

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Jun 2026

### Comparison of neurofeedback training and perceptual-motor therapy on sustained attention in children with Attention deficit hyperactivity disorder 5-12 years

#### Protocol summary

##### Study aim

This study aimed to evaluate and compare the effectiveness of neurofeedback training and perception-motion exercises on sustained attention of children with ADHD 12-5 years old. .

##### Design

Two arm parallel group randomised trial with blinded postoperative care and outcome assessment

##### Settings and conduct

The study population was selected from hyperactive children with attention deficit who referred to Tehran pediatric's hospitals and in simple random method divided into two groups. Interventions are being conducted at the Tavanesh Rehabilitation Center.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: the diagnosis of hyperactivity / inattention confirmed by a child psychiatrist according to DSM-IV; age 5 to 12 years ; IQ above 70, based on Wechsler's intelligence test ;problems in motor coordination in hyperactivity / inattention ;no other neurological , psychiatric and Orthopedic disorders based on medical records ;normal or corrected vision and hearing based on medical records. Exclusion criteria: quit more than 2 sessions; Changes in drugs regime; infectious disease during the intervention; did not cooperate during the meetings.

##### Intervention groups

40 ADHD children in two equal groups of 20/20 in neurofeedback training and perceptual motor treatment groups. In intervention group 1 they receive neurofeedback training in unipolar method at Cz . Group 2 receives perceptual -motor exercises using JackKapen protocols. In this group coordination problem assessed by Bruininks Oseretsky test, in order to determine the developmental age 1 year younger than chronological age.

##### Main outcome variables

Commission ; Omission ; Reaction time

#### General information

##### Reason for update

##### Acronym

ADHD

##### IRCT registration information

IRCT registration number: **IRCT2015061910806N2**

Registration date: **2015-07-14, 1394/04/23**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-11-04, 1397/08/13**

Update count: **2**

##### Registration date

2015-07-14, 1394/04/23

##### Registrant information

##### Name

Malahat Akbarfahimi

##### Name of organization / entity

Iran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2222 7124

##### Email address

akbarfahimi.m@iums.ac.ir

##### Recruitment status

##### Recruitment complete

##### Funding source

Deputy of Research, Iran University of Medical Sciences

##### Expected recruitment start date

2015-07-06, 1394/04/15

##### Expected recruitment end date

2015-09-23, 1394/07/01

##### Actual recruitment start date

empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
Comparison of neurofeedback training and perceptual-motor therapy on sustained attention in children with Attention deficit hyperactivity disorder 5-12 years

**Public title**  
Comparison of neurofeedback training and perceptual motor exercises

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
the diagnosis of hyperactivity / inattention confirmed by a child psychiatrist according to DSM-IV age 5 to 12 years IQ above 70 based on Wechsler's intelligence test problems in motor coordination in hyperactivity / inattention no other neurological , psychiatric and Orthopedic disorders based on medical records no audio or visual disorders based on medical records

**Exclusion criteria:**  
Quit more than 2 sessions Changes in drugs regime Infectious disease during the intervention Did not cooperate during the meetings

**Age**  
From **5 years** old to **12 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**  
Target sample size: **40**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Participants will select by convenience sampling. Randomizing participants in neurofeedback and perceptual -motor groups will done with randomization digits table by a blind person to the study

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
The outcome assessor is unaware that participants were in which groups of control or intervention. The data will enter in SPSS and statistically analysis by a blind statistician

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Iran university of Medical Sciences

##### Street address

Hemmat Highway, between Chamran and Sheikh Fadlallah, Iran University of Medical Sciences

##### City

Tehran

##### Province

Tehran

##### Postal code

۱۴۳۹۶۱۴۵۳۵

#### Approval date

2014-09-24, 1393/07/02

#### Ethics committee reference number

3058/105/93/۵

## Health conditions studied

### 1

#### Description of health condition studied

Hyperactivity/inattention

#### ICD-10 code

F90.0

#### ICD-10 code description

Disturbance of activity and attention

## Primary outcomes

### 1

#### Description

Commision

#### Timepoint

The day before the first intervention session- The day after the last intervention session

#### Method of measurement

Computerized Continuos performance test

### 2

#### Description

Ommision

#### Timepoint

The day before the first intervention session- The day after the last intervention session

#### Method of measurement

Computerized Continuos performance test

### 3

#### Description

Reaction time

### Timepoint

The day before the first intervention session- The day after the last intervention session

### Method of measurement

Computerized Continuous performance test

## Secondary outcomes

### 1

#### Description

Perceptual-motor skills

#### Timepoint

The day before the first intervention session- The day after the last intervention session

#### Method of measurement

Bruininks-Oseretsky Test of Motor Proficiency

## Intervention groups

### 1

#### Description

Intervention group: Treatment occurs in 20 therapy sessions during 3 days in week for 7 weeks. The protocol of Neurofeedback treatment consists of unipolar montage in Cz in the central region .

#### Category

Rehabilitation

### 2

#### Description

Intervention group2: Treatment occurs in 20 therapy sessions, 45 minutes ,during 3 days in week for 7 weeks . Perceptual motor exercises demonstrate and including the timing, sequence, rhythm and movement which are planned by Jack Kypvn protocol.

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Tehran pediatric's hospitals

##### Full name of responsible person

Neda Ghadamghahi

##### Street address

Azadi street, south Jamalzadeh ,78. unit 4 &5

##### City

Tehran

##### Province

Tehran

##### Postal code

1313815867

##### Phone

+98 21 2222 7124

##### Email

n\_sani87@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Dr Seyed Ali Javad Moosavi

##### Street address

Hemmat Highway, between Chamran and Sheikh Fadlallah, Iran University of Medical Sciences

##### City

Tehran

##### Province

Tehran

##### Postal code

14665-354

##### Phone

+98 21 86709

##### Email

akbarfahimi.m@iums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Iran 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

Iran University of Medical Sciences

#### Full name of responsible person

Dr. Malahat Akbarfahimi

#### Position

Assistant Professor, Master of occupational therapy- PhD of cognitive neurosciences

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Occupational Therapy

#### Street address

rehabilitation faculty, Nezam Aly-shah nazari street, Madar square, Mirdamad blvd

#### City

Tehran

#### Province

Tehran

**Postal code**  
158754391  
**Phone**  
+98 21 2222 7124  
**Fax**  
**Email**  
akbarfahimi.m@iums.ac.ir  
**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Iran University of Medical Sciences  
**Full name of responsible person**  
Dr Malahat Akbarfahimi  
**Position**  
Assistant Professor/Phd of cognitive neuroscience-MS  
occupational therapy  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
occupational therapy  
**Street address**  
Rehabilitation faculty, Nezam Aly-shah nazari street,  
madar square, Mirdamad blvd  
**City**  
Tehran  
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158754391  
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+98 21 2222 7124  
**Fax**  
**Email**  
akbarfahimi.m@iums.ac.ir  
**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Iran University of Medical Sciences  
**Full name of responsible person**

Dr. Malahat Akbarfahimi

**Position**  
Assistant Professor/Phd of cognitive neuroscience-MS  
occupational therapy  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Cognitive Neuroscience  
**Street address**  
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**Web page address**

## 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

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