Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparative evaluation of the effect of aromatherapy with the essential oils of lavender and peppermint on sleep quality of cancer patients admitted to Taleghani Hospital in Kermanshah, 2018

Protocol summary

Study aim

To determine the effect of aromatherapy with essential oils of lavender and peppermint on the sleep quality of cancer patients

Design

randomized controlled clinical trials

Settings and conduct

The study place is the oncology ward. Eligible patients will be select by convenience sampling and randomly assign in intervention(groups 1 and 2) and control groups.

Participants/Inclusion and exclusion criteria

The criteria for entering the study include the consent of the patient's physician and the informed consent of the patient to participate in the study; Having full consciousness ; positive reaction to smell; ability to answer questions; lack of physical pain; Stability of vital signs (blood pressure, pulse, respiration and temperature); Not having a history of psychiatric illness; aged 18-65 years; lack of sinusitis and nasal deformities and skin sensitivities; lack of addiction to cigarettes, drugs and alcohol; lack of clinical acute conditions such as nausea and vomiting; no history of respiratory problems such as asthma; Do not drink caffeine drink from an hour before the intervention; Earn points equal to or more than five from the Pittsburgh Sleep Quality Questionnaire. Exit criteria include Unwillingness to continue cooperation by the patient or his physician, transferring to another ward, receiving a narcotic drug during a aromatherapy, Oxygen administration for the patient , and occurrence of Crisis or unforeseen incident.

Intervention groups

Initially the quality of sleep questionnaire will be completed by patients. The study will perform for seven consecutive nights, at bedtime. In groups one and two, of essential oil of Peppermint and lavender will be used respectively and in group three sterile water will be use. The essential oils will be spilled onto the napkin and attached to the patient's clothes for 20 minutes. On the morning of the eighth day, Pittsburgh Sleep Quality Questionnaire will be completed again by the patients.

Main outcome variables

Quality of sleep

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100913004736N21**
Registration date: **2018-03-11, 1396/12/20**
Registration timing: **prospective**

Last update: **2018-03-11, 1396/12/20**
Update count: **0**

Registration date

2018-03-11, 1396/12/20

Registrant information

Name

Alireza Khatony

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date
2018-07-23, 1397/05/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative evaluation of the effect of aromatherapy with the essential oils of lavender and peppermint on sleep quality of cancer patients admitted to Taleghani Hospital in Kermanshah, 2018

Public title
The effect of aromatherapy with the essential oils of lavender and peppermint on sleep quality of cancer patients
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
The satisfaction of the patient's physician and the informed consent of the patient to participate in the study Having full consciousness positive reaction to smell Ability to answer questions The absence of any physical pain the stability of vital signs (blood pressure, pulse, respiration and temperature) having aged 18 to 65 years Lack of sinusitis and nasal septum deviation and skin sensitivities No addiction to drugs and alcohol and smoking The absence of acute clinical conditions such as nausea and vomiting Not having a history of respiratory problems such as asthma Do not drink caffeine drink from an hour before the intervention Earn points equal to or more than five from the Pittsburgh Sleep Quality Questionnaire Lack of primary tumor or metastasis in the central nervous system
Exclusion criteria:
Unwillingness to continue cooperation by the patient or his/her physician Transition to other wards Receiving narcotic during aromatherapy Oxygen administration for the patient Occurrence of Crisis or unforeseen incident
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **105**
Randomization (investigator's opinion)
Randomized
Randomization description
To do this, formulate the Excel software environment and generate random numbers of 5 digits. Anyone who enters the study is assigned a number, the last number on the right will be decisive. Patients with the last digits to the right of these numbers are 1, 2.3, will be in Lavender group.Patients whose last digit is 4, 5, 6, and Patients with a final digit of 7, 8, 9 will be assigned in the peppermint and control group respectively. ,
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
کمیته اخلاق دانشگاه علوم پزشکی کرمانشاه
Street address
Shahid Beheshty Blvd., Kermanshah University of Medical Sciences, Kermanshah, Iran
City
kermanshah
Province
Kermanshah
Postal code
6715847141
Approval date
2018-02-28, 1396/12/09
Ethics committee reference number
kums.rec.1395.647

Health conditions studied

1

Description of health condition studied
Cancer disease
ICD-10 code
Z85.8
ICD-10 code description
Personal history of malignant neoplasms of other organs and systems

Primary outcomes

1

Description
sleep quality; In this study, patients with a score of 5 or more from the Pittsburgh Questionnaire are enrolled in the study.
Timepoint
At the beginning of study and Eighth day
Method of measurement
Pittsburgh Sleep Quality Questionnaire will be used.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In group one , for seven nights before going to sleep at 22 o'clock, the three drops of Peppermint essential oil will be used. Colpermin' is a pharmaceutical brand name for peppermint oil and Its scientific name is Mentha piperita which is produced by Tehran Barich Essence Company. This essential oil will be used in pure form with a concentration of 100 percent. Major chemical compounds included Menthol, Menton and methyl acetate. Essential oils will be dropped by the dropper on napkins and is connected to the patient's clothing at the collar and inhaled for 20 minutes.

Category

Treatment - Other

2

Description

Intervention group: In group Two , for seven nights before going to sleep at 22 o'clock, the Three drops of lavender essential oil will be used. Trade name of this essence is lavender essential oil and its scientific name is Lavandula stoechas which is produced by Tehran Barich Essence Company. This essential oil will be used in pure form with a concentration of 100 percent. Major chemical compounds included are linalyl acetate and linalool. Essential oils will be dropped by the dropper on napkins and is connected to the patient's clothing at the Collar and inhaled for 20 minutes.

Category

Treatment - Other

3

Description

Control group: In this group, for seven nights before going to sleep at 22 o'clock, the three drops of distilled water will be used which is produced by Tehran Samen Company. Distilled water will be dropped by the dropper on napkins and is connected to the patient's clothing at the Collar and inhaled for 20 minutes.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani Hospital of Kermanshah

Full name of responsible person

Alireza Khatony

Street address

Kermanshah School of Nursing and Midwifery, Ashayer Street, Kermanshah

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Farid Najafi

Street address

Vice chancellor for research, Kermanshah University of Medical Sciences, Shahid Beheshty Blvd., Kermanshah, Iran

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Email

farid_n32@yahoo.com

Web page address

http://www.vc-research.kums.ac.ir/

Grant name

Thirty two million three hundred and Eighty thousand rials

Grant code / Reference number

2

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
Alireza Khatony

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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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
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is 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
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 on the main outcome of the study is available for sharing.

When the data will become available and for how long
Six months after the publication of the results in the form of the article

To whom data/document is available
Researchers working in academic institutions

Under which criteria data/document could be used
Only to conduct similar studies in other populations.

From where data/document is obtainable
Alireza Khatuni with below email address: akhatony@gmail.com and phone number 08338282102

What processes are involved for a request to access data/document
A week after receiving an email or phone call, it will take action.

Comments