

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Evaluation of a Cognitive Game with Neurofeedback on Cognitive and Behavioral functions in Children with Attention Deficit Hyperactivity Disorder

Protocol summary

Study aim

Study of the treatment process of children with attention deficit hyperactivity disorder. Dynamic difficulty Adjustment of the game based on the performance and Attention of the participant. Neurofeedback-based game performance evaluation in treatment compared to normal neurofeedback.

Design

Clinical trials with a controlled group, randomized, single blinded

Settings and conduct

After finding children with attention deficit hyperactivity disorder and obtaining consent from their parents, they enter the intervention. These children receive intervention 10 Session, 3 times a week for 40 minutes. Before the intervention and after the intervention, they receive baseline signal. These intervention sessions take place at the Isfahan University Computer Games Center. Data collection tools included: questionnaire, cognitive test and Electroencephalogram recorder.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Children with Attention Deficit Hyperactivity Disorder Exclusion criteria: Children with autism spectrum disorder - Children with epilepsy

Intervention groups

children with attention deficit hyperactivity disorder

Main outcome variables

The amount of theta to beta This is a parameter extracted from the brain signal that is related to focus or attention. The value of theta to beta is actually the ratio of the amplitude of theta frequency band to the amplitude of the beta frequency band.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200306046705N1**

Registration date: **2020-05-01, 1399/02/12**

Registration timing: **retrospective**

Last update: **2020-05-01, 1399/02/12**

Update count: **0**

Registration date

2020-05-01, 1399/02/12

Registrant information

Name

Mina Masoudi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

massoudi.mina@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-22, 1398/02/02

Expected recruitment end date

2019-05-20, 1398/02/30

Actual recruitment start date

2019-04-06, 1398/01/17

Actual recruitment end date

2019-06-22, 1398/04/01

Trial completion date

2019-10-23, 1398/08/01

Scientific title

Evaluation of a Cognitive Game with Neurofeedback on Cognitive and Behavioral functions in Children with

Attention Deficit Hyperactivity Disorder

Public title

Evaluation of a Game based on Neurofeedback in Children with Attention Deficit Hyperactivity Disorder

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Children with Attention Deficit Hyperactivity Disorder

Exclusion criteria:

Children with autism spectrum disorder Children with epilepsy

Age

From 7 years old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: 30

Actual sample size reached: 4

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Children are unaware that they are playing with dynamic difficulty or playing with static difficulty.

Placebo

Not used

Assignment

Single

Other design features

Dynamic difficulty Adjustment of the Game based on the Performance and Attention of the participant

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University

Street address

Unit 5-217, Noor residential, Yas 7 Alley, Kharazmi 2 Avenue, Ghadir Blvd, Sepahanshahr

City

Isfahan

Province

Isfahan

Postal code

8179935897

Approval date

2017-11-15, 1396/08/24

Ethics committee reference number

IR.UI.REC.1399.002

Health conditions studied

1

Description of health condition studied

Attention Deficit Hyperactivity Disorder

ICD-10 code

F98

ICD-10 code description

Other behavioral and emotional disorders with onset usually occurring in childhood and adolescence

Primary outcomes

1

Description

Attention score

Timepoint

Before the intervention and after the intervention

Method of measurement

Integrated Visual and Auditory continuous performance test (IVA-test)

Secondary outcomes

1

Description

Behavioral functions Score

Timepoint

Before the intervention and after the intervention

Method of measurement

SNAP-IV questionnaire

Intervention groups

1

Description

Intervention group 1: In this group, the difficulty of the game changes dynamically throughout the game.

Category

N/A

2

Description

Intervention group 2: In this group, the difficulty of the game during the game is static.

Category

N/A

3

Description

Control group: They do not receive any intervention.

Category

N/A

Recruitment centers1**Recruitment center****Name of recruitment center**

Learning Disorders Center (Area Counseling Center 3)

Full name of responsible person

Maryam Motamedi

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Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Cognitive Sciences & Technologies Council

Full name of responsible person

Deputy of Research and Technology

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No. 35, Alvand Ave, Arzhantin square, Tehran

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Web page address**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Cognitive Sciences & Technologies Council

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**

The University of Esfahan

Full name of responsible person

Mina Masoudi

Position

Master's Degree

Latest degree

Master

Other areas of specialty/work

Medical Engineering

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Shareable

When the data will become available and for how long

After printing

To whom data/document is available

researchers

Under which criteria data/document could be used

No conditions

From where data/document is obtainable

Mina Masoudi Phone Number:00989130895420

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

Call

Comments