Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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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
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Province
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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
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Fateme Mahdavi
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kashan University of Medical Sciences
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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
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
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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
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