

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

The effect of transcranial-Photobiomodulation on balance after mental fatigue induction in healthy subjects: a single blind clinical trial

Protocol summary

Study aim

Determining the effect of transcranial photobiomodulation motor and cognitive areas on the balance of healthy people

Design

A controlled, single-blind, randomized, on 34 patients

Settings and conduct

Participants are evaluated in terms of balance and cognitive-attention performance. Then, Visual Stroop is used to create cognitive fatigue. Again, the participants are evaluated in terms of balance and cognitive-attention performance. This study will be conducted in a blind way, where the participants will not know about the intervention and which group they are in. Place: Tabriz University of Medical Sciences

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) Right-handed people in the age range of 18 to 30 years 2) Body mass index from 19 to 25 3) Natural vision 4) Normal blood pressure (8-12 mm Hg) Non-entry criteria: 1) History of untreated eye diseases 2) Nervous or orthopedic disorder of the upper limb 3) Sleep disorder 4) Pregnancy 5) Seizure history 6) Being left-handed 7) Taking medicine or special medicines affecting the nervous system 8) History of neurological-psychological diseases using general health questionnaire 9) Reluctance to continue attending the study

Intervention groups

The intervention using cranial fluoroscopy will be applied to only half of the participants, while the other half of the participants, i.e. the sham group, will be falsely exposed to radiation; In such a way that radiation is only applied to the desired area for 5 seconds per minute it is possible.

Main outcome variables

Balance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221206056727N1**

Registration date: **2023-02-05, 1401/11/16**

Registration timing: **prospective**

Last update: **2023-02-05, 1401/11/16**

Update count: **0**

Registration date

2023-02-05, 1401/11/16

Registrant information

Name

Zoha Daei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3456 8473

Email address

zohadaei1@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-02, 1402/01/13

Expected recruitment end date

2023-06-03, 1402/03/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of transcranial-Photobiomodulation on balance after mental fatigue induction in healthy subjects: a single blind clinical trial

Public title

The effect of transcranial-Photobiomodulation on balance

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Right-handed people in the age range of 18 to 30 years
Body mass index from 19 to 25 Normal vision Normal blood pressure (8-12 mmHg)

Exclusion criteria:

History of untreated eye diseases Sleep disorder
Pregnancy History of seizures Being left handed Taking medicine or special medicines affecting the nervous system History of neurological-psychological diseases using GHQ (General Health) Questionnaire Neurological or orthopedic disorder of the lower limb Unwillingness to continue attending the study

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: **34**

Randomization (investigator's opinion)

Randomized

Randomization description

We have two envelopes, one of which is written for men and the other for women. Inside each of them are 17 small envelopes, which of them is randomly written with sham or intervention. After entering, each person chooses the envelope related to man or woman, I take one of the small envelopes to determine whether the person will be placed 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 Ave, Tabriz University of Medical Sciences

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Tabriz

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East Azarbaijan

Postal code

5166414766

Approval date

2022-11-22, 1401/09/01

Ethics committee reference number

IR.TBZMED.REC.1401.776

Health conditions studied**1****Description of health condition studied**

Mental fatigue

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Balance

Timepoint

Before mental fatigue - after mental fatigue - after transcranial light therapy

Method of measurement

Forceplate

Secondary outcomes**1****Description**

Attentional performance

Timepoint

Before mental fatigue - after mental fatigue - after transcranial light therapy

Method of measurement

Go/No go cognitive task

Intervention groups**1****Description**

Intervention group: For this group, transcranial optical adjustment will be performed in one session. The light

will be emitted through the use of a near-infrared light cap with a specific wavelength of 850 nm. The light will be used continuously with a power of 400 milliwatts and an energy density of 24 J/cm. The source of light production in this projector is light emitting diodes, and the desired wavelength, for 3 minutes, bilaterally on the right and left frontal areas (FP1 and FP2), supplementary motor areas (SMA) and primary motor areas. (equivalent to C3 and C4) will be irradiated. The electrodes are placed on a pre-set light cap, which is adjusted according to the electrode placement method of the 10-20 system in EEG.

Category

Rehabilitation

2**Description**

Control group: The other half of the participants, i.e. the sham group, are falsely exposed to radiation; In this way, radiation is applied to the target area only for 5 seconds per minute.

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Tabriz University of Medical Sciences

Full name of responsible person

Maryam Moghadam Salimi

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

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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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Other areas of specialty/work

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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