Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of lavender essential oil on the sleep quality of children with autism aged 6-12 years: a randomized controlled clinical trial study

Protocol summary

Study aim

Determining the effect of lavender essential oil on the sleep quality of children with autism aged 6-12 years in Isfahan: A randomized controlled clinical trial

Design

A phase 3, randomized, double-blind, parallel-arm controlled clinical trial on 66 children with autism. Participants will be randomly assigned to 2 groups using block randomization with the blockrand package in R software.

Settings and conduct

Lavender essential oil and normal saline, prepared in coded vials by a research assistant according to a randomization list from the statistical consultant, will be given to parents to blind the researcher and the statistical consultant. The research assistant will also provide usage instructions, which include placing 3 drops of the solution on a gauze pad and attaching it to the child's collar every night before sleep for 14 nights.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: province, during the academic year 2025؛ Consent to participate in the study؛ Willingness to cooperate؛ Sleep quality score greater than 41 on the CSHQ؛ No history of rhinitis, allergies, or respiratory problems Exclusion Criteria: Lack of access to patients after the start of the intervention؛ Withdrawal of consent at any stage of the study؛ Incomplete questionnaire؛ Lack of cooperation؛ Development of urticaria (hives)؛ Occurrence of an unforeseen crisis or event؛ Presence of another acute or chronic disorder or disease concurrent with autism

Intervention groups

Children with autism will be randomly assigned to two groups using block randomization: a group receiving lavender essential oil and a control group. They will receive three drops via aromatherapy every night before sleep for fourteen nights.

Main outcome variables

Addressing sleep disturbances, which, if effective, would improve quality of life and sleep

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240828062891N1**
Registration date: **2025-06-08, 1404/03/18**
Registration timing: **prospective**

Last update: **2025-06-08, 1404/03/18**
Update count: **0**

Registration date

2025-06-08, 1404/03/18

Registrant information

Name

Zahra Roshani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 3343 6059

Email address

zahraroshani779@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-09-22, 1404/06/31

Expected recruitment end date

2026-03-19, 1404/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of lavender essential oil on the sleep quality of children with autism aged 6-12 years: a randomized controlled clinical trial study

Public title
The effect of lavender essential oil on the sleep quality of children with autism

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
All children aged 6-12 years with autism in Dast haye Mehraban and Mehr Afarin schools, Isfahan province, during the academic year 2025. Consent to participate in the study. Cooperation throughout the study. Sleep quality score greater than 41 on the CSHQ (Children's Sleep Habits Questionnaire). No history of rhinitis, allergies, or respiratory problems.

Exclusion criteria:

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

Gender
Both

Phase
3

Groups that have been masked

- Investigator
- Data analyser

Sample size
Target sample size: **66**

Randomization (investigator's opinion)
Randomized

Randomization description
Samples were enrolled in the study based on the inclusion and exclusion criteria via convenience sampling until the required sample size was reached. Subsequently, to standardize the distribution of confounding factors (gender and age), stratified blocks were created based on gender (female/male) and age groups (6-9 years and 9-12 years). Using the blockrand package in R software, the study participants will be randomly assigned to 2 groups using block randomization.

Blinding (investigator's opinion)
Double blinded

Blinding description
Lavender essential oil procured from Giahe Kala Company and normal saline will be prepared by the research assistant in coded dark vials based on a randomized block list generated by the statistical consultant and will be delivered to the parents.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Lorestan University of Medical Sciences

Street address
Second Mehr mihan alley, Mehr mihan street, Bozorgmehr street

City
Khorramabad

Province
Lorestan

Postal code
6819681369

Approval date
2025-01-28, 1403/11/09

Ethics committee reference number
IR.LUMS.REC.1403.445

Health conditions studied

1

Description of health condition studied
Autism

ICD-10 code
F84.0

ICD-10 code description
Autistic disorder

Primary outcomes

1

Description
Sleep quality score on the Children's Sleep Habits Questionnaire.

Timepoint
Sleep quality score at baseline (before the start of the intervention) and 14 days after the start of aromatherapy with lavender essential oil.

Method of measurement
Children's Sleep Habits Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention group will receive lavender essential oil, prepared by Giah Kala Company.

This essential oil will be coded and packaged in dark glass bottles by the research assistant. The bottles will be distributed to parents based on a randomized block list prepared by the statistical consultant.The research assistant will also provide training to the parents on the method of use. Parents will be instructed to apply three drops from the provided bottle onto a piece of gauze every night for fourteen consecutive nights, just before their child goes to sleep. This gauze will then be attached to the child's collar so the child can inhale the aroma. Upon waking, the gauze should be removed from the collar and discarded.For any questions or concerns, parents will be provided with a contact number to reach the research assistant. Throughout the two-week intervention period, the research assistant will also conduct follow-up phone calls to monitor the correct application of the aromatherapy.

Category

Rehabilitation

2

Description

Control group:The control group will receive normal saline. This saline will be coded and packaged in dark glass bottles by the research assistant. The bottles will be distributed to parents based on a randomized block list prepared by the statistical consultant.The research assistant will provide training to the parents on the method of use. Parents will be instructed to apply three drops from the provided bottle onto a piece of gauze every night for fourteen consecutive nights, just before their child goes to sleep. This gauze will then be attached to the child's collar so the child can inhale it. Upon waking, the gauze should be removed from the collar and discarded.For any questions or concerns, parents will be provided with a contact number to reach the research assistant. Throughout the two-week control period, the research assistant will also conduct follow-up phone calls to monitor the correct application of the procedure.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Mehr Afarin Educational Complex for Children with Autism

Full name of responsible person

Zahra Rezai

Street address

Bagh-e Fadak, Nakhl Street, Baharan 12 Alley, Shokoofeh 5 Alley, Isfahan, Iran

City

Isfahan

Province

Isfehan

Postal code

8196354832

Phone

+98 31 3457 5558

Email

mehrafarinautism@gmail.com

2

Recruitment center

Name of recruitment center

Autism School of the Kind Hands Charity Foundation

Full name of responsible person

Nakisa Goodarzi

Street address

Vali-Asr Township, Alaviyeh Homayouni Street, next to Milad Hospital, Isfahan, Iran

City

Isfahan

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Isfehan

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817966002

Phone

+98 31 3132 6838

Email

Isfahan.pj@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Bahram kamarei

Street address

Second Mehr mihan alley, Mehr mihan street, Bozorgmehr street

City

Khorramabad

Province

Lorestan

Postal code

6819681369

Phone

+98 66 3343 6059

Email

Zahrarooshani779@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Khoram-Abad 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

Khoram-Abad University of Medical Sciences

Full name of responsible person

Zahra Roshani

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

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Postal code

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Zahra Roshani

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Zahra Roshani

Position

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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