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)

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+98 41 3382 6512

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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
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Tabriz University of Medical Sciences, Golgasht Street, Azadi Street
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noorazars@tbzmed.ac.ir
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
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Psychiatrics
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Tabriz University of Medical Sciences
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Resident of Psychiatry
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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
Not applicable