

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of the supplementary motor area (SMA) transcranial photobiomodulation on characteristics of motor performance during sequential finger tapping task: a randomized controlled trial

Protocol summary

Study aim

Determine the effect of the supplementary motor area (SMA) transcranial photobiomodulation (tPBM) on characteristics of motor performance during sequential finger tapping task

Design

A controlled, parallel-group, single-blind, randomized clinical trial using a simple randomization method on 36 participants.

Settings and conduct

All project participants will be studied in the rehabilitation clinic and the brain and cognition laboratory of Tabriz University of Medical Sciences under treatment with the desired tools. Study subjects will be randomly assigned to two groups: 1. Intervention with tPBM and 2. Sham group. In order to apply tPBM intervention, a transcranial optical modulation cap will be used. This study will be done in a blind way, in which the participants will not know about the intervention and in which of the groups.

Participants/Inclusion and exclusion criteria

Students of rehabilitation faculty of Tabriz University of Medical Sciences with an average age of 18-30 years

Intervention groups

The light will be emitted by a near-infrared wave projector, with a specific wavelength of 850 nm, continuously, with a power of 2400 mW/cm and an energy density of 24 J/cm. The desired wavelength is irradiated on the complementary movement area for 10 minutes. This area is the area that is involved in activities related to motor performance. The intervention using cranial light therapy will be done on only half of the participants, while the other half of the participants, the placebo group, will receive the intervention in the form of a sham. The intervention is similar to the intervention group (10 minutes), but in total, radiation will only be applied for 5 seconds per minute.

Main outcome variables

The order and accuracy of the sequence of tapping, reaction time, time interval between finger taps, round trip time as indicators of motor performance.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230207057347N1**

Registration date: **2023-12-23, 1402/10/02**

Registration timing: **retrospective**

Last update: **2023-12-23, 1402/10/02**

Update count: **0**

Registration date

2023-12-23, 1402/10/02

Registrant information

Name

Zahra Heidari

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 24 3378 2419

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z.heidari_72@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-01, 1402/03/11

Expected recruitment end date

2023-08-02, 1402/05/11

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of the supplementary motor area (SMA) transcranial photobiomodulation on characteristics of motor performance during sequential finger tapping task: a randomized controlled trial

Public title
The effect of transcranial photobiomodulation on motor performance

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Right-handed people Age range from 18 to 30 years
Exclusion criteria:
Uncorrected eye diseases Neurological or orthopedic disorder of the upper limb (trigger finger, CTS,...) sleep disorder pregnancy History of seizures Having a profession or repetitive manual activities (such as being a pianist or a typist) Taking drugs or special drugs affecting the nervous system History of neuro-psychological diseases

Age
From **18 years** old to **30 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **36**

Randomization (investigator's opinion)
Randomized

Randomization description
We have two envelopes, one with men and the other with women. Inside each of them are 18 small envelopes, which are randomly written on each of them. As soon as each person enters, he chooses an envelope related to a man or a woman, and I take a number of small envelopes to determine the person's placement in the sham or intervention group, the participant does not know his group.

Blinding (investigator's opinion)
Single blinded

Blinding description
This study will be done in a blind way. The envelope related to the placement of the person in the sham or intervention group will be opened by the researcher and the participant will not know about his group.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz university of Medical sciences

Street address

29 Bahman avenue, Tabriz University of Medical Sciences

City

Tabriz

Province

East Azarbaijan

Postal code

5166414766

Approval date

2023-04-17, 1402/01/28

Ethics committee reference number

IR.TBZMED.REC.1402.085

Health conditions studied

1

Description of health condition studied

Mental fatigue

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Sequential finger tapping motor performance

Timepoint

Before mental fatigue, after mental fatigue, after transcranial photobiomodulation

Method of measurement

Sequential finger tapping motor task

Secondary outcomes

1

Description

Attentional performance

Timepoint

Before mental fatigue, after mental fatigue, after transcranial photobiomodulation

Method of measurement

Go/No go cognitive test

Intervention groups

1

Description

Intervention group: For this group, transcranial optical adjustment will be performed in one session. The light will be emitted through a near-infrared light cap with a wavelength of 850 nm, with a power of 400 mW and an energy density of 24 J/cm. The source of light production in this projector is light diodes. The desired wavelength, for 10 minutes, is radiated on the motion complementary area on the point with coordinates 3 cm further and 2 cm to the right and left of the central zero point. This area is the area that is involved in activities related to motor function. Electrodes are placed on a pre-set optical cap that is adjusted according to the 20-10 system electrode placement in EEG.

Category

Rehabilitation

2

Description

Control group: The other half of the participants, i.e. the sham group, are exposed to radiation in a false way, in such a way that the radiation is only applied to the target area for 5 seconds per minute.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Rehabilitation Sciences

Full name of responsible person

Maryam Moghadam salimi

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29 Bahman Ave, Tabriz University of medical Sciences

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Maryam Moghadam salimi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Neuroscience

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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

Person responsible for updating data**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

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Assistant Professor

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Other areas of specialty/work

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