

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

Public title

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

Purpose

Treatment

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

Age

From **6 years** old to **15 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

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.

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 Mashhad University of Medical sciences

Street address

Ghoreishi Department, Daneshgah Ave, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9175845643

Approval date

2016-05-07, 1395/02/18

Ethics committee reference number

IR.MUMS.REC.1395.81

Health conditions studied

1

Description of health condition studied

Attention- Deficit Hyperactivity Disorders

ICD-10 code

F90

ICD-10 code description

Attention-deficit hyperactivity disorders

Primary outcomes

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

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Twenty 45 minute sessions, three times a week gets added to the treatment with Ritalin .

Category

Treatment - Devices

2

Description

Control group: Children and adolescents with ADHD treated with Ritalin

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ebne-sina Hospital

Full name of responsible person

Fatemeh Moharary

Street address

Ebne-sina Hospital, Hoorre Ameli Street, Mashhad,
Iran

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9195983134

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Email

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

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Ferdowsi University of Mashhad Azadi square..
pharmaceutics and Mashhad Faculty of
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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 scientific inquiries

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Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact**Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Fatemeh Zahedian

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

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Fax**Email**

zahedianf941@mums.ac.ir

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