

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 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)

##### Phone

+98 83 3827 9394

##### Email address

akhatony@kums.ac.ir

##### 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**

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

##### City

kermanshah

##### Province

Kermanshah

##### Postal code

6715847141

##### Phone

+98 83 3828 2102

##### Email

akhatony@gmail.com

## 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

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

6715847141

##### Phone

+98 83 3838 4185

##### Fax

+98 83 3838 4185

##### 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

**Street address**

kermanshah School of Nursing and Midwifery,  
Ashayer Street, Kermanshah, Iran

**City**

kermanshah

**Province**

Kermanshah

**Postal code**

67

**Phone**

+98 38279394

**Email**

akhatony@gmail.com

## Person responsible for scientific 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

**Street address**

Ashayer Sreet, Kermanshah School of Nursing and  
Midwifery, Kermanshah, Iran

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6714634698

**Phone**

+98 382789394

**Email**

akhatony@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Alireza Khatony

**Position**

associate professor

**Latest degree**

Ph.D.

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**Email**

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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**