

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 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

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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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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

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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

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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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