

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### The effect of transcranial light therapy on quantitative electroencephalographic features after mental fatigue induction in healthy subjects

#### Protocol summary

##### Study aim

The effect of transcranial light therapy on quantitative electroencephalographic features, after mental fatigue induction in healthy subjects

##### Design

In this single blind randomized controlled trial study. Forty participants (20 sham and 20 intervention) will participate.

##### Settings and conduct

This study will be conducted in laboratory of Brain and cognition, Tabriz University of Medical Sciences, faculty of rehabilitation sciences. The study will investigate the effects of transcranial light therapy, after induction of mental fatigue. Participants will not be aware of being in intervention or sham group.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: University students. Mean age of 18-40 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 drugs that affect the nervous system. History of neuropsychological diseases.

##### Intervention groups

One square super-luminous multi-LED array source with 20 cells will apply (Iranbargh, Tehran, Iran) for TCLT in this study. The dimensions of the LED is 14mm\_ 10 mm with 400 mW total radiation power. The device was calibrated before the experiment (Iranbargh, Tehran, Iran). The power density is 285 mW/cm<sup>2</sup> and energy density is 60 J/cm<sup>2</sup> (8). The wavelength of the LED is 850 nm. Light will emit by the LED source continuously for 2.5 minutes on the right frontal pole of the cortex (Fp2, according to the EEG 10 to 20 system. The sham group will be received the same procedure as the real intervention group, yet, they received only a 5-second

light irradiation for each 1-minute of the treatment.

##### Main outcome variables

EEG power spectrum EEG coherency

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191214045738N1**

Registration date: **2020-07-11, 1399/04/21**

Registration timing: **prospective**

Last update: **2020-07-11, 1399/04/21**

Update count: **0**

##### Registration date

2020-07-11, 1399/04/21

##### 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

2020-08-24, 1399/06/03

##### Expected recruitment end date

2020-10-21, 1399/07/30

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of transcranial light therapy on quantitative electroencephalographic features after mental fatigue induction in healthy subjects

**Public title**

The effect of light therapy on quantitative electroencephalographic features after 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 18-40. 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 History of neuropsychological diseases Taking medication or certain drugs that affect the nervous system

**Age**

From **18 years** old to **40 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

A simple randomization method will be used in this study. After filling the questionnaires, each of the eligible participants will be given a code. Then a "Random number table" will be used which is a table without a specific pattern or order. The letter A will be assigned to the intervention group and the letter B will be assigned to the sham group from top to bottom, respectively. The researcher will then select the subject by tapping on any of the numbers.

**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**

2020-02-18, 1398/11/29

**Ethics committee reference number**

IR.TBZMED.REC.1398.1224

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

Absence of any disease

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

EEG absolute power

**Timepoint**

Before and after intervention

**Method of measurement**

EEG recording

**2****Description**

EEG choherency

**Timepoint**

Before and after intervention

**Method of measurement**

EEG recording

**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

One square super-luminous multi-LED array source with 20 cells will apply (Iranbargh, Tehran, Iran) for TCLT in this study. The dimensions of the LED is 14mm\_10 mm with 400 mW total radiation power. The device was calibrated before the experiment (Iranbargh, Tehran, Iran). The power density is 285 mW/cm<sup>2</sup> and energy density is 60 J/cm<sup>2</sup> (8). The wavelength of the LED is 850 nm. Light will emit by the LED source continuously for 2.5 minutes on the right frontal pole of the cortex (Fp2, according to the EEG 10 to 20 system. The sham group will be received the same procedure as the real intervention group, yet, they received only a 5-second light irradiation for each 1-minute of the treatment.

### Category

Treatment - Devices

## 2

### Description

Control group: while for the other half of the participants, In the placebo group, the radiation is applied to the target area for only 5 seconds per each 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 Salim

## 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

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#### Fax

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#### Email

moghadamm@tbzmed.ac.ir

### Grant name

young assistant professors

### 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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Rehabilitation Faculty, Daneshgah avenue, Tabriz

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

Tabriz University of Medical Sciences

**Full name of responsible person**

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**Position**

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**Email**

moghadamm@tbzmed.ac.ir

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

Tabriz University of Medical Sciences

**Full name of responsible person****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**