Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the effect of aromatherapy with Citrus aurantium and chamomile extracts on sleep quality, insomnia severity in breast cancer patients undergoing chemotherapy

Protocol summary

Study aim

Comparison of the effect of aromatherapy with Citrus aurantium and chamomile extracts on sleep quality, insomnia severity in breast cancer patients undergoing chemotherapy

Design

A randomized, double-blind, controlled clinical trial conducted on 186 patients. Randomization was performed using the RAND function in Microsoft Excel.

Settings and conduct

By performing the pre-test and completing the demographic information questionnaire in the patients referred to Iran Mehr birjand Hospital, the groups: chamomile essential oil, spring orange essential oil and distilled water will be used in each group for 7 days. The sleep quality and insomnia severity questionnaire will be completed again at the end of the study. It is a three-way blind type, and the participants, data analysts, and outcome evaluators were not given and will not be informed about how the company was blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: No stressful events in the past six months, age range between 18 and 60 years, willingness to participate in the study, no use of aromatherapy in the past month, no allergic rhinitis, asthma, chronic pulmonary disease, sleep disorders, or other chronic illnesses that may affect the sense of smell, no history of allergy to herbal medicines, no use of sleeping medications, and being patients undergoing chemotherapy (during the second to fourth cycles of chemotherapy).

Intervention groups

Intervention group: pre-test, chamomile essential oil in one group, spring orange essential oil in one group, and distilled water in the other group will be used for 7 days in each group.

Main outcome variables

Investigating sleep quality and severity of insomnia in patients before and after the intervention in the intervention and control groups

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171013036747N4**
Registration date: **2025-08-04, 1404/05/13**
Registration timing: **prospective**

Last update: **2025-08-04, 1404/05/13**
Update count: **0**

Registration date

2025-08-04, 1404/05/13

Registrant information

Name

Rasool Solaimani Moghadam

Name of organization / entity

Birjand University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 5722 3028

Email address

rasool.solaimani@yahoo.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2025-08-21, 1404/05/30

Expected recruitment end date

2027-02-19, 1405/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of aromatherapy with Citrus aurantium and chamomile extracts on sleep quality, insomnia severity in breast cancer patients undergoing chemotherapy

Public title

Comparing the effect of aromatherapy on sleep quality and insomnia severity in patients with breast cancer

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

A lack of stressful events such as near-death or surgery in the last six months Age range from 18 to 60 years Having the consent to participate in the study Do not use the herbal remedy in the past month Not having allergic rhinitis, asthma, chronic pulmonary disease, sleep disorders and other chronic diseases that affect the sense of smell Lack of susceptibility to medicinal herbs Lack of sleeping pills Having breast cancer Patients undergoing chemotherapy (in the second to fourth cycles of chemotherapy)

Exclusion criteria:

Occurrence of stressful events: close lives, divorces and ... during the study Use sleep Palliative interventions during the study Symptoms of allergy to the fragrance used

Age

From **18 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Data and Safety Monitoring Board

Sample size

Target sample size: **186**

More than 1 sample in each individual

Number of samples in each individual: **1**

62 people are examined in each group

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible patients will be enrolled in the study using the accessible method and randomly assigned to one of the aromatherapy with spring orange or aromatherapy with chamomile control groups using a block design. Each block contains numbers one to eight. Each patient is assigned one of the numbers one to eight. A letter is assigned to each group (M) to the aromatherapy with spring orange group, A to the aromatherapy with chamomile group, and C to the control group. A sequence is created for a sample size of 186 people. For the process of concealing the random allocation, 30 opaque envelopes and 186 cards will be prepared. Eight cards are placed inside each envelope in order. The number of blocks is written on each envelope. The name of the desired group is written on each card in order. Patients are assigned to one of the study groups based on the aforementioned letters. The random blocks were prepared by a statistical consultant. The process of randomly assigning patients to the study groups is performed by the researcher. To generate a random sequence, permuted block randomization was used, generating eight blocks for four groups. The random sequence was generated online via www.sealedenvolope.com.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Participants, data analysts, outcome assessors, and the data and safety monitoring committee were not informed about the blinding procedure.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Birjand University of Medical Sciences

Street address

Birjand University of Medical Sciences , Ghafari Street, Birjand

City

Birjand

Province

South Khorasan

Postal code

971785377

Approval date

2022-10-22, 1401/07/30

Ethics committee reference number

IR.BUMS.REC.1401.285

Health conditions studied

1

Description of health condition studied

Cancer

ICD-10 code

Z85.8

ICD-10 code description

Personal history of malignant neoplasms of other organs and systems

2

Description of health condition studied
Sleep disorders
ICD-10 code
G47
ICD-10 code description
Sleep disorders

Primary outcomes

1

Description
sleep quality
Timepoint
Before and 7 days after the intervention
Method of measurement
Standard sleep quality questionnaire Pittsburgh

2

Description
Insomnia intensity
Timepoint
Before and 7 days after the intervention
Method of measurement
Standard sleep quality questionnaire Pittsburgh

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Chamomile essential oil from Oil Darou Company; At 10 pm, the patient inhales 5 deep breaths for 10 minutes at equal intervals, and a handkerchief soaked in essential oil that will emit the scent for at least 8 hours is attached to the front of the patient's clothing at a distance of 10-15 cm from the nose. In this way, the patient is exposed to aromatherapy from 10 pm to 6 am, and aromatherapy is performed every night for 7 days with patient training and researcher supervision. According to previous training, 3 drops are applied to a cotton ball that will be prepared in advance as a necklace. The dropper then places the cotton ball 20-25 cm from the patient's head so that the patient can inhale it during sleep (for 8 hours) and removes it from the neck after waking up and throws it away. At the end of the intervention, the Petersburg Sleep Quality and Insomnia Severity Questionnaire is completed again by the patient and through an interview.
Category
Rehabilitation

2

Description
Intervention group 2: Spring orange essential oil from Oil Daru Company; At 10 pm, the patient inhales the essential oil by taking 5 deep breaths for 10 minutes at equal intervals, and a handkerchief soaked in the essential oil that will emit the aroma for at least 8 hours is attached to the front of the patient's clothes at a distance of 10-15 cm from the nose. In this way, the patient is exposed to aromatherapy from 10 pm to 6 am, and aromatherapy is performed every night for 7 days with patient training and researcher supervision. According to the previous training, 3 drops are placed on a cotton ball that will be prepared in advance as a necklace, the dropper then places the cotton ball at a distance of 20-25 cm from the patient's head so that he can inhale it during sleep (for 8 hours) and after waking up, he removes it from his neck and throws it away. At the end of the intervention, the Petersburg Sleep Quality and Insomnia Severity Questionnaire is completed again by the patient and through an interview.
Category
Rehabilitation

3

Description
Control group: Distilled water; At 10 pm, the intervention is inhaled by the patient by taking 5 deep breaths for 10 minutes at equal intervals, and a handkerchief soaked in essential oil that will emit the aroma for at least 8 hours is attached to the front of the patient's clothing at a distance of 10-15 cm from the nose. In this way, the patient is exposed to aromatherapy from 10 pm to 6 am, and aromatherapy is performed every night for 7 days with patient training and researcher supervision. According to the previous training, 3 drops are applied to a cotton ball that will be prepared in advance as a necklace, the dropper is then placed 20-25 cm from the patient's head so that the patient can inhale it during sleep (for 8 hours) and after waking up, the cotton ball is removed from the neck and thrown away. At the end of the intervention, the Petersburg Sleep Quality and Insomnia Severity Questionnaire is completed again by the patient and through an interview.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Iranmehr Birjand Hospital
Full name of responsible person
Rasool Solaimani Moghaddam
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
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Ghaffari St
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Email
Research@bums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Birjand University of Medical Sciences
Proportion provided by this source
90
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
Birjand University of Medical Sciences
Full name of responsible person
Rasool Solaimani Moghaddam
Position
Nurse
Latest degree
Master
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Only part of the information, such as information on the main outcome or the like, can be shared
When the data will become available and for how long
10 months after printing results
To whom data/document is available
Researchers working in academia and academia
Under which criteria data/document could be used
Just statistical tests
From where data/document is obtainable
To receive the data, they can only send their application to the email address of the person responsible for the study E-mail:rasool.solaimani@yahoo.com
What processes are involved for a request to access data/document
After reviewing the ethics code of the respective research committee and the approval date and the university identification certificate of the applicant
Comments