

# 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 / cm<sup>2</sup>, and energy density of 4 J / cm<sup>2</sup>, 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 / cm<sup>2</sup> and an energy density of 4 J/cm<sup>2</sup>. 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

#### **City**

Tabriz

#### **Province**

East Azarbaijan

#### **Postal code**

5166614766

#### **Phone**

+98 41 3336 4658

#### **Email**

moghadamm@tbzmed.ac.ir

## **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

#### **City**

Tabriz

#### **Province**

East Azarbaijan

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5167631444

#### **Phone**

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#### **Fax**

+98 41 3334 5121

#### **Email**

moghadamm@tbzmed.ac.ir

### **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

**Street address**

Rehabilitation Faculty, Daneshgah avenue, Tabriz

**City**

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

Tabriz University of Medical Sciences

**Full name of responsible person**

Maryam Moghadam Salimi

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

Tabriz University of Medical Sciences

**Full name of responsible person**

Maryam Maghadam Salimi

**Position**

Assistant Professor

**Latest degree**

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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**