

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of add Neurofeedback to Ritalin in the treatment of children and adolescents with attention deficit-hyperactivity disorder

Protocol summary

Study aim

Effect of add Neurofeedback to Ritalin in the treatment of children and adolescents with attention deficit-hyperactivity disorder

Design

Randomized clinical trial

Settings and conduct

Children Psychiatric Clinic of Ibn Sina Hospital in Mashhad. Children referred by pediatric psychiatrist about the interview and the detection rate and have been treated with Ritalin are studied. After obtaining the informed consent of their legal guardians, randomly using the envelope enclosed in two groups of case and Control Division. Before the start of the study, parental and teacher canners questionnaire in both groups will be completed. the case, added on the treatment with Ritalin, treated with 20 45-minute session of Neurofeedback (3 times a week) are supposed to be the control group treated with Ritalin. At the end of the study parents and teachers canners questionnaire again in both groups.

Participants/Inclusion and exclusion criteria

42 children with attention deficit and hyperactivity disorder, Their age ranges from 5 to 15 years old and they have been receiving Ritalin for ADHD treatment , and informed consent has been completed by legal guardians. Exit criteria include the patient's unwillingness to continue to participate in a research project for systemic and psychiatric illnesses.

Intervention groups

Intervention group: children and adolescents with ADHD treated with Ritalin, they get a 45-minute 20sessions (three sessions per week) Neurofeedback.treatment-drugs Control group:children and adolescents with ADHD treated with Ritalin

Main outcome variables

Effect of add Neurofeedback in the treatment of children and adolescents with ADHD.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180723040568N1**

Registration date: **2018-12-29, 1397/10/08**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-29, 1397/10/08**

Update count: **0**

Registration date

2018-12-29, 1397/10/08

Registrant information

Name

fatemeh zahedian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3700 2310

Email address

zahedianf941@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-01-20, 1397/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of add Neurofeedback to Ritalin in the treatment of children and adolescents with attention deficit-hyperactivity disorder		Postal code 9175845643
Public title Effect of add Neurofeedback to Ritalin in the treatment of children and adolescents with attention deficit-hyperactivity disorder		Approval date 2016-05-07, 1395/02/18
Purpose Treatment		Ethics committee reference number IR.MUMS.REC.1395.81
Inclusion/Exclusion criteria Inclusion criteria: Diagnosis of ADHD based on DSM-5 criteria aged 7-12 years Complete consent form by parent or guardian Normal IQ Exclusion criteria: En The patient's unwillingness to participating in the research project Systemic disease Interventional psychiatric illness intellectual disability		Health conditions studied
Age From 6 years old to 15 years old		1 Description of health condition studied Attention- Deficit Hyperactivity Disorders ICD-10 code F90 ICD-10 code description Attention-deficit hyperactivity disorders
Gender Both		Primary outcomes
Phase 3		1 Description The symptoms of attention deficit hyperactivity disorder/attention deficit and impulsivity in children and adolescents with ADHD . Timepoint The beginning and end of the study Method of measurement parents and teacher Canners questionnaire
Groups that have been masked <i>No information</i>		Secondary outcomes empty
Sample size Target sample size: 42		Intervention groups
Randomization (investigator's opinion) Randomized		1 Description Intervention group: Twenty 45 minute sessions, three times a week gets added to the treatment with Ritalin . Category Treatment - Devices
Randomization description Patients are selected through available sampling. They are randomly divided into two groups of case and control according to the random numbers table.		2 Description Control group: Children and adolescents with ADHD treated with Ritalin Category Treatment - Drugs
Blinding (investigator's opinion) Not blinded		Recruitment centers
Blinding description Placebo Not used		1 Recruitment center Name of recruitment center Ebne-sina Hospital Full name of responsible person Fatemeh Moharary
Assignment Parallel		
Other design features		
Secondary Ids empty		
Ethics committees		
1 Ethics committee Name of ethics committee Ethics committee of Mashhad University of Medical sciences Street address Ghoreishi Department, Daneshgah Ave, Mashhad City Mashhad Province Razavi Khorasan		

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Moharerif1@mums.ac.ir

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

mohsen tafaghodi

Street address

Ferdowsi University of Mashhad Azadi square..
pharmaceutics and Mashhad Faculty of
pharmaceutical nanotechnology researches group

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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

Mashhad University of Medical Sciences

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**

Mashhad University of Medical Sciences

Full name of responsible person

Fatemeh Mohareri

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Psychiatrics

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Person responsible for updating data

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Resident

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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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

The total individual participants' data and the results of the study after the deidentification of the individuals are shared.

When the data will become available and for how long

starting in April 2019

To whom data/document is available

All researchers are able to access the study results

Under which criteria data/document could be used

Unidentifiable information is not shared with another organization

From where data/document is obtainable

Unidentifiable information is not available to applicants

What processes are involved for a request to access data/document

Study data is published in the course of the paper and no other personal data is available to applicants

Comments