

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparing the efficacy of methods of Neurofeedback, Neurofeedback and Barkly's Parent Training, Neurofeedback and Computerized Cognitive Rehabilitation on children with Attention -Deficit/Hyperactivity Disorder

Protocol summary

Study aim

Comparing the efficacy of Neurofeedback, Neurofeedback and Barkly's Parent Training, Neurofeedback and Computerized Cognitive Rehabilitation on children with ADHD

Design

Quasi-experimental study with pretest- post test and follow up by control group In this study 56 ADHD children referring to education concealing center with entrance criteria will be chosen purposefully and randomly divided to 3 experimental groups and 1 control group

Settings and conduct

In this single-blind clinical trial with pretest- posttest, after random sampling and arranging groups , pre-test will be performed for all groups . Then Neurofeedback group will have 30 sessions training 3 times a week each secession 30 minutes. second group, beside Neurofeedback, will have 9 session parental training for 60 minutes once a week. The third group beside Neurofeedback , there will be 15 sessions Computerized Cognitive Rehabilitation training for 30 minutes 3 times a week. Control group will have sham sessions for 30 minutes 3 times a week. Experiment place:Isfahan educational counseling center

Participants/Inclusion and exclusion criteria

Elementary ADHD boys in Isfahan Including criteria: psychiatrist diagnosis of ADHD Being in Elementary school Having IQ more than 85 score according to Wechsler IQ test No using drugs affecting the CNS completing informed consent form Being boy Age group 6-13 years old Excluding criteria: Having other psychiatric and cognitive disorders Having Epileptic seizure in last two years

Intervention groups

Only Neurofeedback training Neurofeedback and Barkly's Parent training Neurofeedback and Computerized Cognitive Rehabilitation training control group

Main outcome variables

Attention deficit hyperactivity

General information

Reason for update

Acronym

ADHD

IRCT registration information

IRCT registration number: **IRCT20180106038230N1**

Registration date: **2018-06-30, 1397/04/09**

Registration timing: **retrospective**

Last update: **2018-06-30, 1397/04/09**

Update count: **0**

Registration date

2018-06-30, 1397/04/09

Registrant information

Name

Elahe Hajeforush

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3630 3512

Email address

e.hajeforush@khuisf.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-22, 1397/03/01

Expected recruitment end date

2018-06-20, 1397/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the efficacy of methods of Neurofeedback, Neurofeedback and Barkly's Parent Training, Neurofeedback and Computerized Cognitive Rehabilitation on children with Attention - Deficit/Hyperactivity Disorder

Public title

Comparing the efficacy of Neurofeedback and combined treatments in ADHD

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

psychiatrist diagnosis of ADHD Being an Elementary school student Having IQ more than 85score according to Wechsler IQ test No using drugs affecting the CNS completing informed consent form Being male Age group 6 to 13 years

Exclusion criteria:

Having other psychiatric and cognitive- neurological disorders having Epileptic seizure in the last two years

Age

From **6 years** old to **13 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **56**

Actual sample size reached: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

According to entrance criteria fifty six individuals will be selected from available sample community then assigned randomly based on equal chance and in sequential drawing to 4 experiment groups including group 1,2,3 and the control group. Each group will be included 14 members. Nobody knows anything about the participants' list and numbers except the researcher.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study control group participants will have sham, however they will be unaware, their parents are aware. Also the statistical analyzer has no data about the research process.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Islamic Azad university Isfahan(Khorasgan) branch

Street address

Daneshgah Blvd, Arghavanyeh, East Jey Ave, Azad Islamic Univercity Isfahan(Khorasgan) branch

City

Isfahan

Province

Isfahan

Postal code

۸۱۵۵۱۳۹۹۹۸

Approval date

2018-04-16, 1397/01/27

Ethics committee reference number

IR.IAU.KHU.IF.1397-27

Health conditions studied**1****Description of health condition studied**

Attention Deficit Hyperactivity Disorder

ICD-10 code

F90

ICD-10 code description

Attention-deficit hyperactivity disorders

Primary outcomes**1****Description**

Symptoms of ADHD measured by IVA+ PLUS test

Timepoint

Pretest,two and a half month post test & two and a half month follow up

Method of measurement

Integrative Visual and Auditory performance test

Secondary outcomes

empty

Intervention groups**1****Description**

First intervention group: Only Neurofeedback training, the intervention will be performed during 30 training

sessions 3 days per week and each session will be lasted 30 minutes using a set of Procomp 2 and BioGraph INFINITI software made by Canada (having treatment protocol based on BioGraph INFINITI baseline).

Category

Rehabilitation

2

Description

Second intervention group: Neurofeedback and Barkly Parental training. The intervention will be performed during 30 training sessions 3 days per week and each session will be lasted 30 minutes using the set of Procomp 2 and BioGraph INFINITI software made by Canada (having treatment protocol based on BioGraph INFINITI baseline), beside 9 session Barckly parental training for 60 minutes once in a week.

Category

Rehabilitation

3

Description

The third intervention group: Neurofeedback and Computerized Cognitive Rehabilitation training, This group will have 30 sessions training, 3 days per week and each session will be lasted 30 minutes using the set of Procomp 2 and BioGraph INFINITI software made by Canada (having treatment protocol based on BioGraph INFINITI baseline), beside, 15 session Computerized Cognitive Rehabilitation training for 30 minutes 3 times a week by Cogiplus software made by SCHUHFRIED company in Austria.

Category

Rehabilitation

4

Description

Control group: The intervention will be performed during 30 sham training sessions, 3 days per week and each session will be lasted 30 minutes using the set of Procomp 2 and BioGraph INFINITI software made by Canada.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Concelling Center of Isfahan Educational Administration Region 2

Full name of responsible person

Zahra Kashefi

Street address

Concelling Center of Isfahan Educational Administration Region 2 , Nasr Ave, Bozorgmehr street

City

Isfahan

Province

Isfahan

Postal code

۸۱۵۳۹۷۶۹۹

Phone

+98 31 3267 4328

Email

zahra_ka52@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Majid Toghiani

Street address

Daneshgah Blvd, Arghavanyeh, East Jey Street, Islamic Azad university Isfahan (Khorasgan) branch

City

Isfahan

Province

Isfahan

Postal code

۸۱۵۵۱۳۹۹۹۸

Phone

+98 31 3500 2551

Email

toghiani@hotmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Islamic Azad University

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

Esfahan University of Medical Sciences

Full name of responsible person

Elahe Hajeforoush

Position

PHD student

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

No.4 Aseman Flat, Harandizade Dead end, Majlesi
Allay, 2Apadana Ave,

City

Isfahan

Province

Isfahan

Postal code

8166763631

Phone

+98 31 3630 3512

Fax

Email

E.Hajeforush@khuisf.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Elahe Hajeforush

Position

PHD student

Latest degree

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Other areas of specialty/work

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Email

E.Hajeforush@khuisf.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Elahe Hajeforush

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PHD student

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+98 31 3630 3512

Fax

Email

E.Hajeforush@khuisf.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

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