

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

The effect of exercise therapy on attention deficit hyperactivity disorder in elementary school students

Protocol summary

Summary

Objectives: Children with attention deficit hyperactivity disorder are the first victims of emotional, behavioral and educational neglect. Therefore, treating of these children is necessary. The purpose of this study is to examine the impact of exercise therapy on hyperactivity, impulsivity and distractibility of children with attention deficit hyperactivity disorder. Setting and conduct: Eighty elementary school-age children with attention deficit hyperactivity disorder will select by using of clinical interview based on the diagnostic and statistical manual of mental disorders, 4th edition (DSM-IV). The parents will complete Conner's scale. Then children after matching for age and sex, randomly will divide in control and experimental groups. Major Inclusion and Exclusion criteria: The children with psychiatric drug use and heart disease history excluded. Intervention: The experimental group will receive exercise therapy 10 sessions by Tatami therapy method. This method includes a series of physical and intellectual exercise. Balance and concentration is important in this method. After completion of therapy sessions, and a month later, parents of both groups will complete Connors scale (post-test and follow-up test). Data will be collected and analyze.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2015031721497N1**

Registration date: **2015-06-13, 1394/03/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-06-13, 1394/03/23

Registrant information

Name

Mohammadreza Mokhtaree

Name of organization / entity

Rafsanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Islamic Azad University, Anar branch

Expected recruitment start date

2015-04-04, 1394/01/15

Expected recruitment end date

2015-05-05, 1394/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of exercise therapy on attention deficit hyperactivity disorder in elementary school students

Public title

Exercise therapy and attention deficit hyperactivity disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: The diagnostic criteria for attention

deficit hyperactivity disorder according to statistical manual of mental disorders, 4th edition (DSM-IV); education in school Exclusion criteria: Use of psychiatric drugs; heart diseases

Age

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

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Eighty children after selection and matching for age and sex, randomly will divide into two equal groups. Randomization will be based on a table of random numbers.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Islamic Azad University, Anar branch

Street address

Anar-Shahrbabak Road

City

Anar

Postal code

Approval date

2013-09-23, 1392/07/01

Ethics committee reference number

8120

Health conditions studied

1

Description of health condition studied

Attention deficit: disorder with hyperactivity

ICD-10 code

F90

ICD-10 code description

Disturbance of activity and attention

Primary outcomes

1

Description

Impulsivity

Timepoint

Before the intervention, after the intervention, one months after the intervention

Method of measurement

Connors Questionnaire, Parent form

2

Description

Inattention

Timepoint

Before the intervention, after the intervention, one months after the intervention

Method of measurement

Connors Questionnaire, Parent form

3

Description

Hyperactivity

Timepoint

Before the intervention, after the intervention, one months after the intervention

Method of measurement

Connors Questionnaire, Parent form

Secondary outcomes

1

Description

-

Timepoint

-

Method of measurement

-

Intervention groups

1

Description

Intervention group: Exercise therapy, Play therapy, physical and mental plays. In 10 sessions, each session 30-45 minutes, three times a week. Including intellectual games such as puzzles, exercises to improve balance and concentration such as walking on a line or string beads, exercises to increase energy efficiency such as drawstring.

Category

Behavior

2

Description

Control group: No specific intervention

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Education Office

Full name of responsible person

Mohammad Nazer

Street address

Shariati street

City

Rafsanjan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Islamic Azad University, Anar branch

Full name of responsible person

Mohammad Khajezadeh

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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

Vice chancellor for research of Islamic Azad University, Anar branch

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty