

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluating the effectiveness of transcranial light therapy method on number sense, computation, visuospatial memory, phonological processing, academic progress, electrophysiological function, and brain map of children with a math learning disorder

Protocol summary

Study aim

This research intends to evaluate the effectiveness of transcranial light therapy on children with math learning disorders.

Design

A controlled, single-blind

Settings and conduct

20 students will be selected from the special centers for children with specific learning disabilities in Tabriz city based on the entry/exit criteria, using a diagnostic interview and viewing academic records. Participants in the experimental group will undergo transcranial phototherapy intervention. On the other hand, the participants in the control group will not receive any amount of the energy density received by the experimental group by placing a metal filter on the laser radiation site. The present research will be conducted in the Faculty of Modern Sciences and Rehabilitation of Tabriz University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Eligibility criteria: • Normal IQ • Age range from 8 to 13 years
Criteria for not entering the study: • History of seizures, epilepsy, or family history • Taking medicine or special medicines affecting the nervous system • Presence of other neuropsychological diseases • Non-cooperation in meetings • Absence of more than two sessions

Intervention groups

Participants in the experimental group will undergo transcranial phototherapy intervention. On the other hand, the participants in the control group will not receive any amount of the energy density received by the experimental group by placing a metal filter on the laser radiation site.

Main outcome variables

Number sense, computation, visuospatial memory,

phonological processing, academic achievement, electrophysiological function, brain map

General information

Reason for update

Acronym

transcranial Low-Level Light Therapy (LLLT)

IRCT registration information

IRCT registration number: **IRCT20220228054148N1**

Registration date: **2023-02-20, 1401/12/01**

Registration timing: **prospective**

Last update: **2023-02-20, 1401/12/01**

Update count: **0**

Registration date

2023-02-20, 1401/12/01

Registrant information

Name

Leyla Rastgar Farajzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-06, 1401/12/15

Expected recruitment end date

2023-06-20, 1402/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effectiveness of transcranial light therapy method on number sense, computation, visuospatial memory, phonological processing, academic progress, electrophysiological function, and brain map of children with a math learning disorder

Public title

Evaluating the effectiveness of transcranial light therapy method on children with a math learning disorder

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having a math learning disorder Age range 8 to 13 years Normal IQ

Exclusion criteria:

History of seizures, epilepsy or its family history Taking medicine or special medicines affecting the nervous system Presence of other neuropsychological diseases Non-cooperation in sessions Absence of more than two sessions

Age

From **8 years** old to **13 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description

None of the participants will know whether they are in the intervention or control group. Participants in the intervention group will undergo transcranial light therapy through laser radiation. On the other hand, the participants in the control group will not receive any amount of laser by placing a metal filter on the place of laser radiation as an obstacle. More precisely, none of the participants will know whether they have been exposed to laser radiation or not.

Placebo

Used

Assignment

Parallel

Other design features

no

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tabriz University of Medical Sciences

Street address

No. 97, 12m Laklar Alley, Jonubi Shariati Street, Tabriz, East Azerbaijan Province, Iran.

City

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Postal code

5138837311

Approval date

2023-02-06, 1401/11/17

Ethics committee reference number

IR.TBZMED.REC.1401.1000

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

Math learnin disability

ICD-10 code

F81.2

ICD-10 code description

Mathematics disorder

Primary outcomes**1****Description**

number sense

Timepoint

Before and after the intervention

Method of measurement

Numerical Stroop test

2**Description**

computation

Timepoint

Before and after the intervention

Method of measurement

Single or multi-digit calculations (addition, subtraction, multiplication, and division)

3**Description**

Visual-spatial memory

Timepoint

Before and after the intervention

Method of measurement

Corsi Block

4

Description

Phonological processing

Timepoint

Before and after the intervention

Method of measurement

Wechsler intelligence test supplementary scale 5 (naming speed)

5

Description

Achievement

Timepoint

Before and after the intervention

Method of measurement

Educational reports of the child

6

Description

Electrophysiological function

Timepoint

Before and after the intervention

Method of measurement

Event-related potentials (ERPs)

7

Description

brain map

Timepoint

Before and after the intervention

Method of measurement

Quantitative electroencephalography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the transcranial light therapy intervention, light will be emitted by the Lumix 3 laser device, with a wavelength of 1064 nm, continuously, with a power density of 250 mW/cm² and an energy density of 60 J/cm². The source of light production in this projector will be light diodes. The desired wavelength will be irradiated bilaterally in the intraparietal sulcus (IPS) for 10 minutes. The number of transcranial light therapy sessions will be 1 session and the cumulative dose will be 600 mW/cm².

Category

Treatment - Devices

2

Description

Control group: The participants in the control group will not receive any amount of the energy density received by the experimental group by placing a metal filter on the laser radiation site.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz University of Medical Sciences, Faculty of Rehabilitation

Full name of responsible person

Maryam Moghadam Salimi

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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
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Full name of responsible person
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Position
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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