Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The Investigation of effects of aromatherapy with lavender extract in comparison with placebo on the anxiety and sleep quality of the patients with COVID-19

Protocol summary

Study aim
Determining the effect of aromatherapy with lavender essential oil on anxiety and sleep quality in patients with COVID-19

Design
Clinical trial with control and intervention groups, single blind, randomized block using R software on 60 patients

Settings and conduct
This study will be performed on patients with Covid-19 hospitalized in the infectious ward of Afzalipour Hospital in Kerman.The type of blindness in this study is single blind, so that the statistician is not aware of the study groups and the data analyst does not know which data is related to the intervention group and which data is related to the control group.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Approved patients with Covid-19, Physical and mental ability to answer questions, Ability to understand and speak Persian, Being able to give informed consent. Non-inclusion criteria: Lack of a healthy sense of smell, Having a history of allergy to lavender essential oil, Having severe dyspnea, Use of sedatives and anti-anxiety drugs, and Suffering from sleep disorders, depression and anxiety before illness

Intervention groups
Intervention in this study includes aromatherapy with lavender essential oil for the intervention group. The intervention lasts 3 consecutive nights and each night lasts for 20 minutes. Distilled water is used in the control group.

Main outcome variables
Anxiety, sleep quality

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201020049088N1**
Registration date: **2020-11-15, 1399/08/25**
Registration timing: **registered_while_recruiting**

Last update: **2020-11-15, 1399/08/25**
Update count: **0**

Registration date
2020-11-15, 1399/08/25

Registrant information

Name
mehdi Alinejad motlagh

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 71 3823 1472

Email address
nu.mehdialinejad@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-11-05, 1399/08/15

Expected recruitment end date
2021-03-20, 1399/12/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Investigation of effects of aromatherapy with lavender extract in comparison with placebo on the

anxiety and sleep quality of the patients with COVID-19

Public title
The effects of aromatherapy on the anxiety and sleep quality of the patients with COVID-19
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Confirmed COVID-19 Physical and mental ability to answer questions Ability to understand and speak Persian Being able to give informed consent
Exclusion criteria:
Absence of healthy sense of smell Having a history of allergy to lavender essential oil Having severe dyspnea Use of sedatives and anti-anxiety drugs Suffering from sleep disorders, depression and anxiety before illness
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Block random allocation is used to assign the subjects to the intervention and control groups. In this method, blocks of size 4 are used, in each block two participant are in the intervention group and two participant are in the control group.
Blinding (investigator's opinion)
Single blinded
Blinding description
Blindness in this study is single blind, so that the statistician is not aware of the study groups and the data analyst does not know which data is related to the intervention group and which data is related to the control group.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Kerman University of Medical Sciences
Street address
Medical University Campus; Kerman University of Medical Sciences; Haft-Bagh Highway
City
Kerman
Province
Kerman
Postal code
7616913555
Approval date
2020-10-20, 1399/07/29
Ethics committee reference number
IR.KMU.REC.1399.423

Health conditions studied

1

Description of health condition studied
COVID-19
ICD-10 code
U07.1
ICD-10 code description
COVID-19, virus identified

Primary outcomes

1

Description
Anxiety
Timepoint
Before the intervention and after the intervention for 3 consecutive nights
Method of measurement
Spielberger state- trait anxiety

2

Description
sleep quality
Timepoint
Before the intervention and on the morning of the fourth day at the end of the intervention
Method of measurement
Verran and Snyder-Halpern Sleep Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: includes aromatherapy with lavender essential oil (Zardband company) for the intervention group. The intervention in 3 consecutive nights and lasts 20 minutes each night; For aromatherapy, 2 drops of 2% lavender essential oil will be dropped on a napkin and will be attached it to the patient's clothes near the nose.

Category
N/A

2

Description
Control group: on 3 consecutive nights and every night for 20 minutes; 2 drops of distilled water will be dropped on a napkin and will be attached it to the patient's clothes near the nose.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Afzalipour Hospital in Kerman
Full name of responsible person
Mohammad Hossein Mehrolhassani
Street address
Afzalipour Educational and Medical Center, next to Shahid Bahonar University, Imam Khomeini Highway, kerman
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Email
mhmhealth@gmail.com
Web page address
http://ah.kmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Abbas Pardakhti
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No 2, Research and Technology Deputy, Ibnsina avenue
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abpardakhty@kmu.ac.ir
Web page address
http://kmu.ac.ir/fa/vcrt
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Kerman 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
Kerman University of Medical Sciences
Full name of responsible person
Behnaz Bagherian
Position
Assistant Professor
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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
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable