

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

The effect of combined neurofeedback therapy and transcranial electrical stimulation on the development of cognitive abilities and problem solving of high school students

Protocol summary

Cognitive Abilities - Math Problem Solving

Study aim

Reinforce the cognitive abilities in math problem-solving with combined TDCS & neurofeedback Therapy

Design

First, two baseline lines of brain waves at points P3-P4 of the brain are taken from each participant along with the Wechsler test. The math score of the previous semester is also calculated. Then, in each treatment session, TDCS is stimulated for 15 minutes with an intensity between 1-2 mA on points P3-P4 as the cathode and FZ as the cathode. The student must complete his / her math homework at the same time. Then, for 30 minutes, neurofeedback therapy will be performed on the same points with the aim of promoting alpha and theta and suppressing the stress wave beta 3. In both sessions, the student will be re-assessed with the above tools. At the end of the eighth session, the Wechsler test is taken again and at the same time, his school math scores are taken into account.

Settings and conduct

Students with poor math problem solving are referred to Irana Psychology and Counseling Clinic from two schools in Karaj with the consent of their parents. The study process was presented in full in the design.

Participants/Inclusion and exclusion criteria

5 ninth grade male students, with the consent of their parents, participate in this study purposefully and voluntarily. Entry Criteria: Ages 14 -16 years, weakness in solving math problem, math score 12-13.5, non-clinical diagnosis in the learning and cognitive activities, no reinforcement classes. Exclusion criteria: Absence from more than one session of treatment sessions and attending out-of-school remedial classes.

Intervention groups

The intervention will be performed for eight weeks and twice a week (50 minutes) for all five participants.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220406054427N1**

Registration date: **2022-04-12, 1401/01/23**

Registration timing: **prospective**

Last update: **2022-04-12, 1401/01/23**

Update count: **0**

Registration date

2022-04-12, 1401/01/23

Registrant information

Name

Ghazal Zandkarimi

Name of organization / entity

Alzahra University

Country

Iran (Islamic Republic of)

Phone

+98 21 3507 4315

Email address

zandkarimi@refah.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-21, 1401/02/01

Expected recruitment end date

2022-06-22, 1401/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
The effect of combined neurofeedback therapy and transcranial electrical stimulation on the development of cognitive abilities and problem solving of high school students

Public title
Effect of Brain stimulation in Math Problem Solving

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Students weakness in math problem-solving whose math score in the following transcript is between 12 and 13.5. , Lack of clinical diagnosis in the field of learning disability Normal diagnosis in the field of cognitive activities by a clinician Absence from math reinforcement classes

Exclusion criteria:

Absence of more than one session of treatment sessions Attendance at out-of-school remedial classes

Age
From **14 years** old to **16 years** old

Gender
Male

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **5**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Alzahra University

Street address

Deh- Vanak

City

Tehran

Province

Tehran
Postal code
1473776531

Approval date
2021-09-29, 1400/07/07

Ethics committee reference number
IR.ALZAHRA.REC.1400.051

Health conditions studied

1

Description of health condition studied

Weakness in math problem-solving

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

cognitive abilities and Weakness in math problem-solving

Timepoint

Brain wave recording is started with two baselines from the beginning and is done once after both treatment sessions. But Wechsler test and student math scores are taken only at the beginning and end of the study.

Method of measurement

The Wechsler Fourth Edition Scale will be used to measure cognitive abilities using verbal comprehension, perceptual reasoning, working memory, processing speed, and total intelligence scales. To check for changes in math score, math scores from the previous semester and the new semester will be reviewed. To measure the changes of alpha, theta and beta 3 waves at points P3-P4, brain wave recording will be used by recording the EEG waves of the neurofeedback device.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention 1: Students with poor math problem solving are referred to Irana Psychology and Counseling Clinic from two schools in Karaj with the consent of their parents. The study process was presented in full in the design. Five ninth grade male students, with the consent of their parents, participate in this study purposefully and voluntarily. Inclusion criteria between the ages of 14 and 16, weakness in solving mathematical problems, mathematical score of transcripts between 12 to 13.5, lack of clinical diagnosis in the field of learning disabilities and cognitive activities by a clinical specialist, absence from math reinforcement classes are also criteria for entry and absence More than one session of

treatment sessions and attending out-of-school remedial classes will be the exclusion criteria. Then the fourth edition Wechsler test, which is for 10 to 18 year olds. Taken. In this study, 4 cognitive scales of Wechsler test (verbal comprehension, perceptual reasoning, working memory, processing speed) are considered and scores such as verbal and practical intelligence are not considered because the study is not in the field of intelligence assessment. Rather, only cognitive abilities are considered. Because the Wechsler test is factor analyzed, the use of subscales does not reduce validity. The math score of the previous semester is also calculated. The whole study will be conducted on 5 participants. Interventions will be performed individually for each of the 5 participants as a single control group. Independent variables will be extracranial electrical stimulation therapy with simultaneous solution of mathematical and neurofeedback problems. Dependent variables are also cognitive abilities (verbal comprehension, perceptual reasoning, working memory, processing speed) and mathematical problem solving. In intervention 1, participants will be exposed to transcranial direct current stimulation twice a week for 8 sessions, each session lasting 15 minutes. Electric excitation with direct transcranial current is performed through two extracorporeal excitation devices made by Medina Teb Iran Company. The method of excitation is that first the anode electrodes are placed by wet pads on the points P3, P4 of the parietal part. And the left shoulder and right shoulder cathode electrodes are cross-sectioned to direct current. The current from the first to the eighth session is as follows: the first session 1 mA, the second session 1.2 mA, the second session 1.4 mA, the third session 1.6 mA, the fourth session 1.8 mA and from the fifth session to the eighth session 2 Will be milliamperes. The aim of this stimulation is to increase the amplitude of alpha and theta relaxation and reduce the wave of beta 3 stress at the right and left points of the nostril. Because according to previous theories and research, increasing relaxation in the left parietal increases cognitive ability in mathematical details and increasing relaxation in the right parietal leads to understanding mathematical generalities. This stimulation increases blood flow to these areas and does not cause any harm or danger to the brain, and its safety has been proven time and time again in internal and external studies.

Category

Treatment - Devices

2

Description

Intervention 2: Intervention 2 will be performed simultaneously with Intervention 1. In such a way that in the 15 minutes that each participant in each session of extracranial electrical stimulation to activate the brain in the right and left parietal points, he must simultaneously bring and do math exercises related to his class lesson and do at the same time. It does not matter if you do the exercise correctly or incorrectly. Rather, we know from theory that transcranial stimulation prepares neurons for action potential but does not create action potential.

Therefore, there must be training or performing a skill that stimulates the brain and is ready to act, this time with great strength and power to create action potential. Therefore, they pursue such intentions. Participants in each session performed math homework with electrical stimulation.

Category

Rehabilitation

3

Description

Intervention 3: In intervention 3, just after the end of 15 minutes of transcranial electrical stimulation, the electrodes of the electrical stimulation device are separated and the neurofeedback electrodes are connected to the suture points P3, P4. The neurofeedback device will be dual channel Procomb 2 from Canada. Therefore, the source and reference electrodes will be placed on both P3, P4 and ground electrodes on the ear. In neurofeedback therapy, the participant is placed in front of a lip screen and a cartoon is played to him or her as desired. But the difference between this broadcast and the normal broadcast is that the performance and distribution of the cartoon depends on the model of concentration, breathing, and attention of the participant. The participant must, through trial and error and through the feedback given to him by the system, by keeping his concentration, breathing and eye movements, keep the alpha and theta levels in the parietal section in a position where the cartoon is broadcast. Otherwise the image will stop. Carba neurofeedback is done every 35 minutes after stimulation and its purpose is to stabilize the action potential created after the math exercises. At the end of intervention 3 in each session, the baseline is taken again from the participants to examine the changes in alpha, theta and beta 3 in each session. At the end of the eighth session, the participants are taken again from the Wechsler test, and their new math scores will be compared with the math score before the intervention, which will be reported to the researcher by the school. Data will be analyzed by Cohen's recovery percentage and effect size tables and visual analysis.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

کلینیک تخصصی روانشناسی و مشاوره ابرانا

Full name of responsible person

Mohammad Bagher Hasanvand

Street address

Taleghani crossroads to Shohada Square - Arad
Doctors Building - 7th floor

City

Karaj

Province

Alborz
Postal code
1469684441
Phone
+98 26 3499 0205
Email
B.hasanvand@gmail.com

Baharestan - Mardon street
City
Tehran
Province
Tehran
Postal code
1469684441
Phone
+98 21 3507 4315
Email
fatemeh.fazlali99@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Refah University College
Full name of responsible person
Dr. Hajar Bakhtari
Street address
Baharestan- Mardom Street
City
Tehran
Province
Tehran
Postal code
1157513838
Phone
+98 21 3507 4315
Email
zandkarimi@refah.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Refah University College
Proportion provided by this source
20
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Refah University College
Full name of responsible person
Fatemeh Fazlali
Position
Psychologist
Latest degree
Master
Other areas of specialty/work
Psychology
Street address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Refah University College
Full name of responsible person
Ghazal Zandkarimi
Position
Assistant professor faculty member
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
Street address
Baharestan- Mardom Street
City
Tehran
Province
Tehran
Postal code
1469684441
Phone
+98 21 3507 4315
Email
zandkarimi@refah.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Refah University College
Full name of responsible person
Fatemeh Fazali
Position
education expert
Latest degree
Master
Other areas of specialty/work
Psychology
Street address
Baharestan - Mardom St
City
Tehran
Province
Tehran
Postal code
1157513838
Phone
+98 21 3507 4338

Email

fatemeh.fazlali99@gmail.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data will be provided to the relevant organizations in compliance with ethical standards and there is no conflict in this regard.

When the data will become available and for how long

Six months after the results were published

To whom data/document is available

The data will be available to researchers, academics and clinical therapists.

Under which criteria data/document could be used

Researchers who want to assess the intelligence and cognitive abilities of students with a disability in mathematics will be able to have and check the questionnaires.

From where data/document is obtainable

Correspond to Zandkarimi@refah.ac.ir.

What processes are involved for a request to access data/document

Confirmation of the applicant as an academic, researcher or clinical therapist and confirmation of the purpose of the information request will be provided.

Comments