

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 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

Country

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		Placebo Not used
		Assignment Parallel
		Other design features
Public title Psychological interventions and Pharmacotherapy on improving the condition of children with attention deficit-hyperactivity disorder	Secondary Ids empty	
Purpose Treatment	Ethics committees	
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	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 ۴۱۳۶۵۴۹۱۹ Approval date 2022-01-26, 1400/11/06 Ethics committee reference number IR. IAU. RASHT. REC. 1400. 036	
Age From 8 years old to 12 years old	Health conditions studied	
Gender Male	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	
Phase 3	Primary outcomes	
Groups that have been masked No information	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)	
Sample size Target sample size: 45 Actual sample size reached: 36	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)	
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		

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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Fajr Town, Azadegan Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University, Rasht Branch

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?

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

Latest degree

Master

Other areas of specialty/work

Psychology

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Position

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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