Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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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
Tabriz
Province
East Azarbaijan
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
Street address
Faculty of Rehabilitation, Tabriz University of Medical Sciences, Tabriz, Iran.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Abbas Ebrahimi Kalan
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Faculty of Modern Medical Sciences, Tabriz University of Medical Sciences, Tabriz, Iran
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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
Abbas Ebrahimi Kalan

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Anatomy

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Mohammad Ali Nazari

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Neuroscience

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Person responsible for updating data

Contact

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Position
PhD student

Latest degree
Master

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
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