

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### Effectiveness of Medication and combined Medication and Parent Management Training on Visuo constructive, Attentional, Behavioral and Emotional Indicators of children with Attention Deficit/Hyperactivity Disorder

#### Protocol summary

##### Summary

The aim of the present study was to investigate the effectiveness of Medication and combined Medication and parent Management Training on Visuoconstructive, Attentional, Behavioural and Emotional indicators of children with Attention Deficit/Hyperactivity Disorder. using simple randomized sampling, 18 children 8 to 10 years old with Attention Deficit/Hyperactivity Disorder (Combined type) and IQ above 90 and without pervasive developmental disorder with their mothers were participated in this study. They were inserted into two different groups(9 persons in each group): medication and combined medication and Parent management training. Afterwards subjects were evaluated with child symptom inventory, Bender- Gestalt test, Stroop color -word test and Conner's parent rating scale-revised before and after treatment (which consists of minimum 5 weeks of medication for both groups plus 10 sessions of parent training for combined group).

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013012712302N1**

Registration date: **2013-04-15, 1392/01/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2013-04-15, 1392/01/26

##### Registrant information

Name

Zahra Fazeli

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 26 3448 0257

##### Email address

a-afkham@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tehran University of Medical Sciences

##### Expected recruitment start date

2010-11-20, 1389/08/29

##### Expected recruitment end date

2011-06-20, 1390/03/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effectiveness of Medication and combined Medication and Parent Management Training on Visuo constructive, Attentional, Behavioral and Emotional Indicators of children with Attention Deficit/Hyperactivity Disorder

##### Public title

Effectiveness of Medication and Combined Medication and Parent Management Training on children with Attention Deficit/Hyperactivity Disorder

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

inclusion criteria: Having diagnostic criteria for Attention Deficit/Hyperactivity Disorder ( combined type )according to DSM-IV-TR diagnostic criteria and diagnoses based on child and adolescent psychiatrist and diagnostic criteria required to fill in a questionnaire CSI and T scores above 65 on Scale D from Conners parent rating scale; Having a calendar age of 8 years (boys and girls who have completed their first year of primary school) to 10 years; Lack of medical and psychological treatment during the 1-month; IQ above 90 on the Raven test and the psychiatrist, content, and overall academic records; Enjoying a high school diploma by parents Exclusion criteria : Having epilepsy, mental retardation and pervasive developmental disorders according to psychiatrist, case information, education and testing Raven; Impact of brain damage or prematurity

**Age**

From **8 years** old to **10 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **18**

**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**

Tehran University of Medical Sciences

**Street address**

Keshavarz Blvd, Tehran

**City**

Tehran

**Postal code****Approval date**

2011-08-02, 1390/05/11

**Ethics committee reference number**

729/130/90/5

**Health conditions studied****1****Description of health condition studied**

Attention Deficit/Hyperactivity disorder

**ICD-10 code**

F90.8

**ICD-10 code description**

Other hyperkinetic disorders

**Primary outcomes****1****Description**

Visuo constructive index

**Timepoint**

before intervention and after 5th week of intervention

**Method of measurement**

bender-gestalt test

**2****Description**

attentional index

**Timepoint**

before intervention and after 5th week of intervention

**Method of measurement**

stroop color- word test

**3****Description**

emotional indicator

**Timepoint**

before intervention and after 5th week of intervention

**Method of measurement**

bender- gestalt test

**4****Description**

behavioral index

**Timepoint**

before intervention and after 5th week of intervention

**Method of measurement**

conners test

**Secondary outcomes****1****Description**

IQ

**Timepoint**

before intervention

**Method of measurement**

raven test

## Intervention groups

1

### Description

group A: medication(MPH)ritalin10mg for 5 weeks

### Category

Treatment - Drugs

2

### Description

group B: medication as noted plus 10 sessions of parent management training

### Category

Other

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Ali Asghar Hospital

#### Full name of responsible person

Dr Shirazi

#### Street address

Zafar St, Tehran

#### City

Tehran

2

### Recruitment center

#### Name of recruitment center

Roosbeh Hospital

#### Full name of responsible person

Dr Shahrivar

#### Street address

South Kargar St, Tehran

#### City

Tehran

3

### Recruitment center

#### Name of recruitment center

Tehran Psychiatric Institute

#### Full name of responsible person

MS Alimohammadi

#### Street address

Sattarkhan St, Tehran

#### City

Tehran

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Tehran University of Medical Sciences

### Full name of responsible person

Dr Akbar Fotoohi

### Street address

Keshavarz Blvd, Tehran

### City

Tehran

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Tehran University of Medical Sciences

### 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

Tehran University of Medical Sciences

#### Full name of responsible person

Zahra Fazeli

#### Position

M.S in clinical psychology

#### Other areas of specialty/work

#### Street address

Number 41, Hmze Ali, Aboozar St, Motahati St, Karaj

#### City

Karaj

#### Postal code

#### Phone

+98 26 3448 0257

#### Fax

#### Email

zfazeli300@yahoo.comzfazeli300@gmail.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Zahra Fazeli

#### Position

M.S in clinical psychology

#### Other areas of specialty/work

#### Street address

Number 41, Hmze Ali, Aboozar St, Motahati St, Karaj

#### City

Karaj

**Postal code**  
**Phone**  
+98 26 3448 0257  
**Fax**  
**Email**  
zfazeli300@yahoo.com  
**Web page address**

**Phone**  
+98 26 3448 0257  
**Fax**  
**Email**  
zfazeli300@gmail.com  
**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Zahra Fazeli  
**Position**  
M.S in clinical psychology  
**Other areas of specialty/work**  
**Street address**  
Number 41, Hmze Ali, Aboozar St, Motahati St, Karaj  
**City**  
Karaj  
**Postal code**

## 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*