Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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Iran (Islamic Republic of)

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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
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kashan
Province
Isfehan
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

Weekely

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

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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
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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