ethics committee reference number

IR.SBMU.RETECH.REC.1399.268

## Health conditions studied

### 1

#### Description of health condition studied

Motor learning

#### ICD-10 code

Z50

#### ICD-10 code description

Care involving use of rehabilitation procedures

## Primary outcomes

### 1

#### Description

Reaction time

#### Timepoint

Before and after intervention, 1 and 10 days after intervention

#### Method of measurement

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, Panardeh Khordad Boulevard, Qom City, Iran

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3716713745

##### Phone

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##### Email

asayeshgahqom@yahoo.com

## 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.

##### City

Tehran

##### Province

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19839-63113

##### Phone

+98 21 2243 9770

##### Fax

+98 21 2243 3455

##### Email

zarghi@sbmu.ac.ir

##### 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

##### Street address

SBMU School of Rehabilitation Sciences., Damavand Ave., Imam Hossein Square (AS), Tehran., Iran

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##### Province

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1616913111

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Razieh Abedi

##### Position

MSC Student

##### Latest degree

Bachelor

##### Other areas of specialty/work

Physiotherapy

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Razieh Abedi

**Position**

MSC Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Physiotherapy

**Street address**

SBMU School of Rehabilitation Sciences.,Damavand Ave., Imam Hossein Square (AS),Tehran., Iran

**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