Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the Effectiveness of Pharmacotherapy and Neurofeedback on Improving Executive Functions and Externalizing Behavior Disorders in children with attention deficit-hyperactivity disorder

Protocol summary

Study aim
The aim of this study is to Comparison of the Effectiveness of Pharmacotherapy and Neurofeedback on Improving Executive Functions and Externalizing Behavior Disorders in children with attention deficit-hyperactivity disorder

Design
Clinical trial with control group, were conducted with double-blind, randomized parallel groups on 36 patients and sealed envelope was used for randomization.

Settings and conduct
Experimental half method in which random clinical trial project with active control group (Pre-test Post-test) will have been used. The place of experiment will be the psychological clinic.

Participants/Inclusion and exclusion criteria
Inclusion/Exclusion criteria are receiving informed consent, gender (boy), age range (8 to 12 years), Average IQ (90 to 109), definitive diagnosis of attention deficit hyperactivity disorder, obtaining the necessary cut score in the scales for all three groups

Intervention groups
The two experimental groups included a drug therapy group that will receive methylphenidate twice daily in the morning and evening for 10 weeks (starting at 5 mg and increasing to 10 mg within one week by the end of the intervention period) and the neurofeedback intervention group, in which subjects will receive neurofeedback 3 times a week (for 10 weeks) in 30 sessions of 45 minutes. The control group will be on the waiting list and will not receive any treatment.

Main outcome variables
Executive Function and Externalizing Behavior Disorders

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20161122031016N2**
Registration date: **2022-08-30, 1401/06/08**
Registration timing: **retrospective**

Last update: **2022-08-30, 1401/06/08**
Update count: **0**

Registration date
2022-08-30, 1401/06/08

Registrant information

Name
Bahman akbari

Name of organization / entity
Islamic Azad University of Rasht Branch

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-02-09, 1400/11/20

Expected recruitment end date
2022-03-16, 1400/12/25

Actual recruitment start date
2022-04-06, 1401/01/17

Actual recruitment end date
2022-05-23, 1401/03/02

Trial completion date
2022-05-23, 1401/03/02

Scientific title

Comparison of the Effectiveness of Pharmacotherapy and Neurofeedback on Improving Executive Functions and Externalizing Behavior Disorders in children with attention deficit-hyperactivity disorder

Public title
Psychological interventions and Pharmacotherapy on improving the condition of children with attention deficit-hyperactivity disorder

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Receiving written consent from parents and informed consent of the child gender (boy) age range (8 to 12 years) Average IQ (90 to 109) based on the Wechsler IQ test that is recorded in the child's file and clinical observations recorded by experts definitive diagnosis of Attention Deficit Hyperactivity Disorder based on the criteria of the fifth edition of the Diagnostic and Statistical Manual of Mental Disorders by a pediatric psychiatrist and child and adolescent clinical psychologist obtaining the necessary cut score in the Behavior Rating Inventory of Executive Function (BRIEF), Gerard et al. (2000), and Achenbach's Child Behavior Checklist (CBCL), Achenbach (2001) for all three groups (two experimental groups and one control group)

Exclusion criteria:
Suffering from neurological-developmental or other psychological disorders at the same time receiving other medical and psychological interventions at the same time

Age
From **8 years** old to **12 years** old

Gender
Male

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **45**
Actual sample size reached: **36**

Randomization (investigator's opinion)
Randomized

Randomization description
The limited block randomization method was used for randomization. In order to determine the 2 experimental and 1 control groups, 15 balls with code A for the experimental group 1, 15 balls with code B for the experimental group 2, and 15 balls with code C for the control group were considered. They will then be placed inside the lottery container and, without replacement, the balls will be randomly removed from the container and the sequence created will be recorded. Next, based on the research sample size, a number of aluminum envelopes are prepared and each random sequence is recorded on a card and the cards are placed in the envelopes in order.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Islamic Azad University of Rasht

Street address
Darvazeh Lakan Street, Gas Square

City
Rasht

Province
Guilan

Postal code
۴۱۴۷۶۵۴۹۱۹

Approval date
2022-01-26, 1400/11/06

Ethics committee reference number
IR. IAU. RASHT. REC. 1400. 036

Health conditions studied

1

Description of health condition studied
Attention deficit_ hyperactivity disorder

ICD-10 code
F90.2

ICD-10 code description
Attention-deficit hyperactivity disorder, combined type

Primary outcomes

1

Description
Executive Functions

Timepoint
Before the start of the intervention, after the end of the intervention, Two month after the end of the intervention

Method of measurement
Behavior Rating Inventory of Executive Function (BRIEF)

2

Description
Externalizing Behavior Disorders

Timepoint
Before the start of the intervention, after the end of the intervention, Two month after the end of the intervention

Method of measurement
Achenbach's Child Behavior Checklist (CBCL)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Methylphenidate was started twice daily in the morning and evening for 5 weeks at a dose of 5 mg and increased to 10 mg twice daily for one week until the end of the intervention period.
Category
Treatment - Drugs

2

Description
Intervention group: Neurofeedback, 30 sessions for 10 weeks (three times a week, each session 45 minutes)
Category
Treatment - Devices

3

Description
Control group: Without intervention
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Khazaeli Special School
Full name of responsible person
Parvaneh Seyedi
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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Islamic Azad University, Rasht Branch
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
Name of organization / entity
Islamic Azad University, Rasht Branch
Full name of responsible person
Fatemeh Hedayati Shalkouhi
Position
PhD Candidate in Psychology
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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
There is no more information

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Not applicable

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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
There is no more information

When the data will become available and for how long
There is no more information

To whom data/document is available
There is no more information

Under which criteria data/document could be used
There is no more information

From where data/document is obtainable
There is no more information

What processes are involved for a request to access data/document
There is no more information

Comments