Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
+98 83 3835 8943

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

City
Kermanshah

Province
Kermanshah

Postal code
6714869914

Phone
+98 83 3835 8943

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
Kermanshah University of Medical Sciences, Shahid Beheshti Blvd

City
Kermanshah

Province
Kermanshah

Postal code
6714869914

Phone
+98 83 3835 8943

Email
tohidimohamadreza63@gmail.com

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
Pharmcy school, Kermanshah university of medical sciences, Razi Blvd

City
Kermanshah

Province
Kermanshah

Postal code
6714869914

Phone
+98 81 3821 3576

Fax

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