Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of physical activity with and without cognitive demand on the improvement of executive function and behavioral symptoms in children with ADHD

Protocol summary

Study aim

Investiging the effect of moving activities demanding cognitive exercises and without cognitive exercises on the improvement of behavioral symptoms and executive functions in children with attention deficit disorder and hyperactivity.

Design

Clinical trial with active control group, will be conducted with double-blind randomized parallel groups on 30 patients and sealed envelope will be used for randomization.

Settings and conduct

-Experimental half in which random clinical trial project with active control group (Pre-test Post-test) will have been used. The place of experiment will be the psychological clinic.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Being diagnosed with attention deficit hyperactivity disorder by a psychiatrist Being 7 to 12 years old Having informed consent to participate in research Exclusion criteria: Having comorbid disorders such as learning disabilities, conduct disorders, etc. Having borderline IQ.

Intervention groups

In the intervention group, the motor activities performed require cognitive exercises that can be effective in improving the behavioral symptoms and executive functions of children with attention deficit hyperactivity disorder. In the control group, only aerobic exercise activities without cognitive exercises are presented.

Main outcome variables

pCognitive rehabilitation based on movement, executive functions, behavioral symptoms, attention deficit disorder and hyperactivity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200706048032N1**
Registration date: **2020-10-22, 1399/08/01**
Registration timing: **prospective**

Last update: **2020-10-22, 1399/08/01**
Update count: **0**

Registration date

2020-10-22, 1399/08/01

Registrant information

Name
Vahid Nejati
Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-31, 1399/08/10

Expected recruitment end date

2020-11-20, 1399/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of physical activity with and without cognitive demand on the improvement of executive function and behavioral symptoms in children with ADHD

Public title
Physical activity in children with attention deficit hyperactivity disorder

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Diagnosis of attention deficit hyperactivity disorder by a psychiatrist Placement between the ages of 7 and 12. Having informed consent to participate in research

Exclusion criteria:
Having other comorbid disorders such as learning disability, conduct disorder, etc. Having borderline IQ.

Age
From **7 years** old to **12 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
The limited block randomization method will be used for randomization, so that in order to determine the experimental and control groups, 15 balls with code A will be considered for the experimental group and 15 balls with code B for the control group. They will then be placed inside the lottery container and, without replacement, the balls will be randomly removed from the container and the sequence created will be recorded. Next, based on the research sample size, a number of aluminum envelopes are prepared and each random sequence is recorded on a card. The cards are placed in the envelopes in order. To maintain the random sequence, the envelopes are numbered in the same way on their outer surface. Finally, the flaps of envelopes will be glued and then they are placed in a box in order. At the beginning of the participants' registration, according to the entry order of participants qualified for including in the study, one of the envelopes will be opened in order and the assigned group of that participant will be revealed

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, participants after obtaining informed consent and being randomly placed in the experimental and control groups, will not receive any information about how the other group is intervened, as well as how they themselves are positioned as the experimental group or the control group; and also the evaluators of individual results will be selected from outside the study team. In this case, the researcher's own knowledge of the type of intervention assigned to the study participants can not affect the data analysis.

Placebo
Used

Assignment
Parallel

Other design features
In the intervention, motor activities are performed with cognitive exercises.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Islamic Azad University of Medical Sciences

Street address
Islamic Azad University of Medical Sciences, Tehran Branch,KHaghani St,Shariyati St,Tehran,Iran

City
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Province
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Postal code
1916893813

Approval date
2019-06-25, 1398/04/04

Ethics committee reference number
IR.IAU.TMU.REC.1398.046

Health conditions studied

1

Description of health condition studied
Attention Deficit Hyperactivity Disorder

ICD-10 code
F90.2

ICD-10 code description
Attention-deficit hyperactivity disorder, combined type

Primary outcomes

1

Description
Behavioral symptoms

Timepoint
At the beginning of the study (before the intervention) and 45, 75 days after the intervention

Method of measurement
Conners Behavioral Symptoms Scale for Parents and

Teachers

2

Description
Working memory
Timepoint
At the beginning of the study (before the intervention) and 45, 75 days after the intervention
Method of measurement
Neurological test (N-back)

3

Description
Inhibit response
Timepoint
At the beginning of the study (before the intervention) and 45, 75 days after the intervention
Method of measurement
Neurological test (go-no go)

4

Description
Cognitive flexibility
Timepoint
At the beginning of the study (before the intervention) and 45, 75 days after the intervention
Method of measurement
Neurological test (Wisconsin)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:: In this group, the intervention is presented in the form of purposeful motor activities that require cognitive tasks. The tools required for the intervention is the cognitive rehabilitation software based on Excir (Nejati) movement, which tries to rehabilitate and strengthen cognitive functions by purposefully increasing the cognitive needs of the movement. For this purpose, considering the principles governing cognitive rehabilitation and movement, motor tasks have been designed that progressively involve various cognitive functions. In this program, in addition to cognitive rehabilitation software, several color banners are used on which different numbers and directions and different colors are designed, and the participants move on the banners according to the cognitive tasks provided in the software. Participants will do these tasks twice a week for one hour.
Category
Rehabilitation

2

Description
Control group:: In this group, aerobic activities such as running, which do not require cognitive tasks, are presented. Participants will perform these movements twice a week for one hour in a safe environment.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Psychology Clinic of Shahid Beheshti University
Full name of responsible person
Vahid Nejati
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Unit5,Floor1, Velenjak St, Daneshjoo Blvd ,Shahid Beheshti Universiti, Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University
Full name of responsible person
Dr. Babak Shokri
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Unit50,Floor4,Velenjak St, Daneshjoo Blvd, University Shahid Beheshti , Tehran, Iran
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor

organization/entity?
Yes
Title of funding source
Shahid Beheshti University
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
Shahid Beheshti University
Full name of responsible person
Vahid Nejati
Position
Associate Professor
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no more information.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available