

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Effects of transcranial light therapy on physical and attentional performance after mental fatigue induction in healthy subjects

Protocol summary

Study aim

Effects of transcranial light therapy on physical and attentional performance after mental fatigue induction in healthy subjects

Design

.Twenty-four participants (12 female and 12 male) participated in this study. A randomized, controlled, randomized clinical trial.

Settings and conduct

All project participants will be studied in the Brain and Neurology Laboratory of Tabriz University of Medical Sciences. And the effects of light therapy on them will be examined. Participants are unaware of intervention or sham.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Students of Rehabilitation Faculty of Tabriz University of Medical Sciences with mean age of 18-30 years All participants' body mass index was less than 25 Natural vision Exclusion criteria: History of unrecognized eye diseases Neurological or orthopedic disorder of the upper extremity sleep disorder Pregnancy History of seizures Taking medication or certain drugs that affect the nervous system. History of neuropsychological diseases

Intervention groups

Half of the participants will be irradiated by transcranial light therapy with a specific wavelength of 850 nm, power of 60 mW / cm², and energy density of 4 J / cm², and the other half will receive a small amount of current under the control group. After light irradiation, subjects are re-studied for electroencephalographic features to investigate the effects of transcranial light irradiation on the cerebral band.

Main outcome variables

Reaction time (RT) for valid status Reaction time (RT) for invalid status Valid response for valid status Correct response to invalid status

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191214045738N2**

Registration date: **2020-07-17, 1399/04/27**

Registration timing: **prospective**

Last update: **2020-07-17, 1399/04/27**

Update count: **0**

Registration date

2020-07-17, 1399/04/27

Registrant information

Name

Farzaneh Fathi Dokht Lahshari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3335 5961

Email address

f.fathidokht@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-20, 1399/04/30

Expected recruitment end date

2020-09-05, 1399/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of transcranial light therapy on physical and attentional performance after mental fatigue induction in healthy subjects

Public title

Effects of light therapy on mental fatigue induction in healthy subjects

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

Students of Rehabilitation Faculty of Tabriz University of Medical Sciences with mean age of 18-30 years Right-handed people in the age group of 18-30. All participants' body mass index (BMI) was less than 25 Natural vision

Exclusion criteria:

History of unrecognized eye diseases Neurological or orthopedic disorder of the upper extremity Sleep Disorders Pregnancy History of seizures Taking medication or certain drugs that affect the nervous system History of neuropsychological 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: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling method: In a convenience sampling method, a total of 24 healthy students, will be included from Tabriz University of medical sciences. The volunteers will be asked to complete an information questionnaire including their name, age, dominant hand, telephone number, and history of the neurological or psychological disease. Each eligible participant will be assigned a code. Random allocation: Simple random allocation strategy, using "random number table" was applied, To assign participants to the study groups. Then a table without a specific pattern or order will be used. From top to bottom, the letter A is assigned to the intervention group and the letter B to the sham group, respectively.

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants in the project are unaware of the intervention or the sham.

Placebo

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

Rehabilitation faculty, Daneshgah avenue, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5167631444

Approval date

2020-01-21, 1398/11/01

Ethics committee reference number

IR.TBZMED.REC.1398.1136

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

Mental fatigue

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

Reaction time (RT) for valid status

Timepoint

Before and after intervention

Method of measurement

By Posner task

2**Description**

RT for invalid status

Timepoint

Before and after intervention

Method of measurement

By Posner task

3**Description**

Correct response for valid status

Timepoint

Before and after intervention

Method of measurement

By Posner task

4

Description

Correct response to invalid status

Timepoint

Before and after intervention

Method of measurement

By Posner task

Secondary outcomes

1

Description

Physical fatigue score

Timepoint

Before and after intervention

Method of measurement

By the Modified Fatigue Impact Scale (MFIS) questionnaire

2

Description

Cognitive fatigue score

Timepoint

Before and after intervention

Method of measurement

By the MFIS questionnaire

3

Description

Social Fatigue Score

Timepoint

Before and after intervention

Method of measurement

By the MFIS questionnaire

Intervention groups

1

Description

Intervention group: Participants in the intervention group, will received light radiation by Near Infrared projector, with a specific wavelength of 850 nm, continuously and with a power of 60 mW / cm² and an energy density of 4 J/cm². The light will be irradiated for 10 minutes on 9th and 10th areas of the Broadman or the right prefrontal cortex according to EEG 10-20 system. This area is involved in activities related to sustained attention.

Category

Treatment - Devices

2

Description

Control group: while for the other half of the participants, ie. In the placebo group, the radiation is applied to the target area for only 5 seconds per minute and other steps are similar.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Maryam Moghadam Salimi

Street address

29 Bahman Avenue, University of Tabriz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mohamad Samiee

Street address

Vice-Chancellor for Research and Technology,
Daneshgah avenue, Tabriz

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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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Study protocol, statistical analysis plan, and informed consent form will be available to share with other investigators if they request by email.

When the data will become available and for how long

6 months after publication

To whom data/document is available

Only available for people working in academic institutions in Iran

Under which criteria data/document could be used

In case of journal or reviewers request for data set

From where data/document is obtainable

Via email and giving documents to prove their identity for administrator Dr Maryam moghadam salimi
moghadamm@tbzmed.ac.ir

What processes are involved for a request to access

data/document

Sending email and documents to prove their identity
Comments