Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the effects of computer-assisted cognitive rehabilitation treatment and taking Methylphenidate (Ritalin) on executive functions and severity of clinical symptoms in children with attention deficit/ hyperactivity disorder.

Protocol summary

Summary

Objectives: comparison of the effects of computer-assisted cognitive rehabilitation and taking Methylphenidate (Ritalin) on executive functions and clinical symptoms of attention-deficit/ hyperactivity disorder. Design: matched, randomized, no blind design, second experimental group as control. Population: inclusion criteria: ADHD diagnosis; age between 7 and 11; IQ>85. Exclusion criteria: sever co-morbid disorder; seizures; IQ<85; disability; sever medical condition; sample size: total of 34. Interventions: computer assisted cognitive rehabilitation (n=14), taking Methylphenidate (n=20). Assessment: pre-test, post-test, and an one month follow-up; measurement instruments: continuous performance test; wechsler digit span test; span board test; Raven's test; Persian version of tower of London test; Swanson, Nolan, and Pelham scale (to measure ADHD symptom intensity). Time: two months period of intervention for both groups; rehabilitation group received 20 one-hour-sessions of computerized training of executive functions, and drug therapy group simultaneously received 2 to 3 doses of Ritalin per day for two months. Original outcome variables: executive function tasks and the scale of severity of symptoms of attention deficit/ hyperactivity disorder.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201106136794N1**
Registration date: **2011-08-03, 1390/05/12**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-08-03, 1390/05/12

Registrant information

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Morteza Nazifi
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, faculty of humanities, Tarbiat Modares university.

Expected recruitment start date

2010-09-23, 1389/07/01

Expected recruitment end date

2011-02-20, 1389/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of computer-assisted cognitive rehabilitation treatment and taking Methylphenidate (Ritalin) on executive functions and severity of clinical symptoms in children with attention deficit/ hyperactivity disorder.

Public title
Comparison of the computerized cognitive rehabilitation and drug therapy in the treatment of attention-deficit/ hyperactivity disorder.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: receiving ADHD diagnosis using psychiatric interviews and behavioral rating scales; having an age between 7 and 11 years; IQ>85. Exclusion criteria: Having sever co-morbid mental disorders such as oppositional defiant disorder, autism or asperger syndrom, and depression; a history of epileptic seizures during past 2 years; IQ<85; having some type of motor or perceptual disability which interferes with computer operation; having some kind of Medical condition which make one to seek immediate treatment.
Age
From **7 years** old to **11 years** old
Gender
Male

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **34**
Randomization (investigator's opinion)
Randomized
Randomization description
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
The ethics committee of university of Tarbiat Modares, faculty of humanities, vice chancellor of res
Street address
Faculty of humananities, Tarbiat Modares university, Jalale Ale Ahmad Highway, Nasr Bridge, Tehran, Iran.
City
Tehran
Postal code
139-14115
Approval date
2010-03-13, 1388/12/22
Ethics committee reference number
60/32304

Health conditions studied

1

Description of health condition studied
Disturbance of activity and attention
ICD-10 code
F90.0
ICD-10 code description
Disturbance of activity and attention

Primary outcomes

1

Description
Intesity of ADHD, combined subtype
Timepoint
preintervention, postintervention, and one month after intervention has finished.
Method of measurement
Persian version of SNAP-IV scale

2

Description
Intesity of ADHD, hyperactive/ impulsive subtype
Timepoint
preintervention, postintervention, and one month after intervention has finished.
Method of measurement
Persian version of SNAP-IV scale

3

Description
Verbal working memory
Timepoint
preintervention, postintervention, and one month after Intervention has finished.
Method of measurement
Digit span test from the WISC-R IQ test (Wechsler, 1981).

4

Description
Visuo-spatial working memory
Timepoint
preintervention, postintervention, and one month after Intervention has finished.
Method of measurement
Span board task from Wechsler RNI batterey (Kaplan, Fein, Morris, and Delis, 1991).

5

Description
Sustained attention
Timepoint
preintervention, postintervention, and one month after Intervention has finished.
Method of measurement
Persian version of continuous performance test (CPT).

6

Description
Intesity of ADHD, inattentive subtype
Timepoint
preintervention, postintervention, and one month after Intervention has finished.
Method of measurement
Persian version of SNAP-IV scale.

7

Description
Raven's IQ test.
Timepoint
preintervention, postintervention, and one month after Intervention has finished.
Method of measurement
Raven's colored progressive matrices (Raven, 1995).

8

Description
Respons inhibition.
Timepoint
preintervention, postintervention, and one month after Intervention has finished.
Method of measurement
Persian version of continuous performance test (CPT).

9

Description
Planning
Timepoint
preintervention, postintervention, and one month after Intervention has finished.
Method of measurement
Persian version of tower of London test.

Secondary outcomes

empty

Intervention groups

1

Description
For first experimental group (computer assisted cognitive rehabilitation): the intervention included 20 hours (20 one-hour-sessions) of executive functions training using a computer. Trained executive functions included: verbal working memory; visuo-spatial working memory; sustained attention; response inhibition; planning and organization; and information processing speed. Total period of intervention was 2 months.
Category
Rehabilitation

2

Description
For second experimental group (drug therapy group): The intervention included 2 or 3 doses of Immediate-release Methylphenidate (Ritalin) per day (each doses included one Ritalin pill). This intervention lasted 2 months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Departement for education of region 4 of Tehran
Full name of responsible person
Rasool Bahrami
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Counselling office, departement for education of region 4 of Tehran, next to the Kerman street, Resalat highway, Tehran.
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor of research, faculty of humanities, Tarbiat Modares University
Full name of responsible person
Dr. Mohamad-Reza Mohamadi
Street address
Faculty of humanities, Tarbiat Modares university, Jalal e Al e Ahmad Highway, Nasr bridge, Tehran.
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor of research, faculty of humanities, Tarbiat Modares University
Proportion provided by this source
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

2

Sponsor
Name of organization / entity

Research Institute for education, Ministry of Education

Full name of responsible person
Dr. Majid Qadami

Street address
number 56, shahid Hojat Doost alley, Vesal e Shirazi Street, Keshavarz Street, Tehran

City
Tehran

Grant name

Grant code / Reference number

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

Title of funding source
Research Institute for education, Ministry of Education

Proportion provided by this source

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
Tarbiat Modares university

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Position
Doctor of psychology

Other areas of specialty/work

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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