

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Effect of Cognitive Rehabilitation Training, Physical Training and Concurrent Training (Cognitive Rehabilitation Games and Physical Training) on Sustained, Selective and Shifting Attentions of Hyperactive Children

Protocol summary

Study aim

the effects of cognitive rehabilitation training, physical and physical and cognitive training on sustained attention, selective attention and shifting attention of children

Design

Clinical trial with control group, with parallel groups, Not blinded , Simple randomization on 40 patients

Settings and conduct

Nine to 12 years old primary school girls with attention deficit / hyperactivity disorder who were referred to Imam Hossein Counseling and Psychological Services Center in Yazd were selected. Then they were randomly divided into control and intervention groups. The attendees trained for 16 minutes and each session for 60 minutes. Posttest was performed 24 and 72 hours later.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Age between 9 to 12 years old; 2. Attention Deficit/Hyperactivity Disorder; 3. Willingness to participate in the study (consent from parents); 4. Not using stimulants to treat ADHD Exclusion criteria: 1. Absence of more than two sessions in the research process; 2. Changing treatment status and medication use

Intervention groups

There were three experimental groups and one control group. Cognitive rehabilitation training, physical training, concurrent training rehabilitation training (cognitive and physical training)

Main outcome variables

Sustained attention, Selective attention, shifting attention

General information

Reason for update

Acronym

ADHD

IRCT registration information

IRCT registration number: **IRCT20180618040143N1**

Registration date: **2020-11-03, 1399/08/13**

Registration timing: **retrospective**

Last update: **2020-11-03, 1399/08/13**

Update count: **0**

Registration date

2020-11-03, 1399/08/13

Registrant information

Name

Mandana Sangari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4496 5441

Email address

mandana.sangari@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-30, 1398/10/09

Expected recruitment end date

2020-01-10, 1398/10/20

Actual recruitment start date

2019-12-30, 1398/10/09

Actual recruitment end date

2020-01-15, 1398/10/25

Trial completion date

2020-03-05, 1398/12/15

Scientific title

Effect of Cognitive Rehabilitation Training, Physical Training and Concurrent Training (Cognitive Rehabilitation Games and Physical Training) on Sustained, Selective and Shifting Attentions of Hyperactive Children

Public title

Effect of Cognitive and Physical Rehabilitation Training on Hyperactive Children Attention

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 9 to 12 years old Attention Deficit/Hyperactivity Disorder Willingness to participate in the study (consent from parents) Not using stimulants to treat ADHD

Exclusion criteria:

Absence of more than two sessions in the research process Changing treatment status and medication use

Age

From **9 years** old to **12 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **55**

Actual sample size reached: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple random using a random numbers table

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Sport Sciences Research Institute of Iran

Street address

No. 3, 5th Alley, Miremad Street, Motahhari Street, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1587958711

Approval date

2019-07-14, 1398/04/23

Ethics committee reference number

IR.SSRC.REC.1399.086

Health conditions studied

1

Description of health condition studied

attention deficit hyperactivity

ICD-10 code

F90.9

ICD-10 code description

Attention-deficit hyperactivity disorder, unspecified type

Primary outcomes

1

Description

Sustained attention

Timepoint

One day before the start of the training intervention (pre-test) and after the last training session (post-test)

Method of measurement

The Integrated Visual and Auditory (IVA) Continuous Performance Test (CPT)

2

Description

Selective attention

Timepoint

One day before the start of the training intervention (pre-test) and after the last training session (post-test)

Method of measurement

Stroop test

3

Description

Shifting attention

Timepoint

One day before the start of the training intervention (pre-test) and after the last training session (post-test)

Method of measurement

Wisconsin Card Sorting Test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: In the pre-test, Integrated Visual

and Auditory Continuous Performance Test, Wisconsin Card Sorting Test and Stroop test will be taken. The cognitive rehabilitation program includes the implementation of working memory training software in 16 sessions of 60 minutes at the school and the sessions will be held intensively 3 sessions per week. Then the post-test will be similar to the pre-test.

Category

Rehabilitation

2

Description

Intervention group 2: In the pre-test, Integrated Visual and Auditory Continuous Performance Test, Wisconsin Card Sorting Test and Stroop test will be taken. The training protocol includes games such as chair play, game train, helmet game, jump in the ring, hand gesture movement in 16 sessions of 60 minutes at the school and the sessions will be held intensively 3 sessions per week. Then the post-test will be similar to the pre-test.

Category

Rehabilitation

3

Description

Intervention group 3: In the pre-test, Integrated Visual and Auditory Continuous Performance Test, Wisconsin Card Sorting Test and Stroop test will be taken. The Cognitive Rehabilitation and Physical Training program consists of a combination of two programs that are performed in one training session in such a way that 30 minutes of cognitive rehabilitation training protocol and 30 minutes of physical training protocol. 16 sessions of 60 minutes are taught at the school and the sessions will be held intensively 3 sessions per week. Then the post-test will be similar to the pre-test.

Category

Rehabilitation

4

Description

Control group: The control group was followed up and did not receive any intervention.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

schools in the city of Yazd

Full name of responsible person

Mandana Sangari

Street address

No. 14, , Behnam Alley 12, Behnam St., Ayatollah Kashani Blvd.,

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1471856151

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

mandana sangari

Street address

17 shahrivar Ave

City

Chalous

Province

Mazandaran

Postal code

4661961367

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+98 11 5224 8782

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Grant name

Grant code / Reference number

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

No

Title of funding source

Islamic Azad University, Chalous Branch

Proportion provided by this source

40

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

Islamic Azad University

Full name of responsible person

Mandana Sangari

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Sport Medicine

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Person responsible for updating data

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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