

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 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

###### Name

Morteza Nazifi

###### Name of organization / entity

Tarbiat Modares University

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8288 3676

###### Email address

nazifi@modares.ac.ir

##### 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**

Intensity 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

##### **Street address**

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

**Full name of responsible person**

Morteza Nazifi

**Position**

Doctor of psychology

**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)**

empty

**Study Protocol**

empty

**Statistical Analysis Plan**

empty

**Informed Consent Form**

empty

**Clinical Study Report**

empty

**Analytic Code**

empty

**Data Dictionary**

empty