Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)

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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
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Province
Isfehan
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 centers

1

Recruitment center
Name of recruitment center
Learning Disorders Center (Area Counseling Center 3)
Full name of responsible person
Maryam Motamedi
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next to Salman Pool, Alam Mosque Alley, next to Salman Pool
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Cognitive Sciences & Technologies Council
Full name of responsible person
Deputy of Research and Technology
Street address
No. 35, Alvand Ave, Arzhantin square, Tehran
City
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88194954
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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
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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