

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### A Study of effect of adding acupuncture to Methylphenidate in treatment of attention deficit hyperactivity disorder(ADHD) in children and adolescents

#### Protocol summary

##### Study aim

The evaluation of efficacy of adding acupuncture to Methylphenidate in treatment of attention deficit hyperactivity disorder in children and adolescents

##### Design

A randomized, double blinded, sham controlled clinical trial with a parallel group design of 90 patients

##### Settings and conduct

This study was conducted on patients with confirmed ADHD referred to Ibn-e-Sina Psychiatric Hospital, Mashhad, Iran between January 2017 and June 2017. Patients were randomly allocated into acupuncture (experimental group) or sham acupuncture (control group). All patients received a standard treatment of 0.3-1 mg/kg of Methylphenidate (Ritalin) in 2 or 3 divided doses. Before the intervention patients were evaluated using home version of ADHD-rating scale (RS) and Continuous Performance Test. Then within 4 weeks the intervention group received acupuncture treatment 3 times a week. Sham acupuncture was used for the control group within the same duration as acupuncture group. The treatment outcomes were measured using home version of ADHD-rating scale (RS) and Continuous Performance Test after 3 weeks. Patients, their parents, child and adolescent psychiatrist and the psychologist who performed before-after tests were not aware of grouping.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 6 to 18 year old patients with the diagnosis of ADHD by DSM-5 criteria who are on the standard treatment with Methylphenidate or Methylphenidate and Clonidine without any dose change from 2 weeks before the study and during the study  
Exclusion criteria: patients with mental retardation, epilepsy, pervasive developmental disorders, schizophrenia, manic episode, mood and anxiety disorders and drug or organic disorder induced

hyperactivity

##### Intervention groups

Acupuncture (experimental group) and sham acupuncture (control group)

##### Main outcome variables

Score of ADHD-rating scale; score of CPT

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015091121852N1**

Registration date: **2016-11-27, 1395/09/07**

Registration timing: **prospective**

Last update: **2018-03-11, 1396/12/20**

Update count: **1**

##### Registration date

2016-11-27, 1395/09/07

##### Registrant information

##### Name

Mahsa Nahidi

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3764 9383

##### Email address

nahidimh@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Mashhad University of Medical Sciences

##### Expected recruitment start date

2016-08-22, 1395/06/01  
**Expected recruitment end date**  
2017-03-20, 1395/12/30  
**Actual recruitment start date**  
2016-12-21, 1395/10/01  
**Actual recruitment end date**  
2017-06-20, 1396/03/30  
**Trial completion date**  
empty

**Scientific title**  
A Study of effect of adding acupuncture to Methylphenidate in treatment of attention deficit hyperactivity disorder(ADHD) in children and adolescents

**Public title**  
Acupuncture in treatment of attention deficit hyperactivity disorder in children and adolescents

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Written and oral informed consent by parents of participants Age between 6 to 18 years The diagnosis of ADHD according to DSM-5 criteria by a child and adolescent psychiatrist Being on the standard treatment with Methylphenidate or Methylphenidate and Clonidine without any dose changes from 2 weeks before and during the study period

**Exclusion criteria:**

Patients with mental retardation, epilepsy, pervasive developmental disorders, schizophrenia, manic episode, mood and anxiety disorders and drug or organic disorder induced hyperactivity Any dose change in the standard drug therapy during the study period

**Age**  
From **6 years** old to **18 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**  
Target sample size: **90**  
Actual sample size reached: **90**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Simple randomization by using a random number table

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
Randomization was done by a researcher who was not aware of the study protocol and outcomes. Patients and their parents, as well as child and adolescent psychiatrist were not aware of grouping, Moreover, the psychologist,

who was the researcher-in-charge of before-after tests, was not aware of interventions. Also, the outcomes of the study were recorded by the psychiatrist who made no other contribution to the study.

**Placebo**  
Used  
**Assignment**  
Parallel  
**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Mashhad University of Medical Sciences

**Street address**

Ghoreshi building, Daneshgah St., Mashhad, Khorasan Razavi, Islamic Republic of Iran

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

1394491388

**Approval date**

2015-06-24, 1394/04/03

**Ethics committee reference number**

IR.MUMS.fm.REC.1394.61

**Health conditions studied**

1

**Description of health condition studied**

Attention Deficit Hyperactivity disorder

**ICD-10 code**

F90.0

**ICD-10 code description**

Disturbance of activity and attention

**Primary outcomes**

1

**Description**

ADHD Rating Scale score

**Timepoint**

Before the intervention and 3 weeks after the intervention

**Method of measurement**

ADHD Rating Scale-IV questionnaire

2

**Description**

Continuous Performance Test score

**Timepoint**

Before the intervention and 3 weeks after the intervention

**Method of measurement**

Continuous Performance Test

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

Patient group will receive acupuncture for 12 sessions(three 40 minute sessions weekly).

**Category**

Treatment - Other

**2**

**Description**

Control group will receive sham acupuncture for 12 sessions(three 40 minute sessions weekly).In this group special needles are used that do not enter the skin and acupoints are different from the patient group.

**Category**

Treatment - Other

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Ebne Sina Hospital Outpatient Clinics

**Full name of responsible person**

Mahsa Nahidi

**Street address**

Hor-e-Ameli Blvd

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Research Affairs of Mashhad University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Reza Fayyazi Bordbar

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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**

Research Affairs of Mashhad University of Medical Sciences

**Proportion provided by this source**

100

**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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mahsa Nahidi

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Psychiatrics

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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Fateme Moharari

**Position**

associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

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## Person responsible for updating data

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**Position**

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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