Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the efficacy of methods of Neurofeedback, Neurofeedback and Barkly's Parent Training, Neurofeedback and Computerized Coginetive 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 cognetive 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 Hajeforoush

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3630 3512

Email address
e.hajeforoush@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 Coginetive 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
Isfehan
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 Isfehan Educational Administration Region 2

Full name of responsible person

Zahra Kashefi

Street address

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

City

Isfehan

Province

Isfehan

Postal code

۸۱۵۴۹۷۷۹۹

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 Isfehan (Khorasgan) branch

City

Isfahan

Province

Isfehan

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
Isfehan

Postal code
8166763631

Phone
+98 31 3630 3512

Fax

Email
E.Hajeforoush@khuisf.ac.ir

Person responsible for scientific 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
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+98 31 3630 3512

Fax

Email
E.Hajeforoush@khuisf.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Elahe Hajeforoush

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PHD student

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Fax

Email
E.Hajeforoush@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