Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
City
Tabriz
Province
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

Street address

29 Bahman Ave, Tabriz University of Medical Sciences

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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

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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Position

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Latest degree

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Person responsible for updating data

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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