

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Investigating the effectiveness of adding acupressure and ear acupuncture treatment to stimulant drugs in children and adolescents with attention deficit hyperactivity disorder

Protocol summary

Study aim

Investigating the effectiveness of adding acupressure and ear acupuncture treatment to stimulant drugs in children and adolescents with attention deficit hyperactivity disorder

Design

Clinical trial with control group, with parallel groups, randomized, on 102 patients. The rand function of Excel software was used for randomization.

Settings and conduct

In this study, children and adolescents referring to the outpatient clinics of Ibn Sina Psychiatric Hospital who meet the inclusion criteria are included in the plan. 102 people are randomly divided into two groups. Based on the standard treatment, clients are placed on the desired drug from the beginning (Ritalin with a maximum dose of 1 mg/kg in divided doses and Etomoxetine 1 mg/kg per day in divided doses) and it continues during their drug treatment.

Participants/Inclusion and exclusion criteria

Age 6 to 18 years, ADHD diagnosis Not suffering from mental retardation Under medical treatment with stimulant drugs Written and verbal informed consent from parents Exclusion criteria: Intolerance of acupressure or ear acupuncture treatment Low compliance Changes in drug therapy during the study

Intervention groups

In the intervention groups, in addition to the use of CNS stimulating drugs, acupressure and ear acupuncture treatments are also used. In the control group, only CNS stimulating drugs are used.

Main outcome variables

Symptoms of hyperactivity in children and adolescents

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101130005280N57**

Registration date: **2022-09-05, 1401/06/14**

Registration timing: **registered_while_recruiting**

Last update: **2022-09-05, 1401/06/14**

Update count: **0**

Registration date

2022-09-05, 1401/06/14

Registrant information

Name

Raheleh Nejati

Name of organization / entity

Mashhad University of Medical Scinces, Ibn-e- Sina Psychiatric Hospital

Country

Iran (Islamic Republic of)

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+98 51 3711 2540

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nejatir2@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-23, 1401/06/01

Expected recruitment end date

2022-11-22, 1401/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effectiveness of adding acupressure and ear acupuncture treatment to stimulant drugs in children and adolescents with attention deficit hyperactivity disorder

Public title

Checking the effectiveness of adding acupressure and ear acupuncture treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 6 to 18 years ADHD diagnosis according to DSM-V with confirmation of a pediatric psychiatry subspecialist Not suffering from mental retardation, epilepsy, pervasive developmental disorders, schizophrenia, manic episodes, anxiety disorders, bipolar disorders, learning disorders of specific skills and hyperactivity symptoms caused by organic disorders or drug reactions based on clinical interview. by a psychiatrist Under medical treatment with stimulant drugs such as methylphenidate or atomoxetine Written and verbal informed consent from parents

Exclusion criteria:

Intolerance of acupressure or ear acupuncture treatment Low compliance Changes in drug therapy during the study

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **102**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization with table of random numbers available at "www.randomization.com" website will be used. Numbers will be placed in sealed envelopes and each envelope is assigned to one participant placing them in one of the two intervention groups.

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

Ethics committee of Mashhad University of Medical Sciences

Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah Street

City

Mashhad

Province

Razavi Khorasan

Postal code

123456

Approval date

2022-03-16, 1400/12/25

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1400.840

Health conditions studied

1

Description of health condition studied

ADHD

ICD-10 code

F90.0

ICD-10 code description

Attention-deficit hyperactivity disorder, predominantly inattentive type

Primary outcomes

1

Description

ADHD Rating Scale

Timepoint

Before the intervention and the end of the first, second, third months

Method of measurement

Examination of the patient's symptoms by the doctor

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention groups, in addition to using CNS stimulating drugs, acupressure and ear acupuncture treatments are also used. The number of treatment sessions for acupressure is 12 sessions per month. At first, the first three sessions will be given the necessary training to the parents by the traditional medicine specialist and acupressure will be done in the presence of the parents, and then the parents will do it on their child at their own home and will be followed up

by the psychiatric assistant who will implement the daily plan over the phone. Pressure has been applied. This process does not take more than a few minutes a day. Parents can be asked to do this on a daily basis as well. The number of ear acupuncture sessions is 12. The patient goes to the traditional medicine clinic of Imam Reza Hospital every day, and is given ear acupuncture sticks in the points by a traditional medicine specialist. It is clearly attached and it is explained to the parents on which sticks to press for how long each day. And in the middle of the day, the location of the sticks is moved by a traditional medicine expert. Before starting the acupuncture and ear acupuncture treatment, the ADHD Rating Scale (1) is checked for all groups.

Category

Treatment - Other

2

Description

Control group: In the control group, only CNS stimulating drugs are used.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Ibn-e-Sina psychiatric Hospital

Full name of responsible person

Fatemeh Moharrari

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Ibn-e-Sina psychiatric Hospital, Horre ameli avenue,boo Ali square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Majid Ghayour

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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

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

Zohreh Mahdianpoor

Position

Specialist assistant

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

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Person responsible for updating data

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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