Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the Effect of Aromatherapy with Orange and Peppermint Essential Oils on Nausea, Vomiting, and Anxiety in Children with Cancer Undergoing Chemotherapy Referred to Hospitals and Clinics Affiliated with Shiraz University of Medical Sciences

Protocol summary

Study aim
Determine the effect of aromatherapy with orange and peppermint essential oils on nausea, vomiting, and anxiety in children with cancer undergoing chemotherapy

Design
Randomized, parallel group, placebo-controlled, single-blind clinical trial on 120 patients will use permutation block method for allocation

Settings and conduct
Aromatherapy will be performed on patients in the pediatric chemotherapy wards of Amir Oncology Hospital and Imam Reza (AS) Specialized and Subspecialized Clinic affiliated with Shiraz University of Medical Sciences.

Participants/Inclusion and exclusion criteria
120 patients undergoing chemotherapy. Main inclusion criteria: Age 9-12 years, definitive diagnosis of cancer, Ability to speak Persian, healthy sense of smell, no respiratory problems, no diseases causing vomiting, no history of psychological problems, no use of sedatives or anti-anxiety medications. Main exclusion criteria: Unwillingness of the child or parents to participate, allergy to plant essential oils.

Intervention groups
In the peppermint essential oil aromatherapy group, in addition to routine ward care, aromatherapy will be administered using two drops of peppermint essential oil placed on a gauze pad. This pad will be attached to the child's collar with a pin, 20 cm from the child's nose. The child will be asked to breathe normally for twenty minutes. In the aromatherapy group with orange essential oil, two drops of orange essential oil will be used for aromatherapy, and in the placebo group, two drops of liquid paraffin will be used to create the appearance of essential oil.

Main outcome variables
Nausea and Vomiting Anxiety

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20260414069075N1**
Registration date: **2026-05-05, 1405/02/15**
Registration timing: **prospective**

Last update: **2026-05-05, 1405/02/15**
Update count: **0**

Registration date
2026-05-05, 1405/02/15

Registrant information
Name
Narges Rahimi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 71 3647 4254
Email address
nargesrahimi@sums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2026-05-24, 1405/03/03
Expected recruitment end date
2026-07-27, 1405/05/05
Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effect of Aromatherapy with Orange and Peppermint Essential Oils on Nausea, Vomiting, and Anxiety in Children with Cancer Undergoing Chemotherapy Referred to Hospitals and Clinics Affiliated with Shiraz University of Medical Sciences

Public title

The Effect of Aromatherapy with Orange and Peppermint Scents on Reducing Nausea, Vomiting, and Anxiety in Children Undergoing Chemotherapy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Children aged 9–12 years of both genders Ability to understand and speak Persian No history of hypersensitivity, allergic rhinitis, and asthma or known respiratory problems Having a healthy sense of smell Receiving chemotherapy with drugs that have moderate to severe emetogenic potential Not having diseases that lead to vomiting The patient’s ability to determine the severity of nausea, vomiting, and anxiety according to the protocol No history of psychological problems or anxiety disorders according to self-report No use of sedative or anxiolytic drugs A history of receiving at least one session of chemotherapy, and reporting nausea and vomiting after that

Exclusion criteria:

Lack of willingness of the child and parents to perform the intervention Sensitivity to herbal essential oils Use of other complementary medicine methods

Age

From **9 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization process will utilize permuted block randomization to assign the participants to the three study groups. A total of 120 participants will be allocated using 20 blocks of size six.

Blinding (investigator's opinion)

Single blinded

Blinding description

The data analyst will be blinded to the allocation of groups to active intervention or placebo groups to prevent potential bias in interpretation the results. The allocation of groups will be disclosed to the analyst once the analysis is fully completed.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Nursing and Midwifery school, Namazi square, Shiraz

City

Shiraz

Province

Fars

Postal code

7134845794

Approval date

2026-01-31, 1404/11/11

Ethics committee reference number

IR.SUMS.NUMIMG.REC.1404.140

Health conditions studied

1

Description of health condition studied

Nausea and Vomiting

ICD-10 code

R11

ICD-10 code description

Nausea and vomiting

2

Description of health condition studied

Anxiety

ICD-10 code

F06.4

ICD-10 code description

Anxiety disorder due to known physiological condition

Primary outcomes

1

Description

Nausea score on the Adapted Rhodes Index of Nausea and Vomiting for Pediatric

Timepoint

Before intervention, 12 and 24 hours after chemotherapy

Method of measurement
Adapted Rhodes Index of Nausea and Vomiting for Pediatric

2

Description
Vomiting score on the Adapted Rhodes Index of Nausea and Vomiting for Pediatric
Timepoint
Before intervention, 12 and 24 hours after chemotherapy
Method of measurement
Adapted Rhodes Index of Nausea and Vomiting for Pediatric

3

Description
Anxiety score on the Spielberger's State-Trait Anxiety Inventory for Children
Timepoint
Before intervention, 12 and 24 hours after chemotherapy
Method of measurement
Spielberger's State-Trait Anxiety Inventory for Children

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the orange essential oil aromatherapy group, in addition to routine ward care, aromatherapy will be administered using two drops of orange essential oil placed on a 2x2 cm gauze pad. This pad will be attached to the child's collar with a pin, 20 cm from the child's nose. The child will be asked to breathe normally for twenty minutes.
Category
Rehabilitation

2

Description
Intervention group: In the peppermint essential oil aromatherapy group, in addition to routine ward care, aromatherapy will be administered using two drops of peppermint essential oil placed on a 2x2 cm gauze pad. This pad will be attached to the child's collar with a pin, 20 cm from the child's nose. The child will be asked to breathe normally for twenty minutes.
Category
Rehabilitation

3

Description
Control group: In the placebo group, in addition to routine ward care, aromatherapy will be simulated using two drops of liquid paraffin placed on a 2x2 cm gauze pad. This pad will be attached to the child's collar with a pin, 20 cm from the child's nose. The child will be asked to breathe normally for twenty minutes.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Amir Oncology Hospital
Full name of responsible person
Narges Rahimi
Street address
Amiral Oncology Hospital, Station 11, Farhang Shahr, Shiraz
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Fars
Postal code
7187915998
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Web page address
https://amirhosp.sums.ac.ir

2

Recruitment center
Name of recruitment center
Imam Reza (AS) Specialized and Subspecialized Clinic
Full name of responsible person
Narges Rahimi
Street address
Imam Reza (AS) Specialized and Subspecialized Clinic, next to Namazi Hospital, Namazi Square, Shiraz
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Postal code
7134814734
Phone
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Email
emamreza@sums.ac.ir
Web page address
https://emamreza.sums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Dr. Seyed Basir Hashemi
Street address
Central Building of Shiraz University of Medical Sciences, Zand Street, Shiraz
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Phone
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Email
info@sums.ac.ir
Web page address
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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
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Narges Rahimi
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Neda Jamali Moghadam
Position
Assistant professor
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Ph.D.
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Phone
+98 71 3647 4254
Email
nedajamali21@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Narges Rahimi
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
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nargesrahimi.hr@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
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is 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

Yes - There is 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

Title and more details about the data/document

Data can be shared after de-identifying individuals.

When the data will become available and for how long

Six months after publication of the article

To whom data/document is available

Research team

Under which criteria data/document could be used

For the use of patients undergoing chemotherapy and to expand knowledge

From where data/document is obtainable

Research team

What processes are involved for a request to access data/document

Written request

Comments