Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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/cm2 and energy density is 60 J/cm2 (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/cm2 and energy density is 60 J/cm2 (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
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Tabriz
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5166614766
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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
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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
Street address
Rehabilitation Faculty, Daneshgah avenue, Tabriz
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Person responsible for scientific inquiries

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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
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 maoghadam 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