

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

The effect of Auriculotherapy on behavioral symptoms of Attention Deficit Hyperactivity Disorder in 6-12 years' children

Protocol summary

Study aim

Determining the effect of Auricular therapy on behavioral symptoms of ADHD in children aged 6-12 years.

Design

Random with parallel groups with control group, study population of 60 children aged 6-12 years with Attention Deficit Hyperactivity Disorder

Settings and conduct

The research is performed in the clinic of Kargarnejhad Psychiatric Hospital in Kashan. The sampling method is convenience and assigned to the two groups using block randomization.

Participants/Inclusion and exclusion criteria

The sample study is 60 children aged 6-12 years with ADHD. Inclusion criteria include diagnosis of Attention Deficit Hyperactivity Disorder by a Pediatric Psychiatry, age range of 6-12 years, having Iranian nationality, living in Kashan and speak in Persian. Exclusion criteria :Unwillingness of the child and parents , infection or wound in the ear, using of acupuncture or acupressure or complementary therapies In the last 3 months.

Intervention groups

Intervention group: Auriculotherapy in the intervention group by applying moderate and uniform pressure of the index finger and thumb of a trained person or parent on a plant septum attached to the points affecting ADHD according to the standard map of ear points (ISAP). It included: Shen Men - Master Cerebral point-Point zero-Nervous Subcortex - Master Oscillation Point is done. The intervention is performed twice a day and each time each point is pressed for 1 minute and continues for 4 weeks. Control group received massage in other points as a placebo.

Main outcome variables

Behavioral symptoms of ADHD

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130721014086N14**
Registration date: **2020-12-10, 1399/09/20**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-10, 1399/09/20**

Update count: **0**

Registration date

2020-12-10, 1399/09/20

Registrant information

Name

Mohammad Aghajani

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 5554 2001

Email address

aghajani_m@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-25, 1399/09/05

Expected recruitment end date

2021-04-21, 1400/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Auriculotherapy on behavioral symptoms of Attention Deficit Hyperactivity Disorder in 6-12 years'

children

Public title

Therapeutic effect of Acupressure in Hyperactive children

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of Attention Deficit / Hyperactivity Disorder based on the case and diagnosis of pediatric psychiatry Willingness of the child and parents to participate in the study (expressing the working method in simple language and asking the child to participate) ADHD children aged 6-12 years who are being treated by a child psychiatrist. Having Iranian nationality, Persian language and living in Kashan

Exclusion criteria:

Existence of ulcer or infection in the ear Do not use acupressure or acupuncture and complementary therapies in the last 3 months

Age

From **6 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization method was used to assign two groups. In this way, the samples were assigned to two intervention and control groups in the form of 7 blocks of 4 using Excel software.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

Street address

Ravandi ghotb st- Kashan

City

Kashan

Province

Isfahan

Postal code

88715973474

Approval date

2020-11-25, 1399/09/05

Ethics committee reference number

IR.KAUMS.NUHEPM.REC.1399.069

Health conditions studied

1

Description of health condition studied

Attention Deficit Hyperactivity Disorder

ICD-10 code

F90.0

ICD-10 code description

Other behavioral and emotional disorders with onset usually occurring in childhood and adolescence

Primary outcomes

1

Description

Severity of ADHD behavioral symptoms

Timepoint

Beginning of the study, weeks 4 and 8

Method of measurement

Aachenbach Child Behavior Inventory (CBCL)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Auriculotherapy in the intervention group by applying moderate and uniform pressure of the index finger and thumb of a trained person or parent on a plant septum attached to the points affecting ADHD according to the standard map of ear points (ISAP) including: Shen Men - Master Cerebral point-Point zero- Nervous Subcortex - Master Oscillation Point is done. The intervention is performed twice a day and each time each point is pressed for 1 minute and continues for 4 weeks.

Category

Treatment - Devices

2

Description

Control group: : receive massage in other places as a placebo

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Kargarnejad Psychiatric Hospital

Full name of responsible person

Fateme Mahdavi

Street address

University of Medical Sciences-Kashan

City

Kashan

Province

Isfahan

Postal code

8715973446

Phone

+98 31 5554 9113

Fax

+98 31 5554 0036

Email

fatememahdavi15165@email.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr. Hamidreza Banafsheh

Street address

Ghotbe Ravandi, Kashan

City

Kashan

Province

Isfahan

Postal code

8715988141

Phone

+98 31 5557 8011

Fax

Email

research@kaums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Mohammad Aghajani

Position

lectuerer

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

School of Nursing and Midwifery, Km 3 Ghotbe Ravandi, Kashan

City

kashan

Province

Isfahan

Postal code

8715988141

Phone

+98 31 5554 3591

Email

aghajani1362@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Mohammad Aghajani

Position

lecturer

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

School of Nursing and Midwifery, Km 3 Ghotbe Ravandi, Kashan

City

Kashan

Province

Isfahan

Postal code

8715988141

Phone

+98 36115550021

Email

aghajani1362@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Mohammad Aghajani

Position

lecturer

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

School of Nursing and Midwifery, Km 3 Ghotbe
Ravandi, Kashan

City

Kashan

Province

Isfahan

Postal code

8715988141

Phone

+98 36 1555 0021

Email

aghajani_m@kaums.ac.ir

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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available