

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of Neuro feedback on Executive Functions of Children with ADHD Who Treated with Methylphenidate in razi Hospital of Tabriz

Protocol summary

Study aim

Evaluation of neurofeedback effect on the executive functions of children with ADHD treated with methylphenidate

Design

Clinical trials with community-based control group, with parallel groups, simple triangular randomized triangles

Settings and conduct

The samples were randomly selected from Razi Hospital and personal offices and were studied using a blinded three-way method.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: The definitive diagnosis of ADHD according to DSM-IV-TR criteria age 5- 14 Years old consent to attend the study through the signing of informed consent Exclusion Criteria: Taking medications other than ADHD drugs-attention deficit History of Head trauma Concomitant major psychiatric disorders such as psychosis History of Epilepsy Serious medical illness Receive simultaneously Medical treatments or psychological treatments History of diagnosed mental retardation Unwillingness of the patient or parents to continue to attend the plan Incomplete parenting questionnaire Students with obvious organic diseases

Intervention groups

Methylphenidate consumer group Mentelenidity and neurofeedback consumer group

Main outcome variables

Change in score of Conners' Parent Questionnaire, Change in score of CPT-2, Change in score (Wave) of QEEG

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140825018927N6**

Registration date: **2018-07-22, 1397/04/31**

Registration timing: **retrospective**

Last update: **2018-07-22, 1397/04/31**

Update count: **0**

Registration date

2018-07-22, 1397/04/31

Registrant information

Name

Seyed Gholamreza Noorazar

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3382 6512

Email address

noorazars@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2016-04-03, 1395/01/15

Expected recruitment end date

2017-12-21, 1396/09/30

Actual recruitment start date

2016-12-21, 1395/10/01

Actual recruitment end date

2017-07-06, 1396/04/15

Trial completion date

empty

Scientific title

Effect of Neuro feedback on Executive Functions of Children with ADHD Who Treated with Methylphenidate in razi Hospital of Tabriz

Public title

Effect of Neuro feedback on ADHD

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 The ADHD according to DSM-IV-TR criteria age 5- 14 Years old consent to attend the study through the signing of informed consent
Exclusion criteria:
 history of head trauma the Co-morbidity of major psychiatric disorders such as psychosis history of seizures there is a serious medical condition get medical treatment or psychological

Age
From **5 years** old to **14 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size
 Target sample size: **40**
 Actual sample size reached: **40**

Randomization (investigator's opinion)
Not randomized

Randomization description
After selecting the patient, a simple randomization method was used to replace the methylphenidate group or methylphenidate with the neurofeedback.

Blinding (investigator's opinion)
Triple blinded

Blinding description
The researcher and evaluator and analyst of the data were not aware of which group (methylphenidate or methylphenidate with neurofeedback) the sample was. Of course each sample has an special code.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Tabriz University of Medical Sciences
Street address
 Tabriz-Tabriz University of Medical Sciences
City
 Tabriz

Province
 East Azarbaijan
Postal code
 5183974511
Approval date
 2016-02-18, 1394/11/29
Ethics committee reference number
 IR.TBZMED.REC.1394.1070

Health conditions studied

1

Description of health condition studied
 Attention deficit hyperactivity disorder (ADHD)
ICD-10 code
 F90.0
ICD-10 code description
 Attention-deficit hyperactivity disorder, predominantly inattentive type

Primary outcomes

1

Description
 Hyperactivity, Inattention/ Cognition
Timepoint
 Before the intervention, three months after the intervention.
Method of measurement
 Connor's parents questionnaire, CPT2 Test, QEEG Test

Secondary outcomes

1

Description
 Change in score of Conners' Parent Questionnaire
Timepoint
 Before the intervention, three months after
Method of measurement
 Conners' Parent Questionnaire

2

Description
 Change in score of CPT-2
Timepoint
 Before the intervention, three months after
Method of measurement
 Continuous Performance Test (CPT-2)

3

Description
 Change in score (Wave) of QEEG
Timepoint
 Before the intervention, three months after
Method of measurement
 Quantitative Electroencephalography (QEEG)

Intervention groups

1

Description

intervention group: Patients will receive 0.5 to 1 mg/kg/day methylphenidate tablet daily with Neuro feedback (third session in week) for 3 month.

Category

Treatment - Devices

2

Description

Intervention group2: Patients will receive 0.5 to 1 mg/kg/day methylphenidate tablet daily.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of Psychiatry at the University of Medical Sciences

Full name of responsible person

seyed Golamreza Noorazar

Street address

Razi Hospital, elgoli road

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr Hasan Soleimanpour

Street address

Tabriz University of Medical Sciences, Golgasht Street, Azadi Street

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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

Private

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

Dr. Noorazar

Position

Associate Professor / Professor of Child and Adolescent Psychiatry

Latest degree

Subspecialist

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Roghayeh Nasiri

Position

Resident of Psychiatry

Latest degree

Medical doctor

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Tabriz University of Medical Sciences

Full name of responsible person

Roghayeh Nasiri

Position

Resident of Psychiatry

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

Street address

Razi Hospital-Tabriz

City**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

Not applicable