

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

The effect of Uriculotherapy on sleep quality in children with Attention Deficit- Hyperactivity Disorder (ADHD)

Protocol summary

Study aim

Evaluation of the effect of Uriculotherapy on sleep quality of children with attention deficit hyperactivity disorder (ADHD) in Kashan in 2021

Design

A randomized double-blind clinical trial with a group design of 52 patients with control group (parallel groups). Block randomization using Sealed Envelope Ltd. software. 2017 was performed.

Settings and conduct

Randomized clinical trial with control group, two-way blind (participants and outcome assessors) on eligible clients in Karegarnejad hospital in Kashan city

Participants/Inclusion and exclusion criteria

Inclusion criteria are; Age 6 to 11 years, Having Attention Deficit- Hyperactivity Disorder (ADHD), Get a score of 41 or higher on the CSHQ, Organ health in the earlobe area, Medicated for ADHD, Resident of Kashan, Iranian citizenship, Living with both parent, willing of mother and child to participate in the study, And non-entry criteria are; Acute serious illness, hospitalization, lack of access, Concomitant use of other non-pharmacological methods, Exposure to severe crises from 3 months prior to study, change in medication schedule for at least two weeks before the start of the study, simultaneous known psychiatric disorders and mental retardation Known chronic diseases, using sleeping pills, Suffering from blindness and deafness

Intervention groups

In the intervention group, Uriculotherapy will be performed using Vakaria sidewalls. In the comparison group, only the seedless label will be pasted on the points and no pressure will be applied on the points.

Main outcome variables

Sleep quality score

General information

Reason for update

Relocation of sampling due to ease of access to samples

Acronym

IRCT registration information

IRCT registration number: **IRCT20100211003329N7**

Registration date: **2021-08-12, 1400/05/21**

Registration timing: **prospective**

Last update: **2022-01-03, 1400/10/13**

Update count: **1**

Registration date

2021-08-12, 1400/05/21

Registrant information

Name

Zahra Sooki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5554 0021

Email address

sooki_z@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2021-12-22, 1400/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Uriculotherapy on sleep quality in children with Attention Deficit- Hyperactivity Disorder (ADHD)

Public title

The effect of Uriculotherapy on sleep quality in children with Attention Deficit- Hyperactivity Disorder (ADHD)

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 6 to 11 years Suffering from Attention Deficit-Hyperactivity Disorder (ADHD) based on the diagnosis of pediatric psychiatrist according to DSM-5 criteria Get a score of 41 or higher (based on the CSHQ tools) Organ health in the earlobe area Medicated for ADHD Resident in Kashan Iranian citizenship Living with both parent Willing of mother and child to participate in the study

Exclusion criteria:

Exposure to acute and severe stress Acute serious illness, hospitalization, lack of access Concomitant use of other non-pharmacological methods Exposure to severe crises from 3 months prior to study Change in medication schedule for at least two weeks before the start of the study Simultaneous known psychiatric disorders and mental retardation Known chronic diseases (heart, respiratory, glandular and allergies diseases) Using sleeping pills Suffering from blindness and deafness

Age

From **6 years** old to **11 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible samples will be assigned to each of the two intervention and comparison groups in the form of block randomization. 52 samples were entered into Sealed Envelope Ltd. software. 2017 through www.sealedenvelope.com. The size of the blocks was chosen unequally so that the person entering the samples into the groups could not guess the next sample group, actually it was defined for the software to divide people into two groups in the form of blocks with sizes 4, 6 and 8. The software defined 1 block of 4, 3 blocks of 8 and 4 blocks of 6.

Blinding (investigator's opinion)

Double blinded

Blinding description

The lead researcher places therapeutic or placebo sides on the participants' ears, and the research's colleague, who is unaware of the nature of the sides, performs further evaluations. Participants also have already been told that their sides may be therapeutic or placebo.

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

Kashan. Qutb Ravandi Blvd., Pezeshk Blvd., Kashan University of Medical Sciences

City

kashan

Province

Isfahan

Postal code

87155981151

Approval date

2021-06-26, 1400/04/05

Ethics committee reference number

IR.KAUMS.REC.1400.015

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

Attention deficit- hyperactivity disorder

ICD-10 code

F90.0

ICD-10 code description

Attention-deficit hyperactivity disorder, predominantly inattentive type

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

Sleep quality score

Timepoint

Before the intervention, 4 weeks after the beginning of the intervention, 4 weeks after the end of the intervention

Method of measurement

Children's Sleep Habits Questionnaire

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

Allergy to sidewalls

Timepoint

Weekly
Method of measurement
Report of mother

Intervention groups

1

Description

Intervention group: In this group, Korean-made DONG BANG brand Vakaria sidewalls are glued by the researcher on Shenman, sympathetic, sub cortex, heart and endocrine points that are related to sleep quality. The mother and child will be instructed to press these sidewalls each time for three minutes with the index finger and thumb by the child (under the supervision of an adult) or a relative. During the 4 weeks of the intervention, the labels will be affixed by the researcher alternately on both ears every other week. The labels are placed on the ear for five days each week and the mother is instructed to remove them by the end of the fifth day to prevent possible allergic reactions. It is also noted that if the labels are removed during the five-day period, the researcher will be notified by telephone; In that case, the researcher will re-affix the labels with the consent of the family at their home, in the Karegarnejad hospital or wherever it is convenient for the family. The method of pressing the sidewalls will be taught to the intervention group by the researcher; In addition, during the intervention, a weekly diary will be provided to mothers, in which mothers will record possible allergic reactions, hypnotic use, frequency and duration of each pressure. Every week, all participants will be visited at the agreed location and new stickers will be affixed to them; A daily note sheet will be delivered to them and another sheet will be delivered to them next week. The information in the diaries is analyzed every week, and if the average number of times of pressure and the duration of each time of pressure on the sides is at least 2 times a day and 2 minutes each time, the sample will remain in the study. Labeling will continue for 4 weeks and samples will be followed up for 4 weeks after the intervention. In addition to starting the study, the CSHQ questionnaire will be completed after the intervention (end of the fourth week) and 4 weeks after the intervention (end of the eighth week) through face-to-face interviews with the mother by the research Fellow (who does not know how to divide the samples into two groups).

Category
Treatment - Drugs

2

Description

Control group: Auriculotherapy will be performed for 4 weeks, five days a week, three times a day and one hour before bedtime. In this group, Vakaria brand DONG BANG brand made in Korea on shenman, sympathetic, subcortex, heart and endocrine points that are related to sleep quality. Only the seedless label will be affixed to the points and no pressure will be applied to the points.

It should be noted that during the 4 weeks of intervention, the labels will be affixed by the researcher alternately on both ears every other week. The labels are placed on the ear for five days each week and the mother is instructed to remove them at the end of the fifth day to prevent possible allergic reactions; It is also noted that if the labels are removed during the five-day period, the researcher will be notified by telephone; In that case, the researcher will re-affix the labels with the consent of the family at their home, in the Karegarnejad hospital or wherever it is convenient for the family.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Kargarnejad Hospital
Full name of responsible person
zahra Tagharrobi
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
Kashan University of Medical Sciences

Full name of responsible person
Zahra Tagharobi

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Not done yet

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