Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the effectiveness of aromatherapy with orange and geranium essential oil on sleep quality and anxiety in patients with major thalassemia

Protocol summary

Study aim
Comparing the effectiveness of aromatherapy with orange and geranium essential oil on sleep quality and anxiety in patients with major thalassemia in Iran Hospital 2025

Design
Clinical trial with control group, with parallel groups, single blind, randomized on 96 patients, using toss a coin for randomization.

Settings and conduct
The research sample includes all thalassemia major patients referred to Iran Hospital in Iranshahr. Participants are randomly assigned to groups. Before and after the intervention, the demographic characteristics form and the Spielberger anxiety and the Pittsburgh sleep quality questionnaire will be completed by the two intervention and control groups. Single-blind means that the study patients do not know which of the groups they belong to.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Definitive diagnosis of thalassemia major, Not having known breathing problems such as asthma, not having an olfactory disorder. Patients who have sleep disorders and anxiety according to the tools...
Exclusion criteria: The occurrence of any serious complications caused by aromatherapy, Failure to complete the questionnaires correctly, Existence of psychological crises such as depression, bereavement and divorce...

Intervention groups
The first intervention group will be exposed to orange extract and the second intervention group will be exposed to geranium extract, and sweet almond oil will be used in the control group. The intervention will be that 3 drops of essential oil will be poured on a sterile gauze, then the patient will be asked to smell the pad for one minute. After that, the gauze is fastened with a pin on a pillow or clothes at a distance of 20-25 cm from the patient's head; to smell it during three shifts and also during sleep.

Main outcome variables
Anxiety؛ Sleep quality

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240629062277N1**
Registration date: **2024-07-13, 1403/04/23**
Registration timing: **registered_while_recruiting**

Last update: **2024-07-13, 1403/04/23**
Update count: **0**

Registration date
2024-07-13, 1403/04/23

Registrant information

Name
Hajare Rigi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-07-12, 1403/04/22

Expected recruitment end date
2025-01-20, 1403/11/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the effectiveness of aromatherapy with orange and geranium essential oil on sleep quality and anxiety in patients with major thalassemia

Public title
Comparison of the effectiveness of aromatherapy with orange and geranium essential oil on sleep quality and anxiety in Thalassemia
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Definitive diagnosis of major Thalassemia Having minimum reading and writing literacy Absence of events and sudden stressful life conditions during the past 6 months Not having known breathing problems such as asthma, not having an olfactory disorder Not suffering from mental illnesses Not addicted to drugs, alcohol and cigarettes Not using sedatives No history of eczema and allergy to plants Satisfaction with participating in the study Not using other aroma therapy methods during the study period Patients who have sleep disorders and anxiety according to the questionnaires
Exclusion criteria:
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **96**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization (toss a coin) In this way, first a list of patients who meet the research inclusion criteria will be prepared, in this study 3 groups numbers 1 and 2 for the first group of orange essential oil, numbers 3 and 4 for the second group of geranium essential oil and numbers 5 and 6 for the third group (control) will be considered. is taken and this work will continue until all research samples are placed in one of the intervention and control groups.
Blinding (investigator's opinion)
Single blinded
Blinding description
This study will be conducted in the form of a blind controlled clinical trial (this means that the subjects do not know which groups they are in).
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Zabol University of Medical Sciences
Street address
Research Vice-Chancellor of the University, Shahid Rajaei St.
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Province
Sistan-va-Balouchestan
Postal code
9861734184
Approval date
2024-07-06, 1403/04/16
Ethics committee reference number
IR.ZBMU.REC.1403.027

Health conditions studied

1

Description of health condition studied
Thalassemia major
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Anxiety score
Timepoint
Before the intervention and every week until the end of the fourth week
Method of measurement
state-trait anxiety inventory

Secondary outcomes

1

Description
Sleep quality score
Timepoint
Before the intervention and one week after the intervention

Method of measurement
Pittsburgh Sleep Quality Index (PSQI)

Intervention groups

1

Description
Intervention group1: For the purpose of aromatherapy, the first group is exposed to orange extract produced by Barij Essan Company of Kashan, which is prepared from orange peel and contains limonene, flandrene, citral (based on the presence of at least 18 mg of limonene per milliliter of the product).The intervention will be that 3 drops of essential oil will be poured on a sterile gauze, then the patient will be asked to smell the pad for one minute. After that, the gauze is fastened with a pin on a pillow or clothes at a distance of 20-25 cm from the patient's head; to smell it during three shifts and also during sleep.Aromatherapy sessions in the intervention groups are conducted three days a week (Saturday, Monday and Wednesday) and three times a day (10 am, 4 pm and at night before bedtime) for 4 weeks.
Category
Other

2

Description
Intervention group2: Intervention group: The second group will be exposed to geranium extract produced by Tabib Daru Company. Geranium essential oil contains alphapinene (1.35%), citronellol (37.53%), geraniol (7.2%) and citronol formate (10.03%). The intervention will be that 3 drops of essential oil will be poured on a sterile gauze, then the patient will be asked to smell the pad for one minute. After that, the gauze is fastened with a pin on a pillow or clothes at a distance of 20-25 cm from the patient's head; to smell it during three shifts and also during sleep. Aromatherapy sessions in the intervention groups are conducted three days a week (Saturday, Monday and Wednesday) and three times a day (10 am, 4 pm and at night before bedtime) for 4 weeks.
Category
Other

3

Description
Control group: In the control group, sweet almond oil will be used. This oil is obtained from a pharmacy and is completely odorless. In similar studies, this substance has been used for the control group.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Iran Hospital
Full name of responsible person
Obaidullah Movahed
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Sponsors / Funding sources

1

Sponsor
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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
Zabol 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
Zabol University of Medical Sciences

Full name of responsible person
Hajare Rigi
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
Not applicable
Data Dictionary
Not applicable