Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

The effect of Ocimum Hydro Alcoholic Extract on Cognitive Function and Sleep Quality in patients with Choronic Obstructive Pulmonary Disease: A randomized controlled clinical trial

Protocol summary

Study aim
The effect of basil extract on cognitive function and sleep quality of patients with chronic obstructive pulmonary disease

Design
Clinical trial with control group, with parallel groups, Triple blind, Randomized controlled trial

Settings and conduct
The intervention will be administration of basil and placebo extract for eight weeks (60 days).The study place is in Khorramabad city.

Participants/Inclusion and exclusion criteria
1) Male and female patients 40 to 80 years old and residing in Khorramabad city 2) Sleep disorder score above 5 (based on Pittsburgh Sleep Disorders Questionnaire) 3) Cognitive dysfunction score below 26 (based on Montreal Cognitive Impairment Questionnaire); 1) Patient worsening, unstable hemodynamic status, life-threatening arrhythmias 2) neurodegenerative diseases, cancer, acute infection and known mental disorders (anxiety, depression and delirium) 3) Need for sleep medications (such as benzodiazepines, etc.) during the study

Intervention groups
The capsules will be packed in 60 envelopes at a dose of 300 mg in two envelopes A and B and delivered to the two groups of patients at the lung clinic. The capsules (containing basil and placebo extract) will be taken by patients once a night, between 22-21pm, one to two hours before bedtime, and with a glass of water.

Main outcome variables
Cognitive performance score based on Montreal questionnaire; Sleep quality score based on Pittsburgh questionnaire, And he is in the specialized clinic of Shahid Rahimi Hospital.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150919024080N15**
Registration date: **2020-03-03, 1398/12/13**
Registration timing: **registered_while_recruiting**

Last update: **2020-03-03, 1398/12/13**
Update count: **0**

Registration date
2020-03-03, 1398/12/13

Registrant information

Name
Mohammad Gholami
Name of organization / entity
Lorestan University of Medical Sciences
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-12-22, 1398/10/01

Expected recruitment end date
2020-06-21, 1399/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The effect of Ocimum Hydro Alcoholic Extract on Cognitive Function and Sleep Quality in patients with Choronic Obstructive Pulmonary Disease: A randomized controlled clinical trial

Public title
The effect of Ocimum on sleep and cognitive function

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Male and female patients 40 to 80 years old and residing in Khorramabad city Sleep disorder with a high score of 5 (based on Pittsburgh Sleep Disorder Questionnaire) Cognitive dysfunction score below 26 (based on Montreal Cognitive Impairment Questionnaire) No history of allergy to ocimum extract Minimum literacy and ability to understand Persian language

Exclusion criteria:
Illness, unstable hemodynamic status, life-threatening arrhythmias Affected by neurological diseases, cancer, acute infection and known mental disorders (anxiety, depression and delirium) The need for sleep medications (such as benzodiazepines, etc.) during the study Hospitalization during the study Participate in other Nairobi yoga and meditation cardiopulmonary rehabilitation programs Sensitivity to ocimum Extract for 2 consecutive days during study and non-use of ocimum Extract Capsule

Age
From **40 years** old to **80 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **96**

Randomization (investigator's opinion)
Randomized

Randomization description
After baseline evaluations such as pulmonary function assessment tests by a pulmonary specialist, patients are included in the study according to inclusion and exclusion criteria. Then, they will be randomly divided into two treatment and control groups. Classification is done using a random number table. Classes by age (in the two age groups below A-50 and B-50 years and older) and literacy (A-read literacy has no web-literacy) It should be noted that the volume of each block is 4 cases, thus creating 6 different combinations of 4 blocks and randomly selecting the blocks.

Blinding (investigator's opinion)
Triple blinded

Blinding description
The capsules will be encoded by the individual as coders in two envelopes A and B. Patients will not be aware of the code allocation to the capsule envelope. Also, the researcher who provides the capsules to the clinic and the data analyst will not be aware of the contents of the envelope and the allocation of patients to the treatment and placebo groups.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Lorestan University of Medical Sciences

Street address
Iran University of Medical Sciences, Lorestan, Khorram Abad, 5 Km.

City
Khorram Abad

Province
Lorestan

Postal code
381351698

Approval date
2019-09-28, 1398/07/06

Ethics committee reference number
IR.LUMS.REC.1398.163

Health conditions studied

1

Description of health condition studied
Chronic obstructive pulmonary disease

ICD-10 code
J44

ICD-10 code description
Other chronic obstructive pulmonary disease

Primary outcomes

1

Description
Cognitive performance score

Timepoint
Before the intervention, and one week after the 60-day treatment period

Method of measurement
Montreal Cognitive Impairment Questionnaire

2

Description
Quality of sleep score
Timepoint
Before the intervention, and one week after the 60-day treatment period
Method of measurement
Pittsburgh Sleep Quality Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this group, 60 basil capsules will be taken by patients at a dose of 300 mg once daily at 22-22 hours, one to two hours before bedtime, and with a glass of water.The drug was developed at the Razi Plant Research Center under the supervision of Lorestan University of Medical Sciences.
Category
Other

2

Description
Control group: In this group, placebo capsules (containing corn flour) will be administered by 60 patients at a dose of 300 mg once a night between 22-21pm, one to two hours before bedtime, and with a glass of water by patients.The placebo was built at the Razi Plant Research Center under the supervision of Lorestan University of Medical Sciences.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Specialty Clinic of Shahid Rahimi Hospital
Full name of responsible person
Seyed Reza Hosseini Fard
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Khorramabad - Freedom Square - Mojahedin Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Khoram-Abad University of Medical Sciences
Full name of responsible person
Ebrahim Falahi
Street address
km 5 Road of Khorram Abad - Boroujerd - opposite to the Kahrizak village- Integrated Lorestan Medical Sciences Khoramabad, Lorestan, Iran
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Web page address
http://research.lums.ac.ir/index.php?module=web_directory&wd_id=4664
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Khoram-Abad University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
Khoram-Abad University of Medical Sciences
Full name of responsible person
Seyed Reza Hosseini Fard
Position
Undergraduate Student
Latest degree
A Level or less
Other areas of specialty/work
Nursery
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Person responsible for scientific inquiries

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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
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available