

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 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

Kermanshah

##### Province

Kermanshah

##### Postal code

6713733135

##### Phone

+98 83 3721 8202

##### 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

Beheshti Blvd

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6714869914

**Phone**

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**Email**

meratisaleh@gmail.com

**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

**Street address**

Kermanshah University of Medical Sciences, Shahid Beheshti Blvd

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**Email**

tohidimohamadreza63@gmail.com

## 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

**Street address**

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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

**Street address**

Pharmacy school, Kermanshah university of medical sciences, Razi Blvd

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**Email**

meratisaleh@gmail.com

## 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