

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of short and long term effects of neurofeedback and transcranial electrical stimulation on the visuomotor skill learning in healthy subjects

Protocol summary

Study aim

Comparison of short and long term effects of neurofeedback and transcranial electrical stimulation on the visuomotor skill learning in healthy subjects

Design

Randomized-parallel-single-blind clinical trial on 100 people. Balanced block randomization and Randomization.com are used for randomization.

Settings and conduct

The study will be conducted in the Rehabilitation Faculty of Tehran University of medical sciences. Participants will be randomly assigned to one of the intervention or control groups. After filling the forms and questionnaires and basic measurements with the help of SRTT software, they receive the intervention. Then he returns to the place and performs his exercises with SRTT software. 35 minutes later, the participants return to perform the short-term retention and transfer test, and 48 hours later, the participants return to perform the long-term retention and transfer test. The researcher who performs the interventions is different from the researcher who collects data and performs the statistical analysis.

Participants/Inclusion and exclusion criteria

Healthy people (both sexes)/age 18-40 years Having no history of neurological diseases, orthopedic or neurological or rheumatological injuries that limit the upper limbs.

Intervention groups

5 groups:transcranial direct current stimulation;sham transcranial direct current stimulation;neurofeedback;sham neurofeedback;passive control group

Main outcome variables

The main outcome variables in this study are normalized reaction time and normalized number of errors

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221016056187N1**

Registration date: **2022-11-19, 1401/08/28**

Registration timing: **prospective**

Last update: **2022-11-19, 1401/08/28**

Update count: **0**

Registration date

2022-11-19, 1401/08/28

Registrant information

Name

Sara Rezaei eshkalak

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 2241 8050

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-22, 1401/10/01

Expected recruitment end date

2023-03-21, 1402/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of short and long term effects of neurofeedback and transcranial electrical stimulation on the visuomotor skill learning in healthy subjects

Public title

Comparison of effects of neurofeedback and transcranial electrical stimulation on motor learning in healthy subjects

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

healthy (both genders) 18-40 years old

Exclusion criteria:

having a history of neurological diseases such as epilepsy and convulsions, concussion and migraine having an orthopedic or neurological or rheumatological injury that limits the upper limbs functions Cognitive and memory disorders ($24 \leq$ (Mini-Mental State Exam Uncorrected vision problems Taking drugs affecting the central nervous system The presence of mental illnesses such as anxiety and depression that are associated with drug use Intense physical activity 2 hours before the test A history of doing activities that require a lot of dexterity in the hands, such as playing the piano pregnancy sleep disorders Intracranial implants or cardiac pacemakers

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

The participants are assigned to 5 groups (real and sham transcranial electrical stimulation, real and sham neurofeedback, and control group) by the sequence created through the randomization.com site and by the balanced block randomization method. The size of the blocks is 10. Also, for the purpose of allocation concealment, sealed and numbered envelopes are used, which are provided to the participants by the secretary.

Blinding (investigator's opinion)

Single blinded

Blinding description

The researcher who conducts interventions is different from the researcher who collects information and conducts statistical analysis. Therefore, the study is single-blind.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in Research Faculty of Nursing and Midwifery and Faculty of Rehabilitation - Tehran

Street address

Faculty of Rehabilitation of Tehran of university
Medical sciences, Pich-e-Shemiran, Enghelab
St, District 12

City

Tehran

Province

Tehran

Postal code

1148956111

Approval date

2022-10-25, 1401/08/03

Ethics committee reference number

IR.TUMS.FNM.REC.1401.100

Health conditions studied

1

Description of health condition studied

The effect of transcranial direct current stimulation and neurofeedback on motor learning

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Normalized reaction time

Timepoint

Before intervention/after training/35 minutes after training/48 hours after training

Method of measurement

Serial Reaction Time Task software

2

Description

The number of normalized errors

Timepoint

Before intervention/after training/35 minutes after training/48 hours after training

Method of measurement

Serial Reaction Time Task software

Secondary outcomes

1

Description

Hand fatigue

Timepoint

Beginning of the first session/End of the first session

Method of measurement

Visual Analogue Scale (VAS)

2

Description

Level of mental fatigue

Timepoint

Beginning of the first session/End of the first session

Method of measurement

Visual Analogue Scale (VAS)

Intervention groups

1

Description

Intervention group 1: transcranial direct current stimulation: To apply tDCS, the transcranial direct current device model neurostim 2 of Medina Tab Gostar Company is used. Before the participant arrives, all the tools, including electrodes, normal saline, stimulator, cable, elastic bands, and measuring tip, are checked to ensure that they are healthy and that there are no possible failures and damages. The participant sits in a chair, then the scalp is examined for any lesions. First, the electrodes are placed in a sponge soaked with normal saline and the skin of the stimulation site is cleaned with alcohol. The size of the electrodes is 5*4. An active electrode is placed on the primary motor area of the dominant side, which corresponds to C3 or C4 according to the international 10-20 system. The cathode electrode is also placed on the supraorbital area of the non-dominant hand. The electrodes are fixed on the head by two adhesive straps. A current with an intensity of 1 milliampere is applied for a period of 30 minutes with ramp up for 30 seconds and ramp down for 30 seconds.

Category

Rehabilitation

2

Description

Intervention group 2: sham transcranial direct current stimulation: In this group, all the conditions are the same as the real tDCS group. Only the current is cut off after 30 seconds of ramp up.

Category

Rehabilitation

3

Description

Intervention group 3: neurofeedback: Electroencephalography active electrodes are placed on the primary motor area of the dominant side, the

reference electrode is placed on the mastoid and the ground electrode is placed on the right arm. Filters are applied so that only the alpha wave is recorded. First, the alpha wave is recorded for three minutes with the eyes open in the primary motor area to determine the basic value of the alpha wave. Then, since the goal of neurofeedback is to increase the excitability of the brain by reducing the alpha wave in the primary motor area. The settings are made in such a way that in seventy percent of the time the threshold that causes the games to be played is below the basic threshold. The participants then train with neurofeedback for 30 minutes by sitting facing the monitor and watching the game being played. When the wave reaches below our desired value, the game will continue, and when the wave rises above our desired value, the game will be stopped. So, the brain will be directed to our desired direction (decrease the alpha wave) with the help of positive feedback (playing the game). 6 games will be played for 5 minutes each to prevent fatigue and reduce cooperation due to boredom. After training, electroencephalography is recorded for 3 minutes with eyes open. During the session, the researcher records the time of rapid head movements or sneezing and coughing of the participants to determine its effects in electroencephalography.

Category

Rehabilitation

4

Description

Intervention group 4: sham neurofeedback: The conditions are like real neurofeedback. 3 minutes of electroencephalography are recorded before and after the exercise, but during the exercise, a pre-recorded video of another participant is shown.

Category

Rehabilitation

5

Description

Control group: passive control: The passive control group does not receive any intervention and spends 30 minutes in the laboratory without physical and mental activity in addition to the normal state and then completes the SRTT task with the same time intervals as the intervention groups.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran University of Medical Sciences - School of Rehabilitation

Full name of responsible person

Roya Khanmohammadi

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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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

Sara Rezaei eshkalak

Position

Master degree student

Latest degree

Bachelor

Other areas of specialty/work

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

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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