

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effectiveness of neurofeedback versus methylphenidate in the treatment of children with Attention Deficit Hyperactivity Disorder

Protocol summary

Summary

Type of study: Randomized clinical trial. Aim: to determine the effectiveness of neurofeedback versus methylphenidate in the treatment of children with Attention Deficit Hyperactivity Disorder. Inclusion criteria: 1-Diagnosis of ADHD based on DSM-IV criteria by child and adolescent psychiatrists; 2- age of 7- 18 years; 3- IQ above 85 based on WISC-III-R. Exclusion criteria:1- major learning problems; 2- request of parent to exit from the study; 3- use of antipsychotic drugs in the month before the initiation of the study. 4- history of neurofeedback intervention at least for 10 sessions. Types of interventions:1) neurofeedback; 2)medication 3)medication +neurofeedback. The participants will be recruited from 4 child psychiatry clinics. Then they will be referred to the main clinic which all the intervention will be conducted there. Methylphenidate dose will be adjusted based on optimal dose by a child and adolescent psychiatrist whom visits all the patients. They will be assessed 1 week before the start and each month through the study ,the last assessment will be on a week after the completion of the research. The main outcome measures are: conners, TOVA. The rater will be blind to the groups of patients. The duration of the treatment is 3 months.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138804132000N2**

Registration date: **2013-02-15, 1391/11/27**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-02-15, 1391/11/27

Registrant information

Name

Rozita Davari Ashtiani

Name of organization / entity

Imam Hossein Hospital, Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 7755 1023

Email address

rodavari@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Behavioral sciences research center, Shahid beheshti university of medical sciences

Expected recruitment start date

2013-04-09, 1392/01/20

Expected recruitment end date

2014-12-22, 1393/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of neurofeedback versus methylphenidate in the treatment of children with Attention Deficit Hyperactivity Disorder

Public title

Neurofeedback in the treatment of Attention Deficit Hyperactivity Disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1-Diagnosis of ADHD based on DSM-IV-

TR criteria by child and adolescent psychiatrists; 2- age of 7- 18 years; 3- IQ above 85 based on WISC-III-R; 4- parent consent for the participation in the study. Exclusion criteria: 1- neurological disorders; 2- major learning problems; 3- request of parent to exit from the study; 4- use of antipsychotic drugs in the month before the initiation of the study; 5- history of neurofeedback intervention at least for 10 sessions.

Age

From **7 years** old to **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

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

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Behavioral sciences Research Center, Shahid Beheshti University of Medical sciences

Street address

Shahid Madani Street, Imam Hossein Hospital, Behavioral Sciences Research center

City

Tehran

Postal code

1617763141

Approval date

2012-12-23, 1391/10/03

Ethics committee reference number

1391-1-91-9876

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

Attention Deficit Hyperactivity Disorder

ICD-10 code

F90.0

ICD-10 code description

Disturbance of activity and attention

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

ADHD symptoms

Timepoint

1 week before the initiation and each month through the study and 1 week after the end of the intervention

Method of measurement

conners ADHD rating scale

Secondary outcomes**1****Description**

attention

Timepoint

1 week before , and 1 week after the end of the trial

Method of measurement

Test of Variables of Attention

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

Group 1:treatment with methylphenidate started with 5mg BD and the dose will adjust in 2 weeks according to response and side effects by a child psychiatrist

Category

Treatment - Drugs

2**Description**

Group 3:treatment with the combination of methylphenidate and neurofeedback. Both of these interventions is implemented in the same instruction as in group 1 and 2

Category

Other

3**Description**

Group 2: treatment with neurofeedback 2 times a week by an expert in a special clinic. In this method , we are going to increase beta waves in the brain and as a result increasing attention

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr Rozita Davari Ashtiani Clinic

Full name of responsible person

Rozita Davari Ashtiani

Street address**City**

Tehran

2

Recruitment center

Name of recruitment center

Dr Elham Shirazi Clinic

Full name of responsible person

Elham Shirazi

Street address**City**

Tehran

3

Recruitment center

Name of recruitment center

Dr Javad Alaghband Rad Clinic

Full name of responsible person

Javad Alaghband Rad

Street address**City**

Tehran

4

Recruitment center

Name of recruitment center

Dr Nasrin Amiri Clinic

Full name of responsible person

Nasrin Amiri

Street address**City**

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Behavioral Sciences Research center, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Alireza Zahiruddin

Street address

Imam Hossein Hospital , Shahid Madani Street

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Behavioral Sciences Research center, Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Javad Alaghband Rad

Position

Associate Professor , Child & Adolescent Psychiatrist

Other areas of specialty/work**Street address**

Roozbeh Hospital, South Kargar Street

City

Tehran

Postal code**Phone**

+98 21 5541 9151

Fax**Email**

alaghbandrad@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of medical Sciences

Full name of responsible person

Dr Javad Alaghband rad

Position

MD, Child & Adolescent psychiatrist

Other areas of specialty/work**Street address**

Roozbeh Hospital, South Kargar Street:

City

Tehran

Postal code**Phone**

+98 21 5541 9151

Fax**Email**

alaghbandrad@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Rozita davari Ashtiani

Position

Associate Professor, child & Adolescent Psychiatrist

Other areas of specialty/work**Street address**

Imam Hossein Hospital, Shahid Madani Street

City

Tehran

Postal code**Phone**

+98 21 7755 1023

Fax**Email**

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty