

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effect of aromatherapy of two essential oils of jasmine and bitter orange on the level of anxiety in children referred to the clinic of Mohammad Kermanshahi Hospital in Kermanshah In a randomized clinical trial

Protocol summary

Study aim

Determining the effect of aromatherapy of jasmine and bitter orange essential oils on stress in children referred to the clinic of Mohammad Kermanshahi Hospital in Kermanshah in a randomized clinical trial

Design

Clinical trial with control group, with parallel, open-label, phase 3, randomized groups, will be performed on 120 patients, block randomization with 6 blocks.

Settings and conduct

The study population will be children referring to Mohammad Kermanshahi Clinic (patients' visiting place) which are finally divided into three groups by the administrators. The trial will be conducted on each of the study groups on a special day using jasmine and bitter orange essential oils and an electric fragrance diffuser in the patient's presence space (30 minutes before attendance).

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 6 to 12 years; the patient's parents' consent to use clinical information. Exclusion criteria: cognitive problems, anxiety disorders; use of drugs affecting the central nervous system, with the effect of sedation or anxiety relief.

Intervention groups

The intervention groups including jasmine essential oil and bitter orange essential oil in the patients' environment. To assess anxiety, children will first be interviewed using tools (FIS). One interview will be done before the intervention and the other after the intervention. Then, in order to reduce the error rate in the results of the study, the child's cortisol level, heart rate and blood pressure will be measured by the doctor before and after the intervention; Also, in order to evaluate the control group and compare between the mentioned groups, the control group will be deprived of

routine treatment, but the anxiety assessment process will be the same in all groups.

Main outcome variables

Anxiety Level; Pulse Rate; Blood Pressure; Cortisol

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220305054184N1**

Registration date: **2022-03-23, 1401/01/03**

Registration timing: **prospective**

Last update: **2022-03-23, 1401/01/03**

Update count: **0**

Registration date

2022-03-23, 1401/01/03

Registrant information

Name

Saleh Merati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3821 3576

Email address

meratisaleh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-21, 1401/02/01

Expected recruitment end date

2022-04-23, 1401/02/03

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of aromatherapy of two essential oils of jasmine and bitter orange on the level of anxiety in children referred to the clinic of Mohammad Kermanshahi Hospital in Kermanshah In a randomized clinical trial

Public title
Investigating the effect of aromatherapy of two essential oils of jasmine and bitter orange on the level of anxiety in children

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Age 6 to 12 years Patient's consent to the use of clinical information in research purposes (in order to maintain the professional principles of research ethics)
Exclusion criteria:
A person has cognitive problems or anxiety disorders
Taking drugs that affect the central nervous system, with a sedative or anxiety relief effect

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

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, block randomization method with 6 blocks will be used. A random sequence will be created by an epidemiologist using the site <https://www.sealedenvelope.com>, and people who assign patients to groups will not be aware of the random sequence. Each person will be assigned a code in this method and only the epidemiologist will know which group these codes belong to. Therefore, hiding the random process will be fully observed; In addition, registration and assignment of patients to study groups will be done by the first and second implementers of the research project. Samples will be randomly assigned to three groups using block randomization method with 6 blocks. Blocking is usually used to balance the number of samples assigned to each of the groups studied. This feature helps researchers to equate the number of samples assigned to each of the study groups in cases where intermediate analyzes are required during the sampling process. Blocking is done in two ways. In this

method, the size of the blocks is randomly selected (for example, blocks 6, 8, 10 and 14 in each block with an equal number of each group)

Blinding (investigator's opinion)
Not blinded

Blinding description
Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees
1
Ethics committee
Name of ethics committee
Ethics committee of Kermanshah University of Medical Sciences
Street address
Ethics committee of Kermanshah University of Medical Sciences, Shahid Beheshti Blvd
City
Kermanshah
Province
Kermanshah
Postal code
6714869914

Approval date
2022-02-08, 1400/11/19

Ethics committee reference number
IR.KUMS.REC.1400.802

Health conditions studied
1
Description of health condition studied
Anxiety
ICD-10 code
F41
ICD-10 code description
Other anxiety disorders

Primary outcomes
1
Description
Anxiety rate
Timepoint
30 minutes after the start of the intervention
Method of measurement
using FIS scale, heart rate, pulse and blood pressure, cortisol ELISA diagnostic kit

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: The substance used in this study in connection with intervention group 1 will contain jasmine essential oil. The electric fragrance diffuser will be used in the patients' presence space on the assigned days according to the sections mentioned). The device will start 30 minutes before the patient is present. Based on clinical experience and to receive essential oil with a constant medium concentration, 2 ml of essential oil will be used. The timer will be set to activate every 10 minutes for 2 minutes. To assess anxiety, children will first be interviewed using the face image scale (FIS) tool. The FIS scale consists of a row of five figures arranged from very happy to very dissatisfied. Children are asked to indicate which face best describes their feelings at that moment. This scale is scored by giving the value of one to the most positive face and five to the most negative face. One interview will be done before the intervention and the other after the intervention. In the next step, in order to increase the confidence and also to reduce the percentage of errors in execution and the results of the study, the child's cortisol level (measured with a commercial kit), heart rate and blood pressure will be measured by the doctor before and after the intervention.

Category

Prevention

2

Description

Intervention group 2: The substance used in this study in connection with intervention group 2 will include bitter orange essential oil. An electric fragrance diffuser will be used in the patient's presence space (on assigned days according to the sections mentioned). The device will start 30 minutes before the patient is present. Based on clinical experience and to receive essential oil with a constant medium concentration, 2 ml of essential oil will be used. The timer will be set to activate every 10 minutes for 2 minutes. To assess anxiety, children will first be interviewed using the face image scale (FIS) tool. The FIS scale consists of a row of five figures arranged from very happy to very dissatisfied. Children are asked to indicate which face best describes their feelings at that moment. This scale is scored by giving the value of one to the most positive face and five to the most negative face. One interview will be done before the intervention and the other after the intervention. In the next step, in order to increase the confidence and also to reduce the percentage of errors in execution and the results of the study, the child's cortisol level (measured with a commercial kit), heart rate and blood pressure will be measured by the doctor before and after the intervention.

Category

Prevention

3

Description

Control group: In relation to the control group in the study, in order to provide a basis for comparing the effect of aromatherapy on the intervention and control groups, this group is deprived of routine treatment, but in order to perform the study in equal conditions to assess anxiety, first interview with children. The face image scale (FIS) tool will be done. The FIS scale consists of a row of five figures arranged from very happy to very dissatisfied. Children are asked to indicate which face best describes their feelings at that moment. This scale is scored by giving the value of one to the most positive face and five to the most negative face. In the next step, in order to increase the confidence and also to reduce the percentage of errors in execution and the results of the study, the child's cortisol level (measured with a commercial kit), heart rate and blood pressure will be measured by the doctor before and after the intervention.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Mohammad Kermanshahi Hospital

Full name of responsible person

Dr.Mohamad Reza Tohidi

Street address

Dr. Mohammad Kermanshahi Hospital,in front of Hosseinieh Andisheh Pak, Red Crescent Crossroads

City

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6713733135

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Email

meratisaleh@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Vice Chancellor for Research and Technology of Kermanshah University of Medical Sciences

Street address

Kermanshah University of Medical Sciences, Shahid

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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

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Dr.Mohamad Reza Tohidi

Position

Associate Professor of Pediatric Nephrology

Latest degree

Subspecialist

Other areas of specialty/work

Medical Education

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr.Mohamad Reza Tohidi

Position

Associate Professor of Pediatric Nephrology

Latest degree

Subspecialist

Other areas of specialty/work

Medical Education

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Person responsible for updating data

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Saleh Merati

Position

Pharmacy student

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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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