

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

The effectiveness of Neurofeedback and Heart Rate Variability Training on QEEG Baseline and Sustained Attention in Children with ADHD

Protocol summary

Study aim

The effectiveness of Neurofeedback and Heart Rate Variability Training on QEEG Baseline and Sustained Attention in Children with ADHD

Design

Randomized Controlled Trial

Settings and conduct

For monitoring treatment progression and clinical outcome, before and after the study and a 6-month follow-up examination; the relations between baseline difference in quantitative electroencephalography, continuous performance testing and Connors rating scale of parents will be determined.

Participants/Inclusion and exclusion criteria

Children with Attention Deficit/Hyperactivity Disorder (ADHD), who are 7 to 12 years old, with definite diagnosis by a psychiatrist, based on DSM-V diagnostic criteria, semi-structured interview and developmental history; referred to the Psychiatric Clinic of Yahya Nejad Hospital and Private Center for Psychiatric Disorders. These criteria are based on such factors as co-occurrence of ADHD with other psychiatric and neurological disorders, mental retardation, as well as parents informed consent who agreed to allow their children to participate

Intervention groups

Eighty children with ADHD randomly divide into five experimental groups, namely a Neurofeedback (NFB) Group, two distinct theta/beta ratio and theta/sensorimotor rhythm training NFB protocols for a cumulative total of 30 minutes (15 minutes each) or more over a 45 minutes' period in 30 sessions/12 weeks, and Neurofeedback/ Biofeedback (BFB) Group, heart rate variability and respiratory BFB Group in which participants encouraged to breathe slowly and diaphragmally for 3-5 minutes, adapting inhalation and exhalation to heart rate fluctuations, and the other Methylphenidate, twice-a-day oral administration contains 5 mg which may be increased in 10 mg

increments at weekly intervals, and Methylphenidate along with Neurofeedback and NeuroBiofeedback Groups.

Main outcome variables

Baseline QEEG; Attention, Impulsivity

General information

Reason for update

Acronym

ADHD: Attention Deficit and Hyperactivity Disorder

IRCT registration information

IRCT registration number: **IRCT20190317043079N2**

Registration date: **2021-03-19, 1399/12/29**

Registration timing: **prospective**

Last update: **2021-03-19, 1399/12/29**

Update count: **0**

Registration date

2021-03-19, 1399/12/29

Registrant information

Name

farzan kheirkhah

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-09, 1400/01/20

Expected recruitment end date

2022-02-20, 1400/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of Neurofeedback and Heart Rate Variability Training on QEEG Baseline and Sustained Attention in Children with ADHD

Public title

The Effect of Neurofeedback/Biofeedback on Brain's Waves Amplitude and Attention Deficit in Children With ADHD

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Children 7-12 years with definite diagnosis of Attention Deficit/Hyperactivity Disorder by a psychiatrist, based on DSM-V diagnostic criteria, semi-structured interview and developmental history; referred to the Psychiatric Clinic of Yahya Nejad Hospital and Private Center for Psychiatric Disorders

Exclusion criteria:

The identification of ADHD in children with other psychiatric and neurological disorders; Mental retardation

AgeFrom **7 years** old to **12 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Participant

Sample sizeTarget sample size: **80****Randomization (investigator's opinion)**

Randomized

Randomization description

Subjects are randomly divided into 5 groups by block method. The size of the blocks is 10 and 8 blocks of 10 will be produced using a table of random numbers. Due to the fact that sampling is done in two centers, two samples of 80 lists will be produced, participants are assigned to two groups of 40 people.

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants are unaware of the allocation of study groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Babol University of Medical Sciences

Street address

Babol University of Medical Sciences

City

Babol

Province

Mazandaran

Postal code

۴۷۱۷۶-۴۷۷۴۵

Approval date

2021-03-13, 1399/12/23

Ethics committee reference number

IR.MUBABOL.REC.1399.503

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

Attention Deficit/Hyperactivity Disorder

ICD-10 code

F90

ICD-10 code description

Attention-deficit hyperactivity disorders

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

Baseline Quantitative Electroencephalography

Timepoint

before and after the study and a 6-month follow-up examination

Method of measurement

Electroencephalography

2**Description**

Sustained Attention and Impulsivity

Timepoint

before and after the study and a 6-month follow-up examination

Method of measurement

Continuous performance testing

3**Description**

Attention deficit and Impulsivity

Timepoint

before and after the study and a 6-month follow-up examination

Method of measurement

Connors rating scale of parents

Secondary outcomes

empty

Intervention groups**1****Description**

First Intervention group: Neurofeedback (NFB) Group, two distinct theta/beta ratio and theta/sensorimotor rhythm training NFB protocols 15 minutes each over a 45 minutes' period in 30 sessions/12 weeks

Category

Rehabilitation

2**Description**

Second Intervention group: Neurofeedback and Heart Rate Variability Training and respiratory Biofeedback Group in which participants encouraged to breathe slowly and diaphragmally for 3-5 minutes, adapting inhalation and exhalation to heart rate fluctuations

Category

Rehabilitation

3**Description**

Control group: Methylphenidate, twice-a-day oral administration contains 5 mg which may be increased in 10 mg increments at weekly intervals

Category

Treatment - Drugs

4**Description**

Third Intervention group: Methylphenidate along with Neurofeedback Group

Category

Rehabilitation

5**Description**

Fourth Intervention group: Methylphenidate along with NeuroBiofeedback Group

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Yahyanezhad Hospital

Full name of responsible person

Arman Masoudi

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2**Recruitment center****Name of recruitment center**

Private Center for Psychiatric Disorders

Full name of responsible person

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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
Babol 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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Since study participants are patients with ADHD, there is no plan to publish participant data except in the final design report
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is 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
Title and more details about the data/document
There is no plan to publish participant data
When the data will become available and for how long
After the publication of the final report of the project
To whom data/document is available
Academic researchers
Under which criteria data/document could be used

If you need more information about the research, it will be available by sending an email to the main researchers.

From where data/document is obtainable

By sending an E-mail to drfarzankh@yahoo.com, and hoseinzadeh_soheila@yahoo.com

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

Within a maximum of one month after sending the email to the main researchers

Comments