Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of aromatherapy massage on fatigue and quality of sleep in Chronic Obstructive Pulmonary Disease patients

Protocol summary

Study aim
The purpose of this study was to evaluate and compare the impact of massage using lavender essence oil, orange essence oil and no oil on fatigue and quality of life sleep in chronic obstructive pulmonary disease patients

Design
The purpose of this study was to evaluate and compare the impact of massage using lavender essence oil, orange essence oil and no oil on fatigue and quality of life in chronic obstructive pulmonary disease. 105 patients were randomly divided into control and 3 intervention groups.

Settings and conduct
Intervention: Massage will be done with the hand thenar and thumb finger with a brief compression, starting from the heel to the fingers, with use of noshad chamomile oil in group one and noshad almond oil in group two and no use of oils in group three for 10 Minutes for every foot. Name of recruitment center: Shahid Modarres Hospital Kashmar

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1- Having Chronic Obstructive Pulmonary Disease Based On Internal Medicine Recognition 2-Having a Sleep Disorder , According To Pittsburgh Sleep Quality Questionnaire Score (Total Score Higher Than 5) Exclusion Criteria: 1-Non-Use Of Hypnotics And Anti-Anxiety Drugs 2-Lack 0f Respiratory Tract Infection

Intervention groups
Intervention group1: Massage will be done with the hand thenar and thumb Finger, start from the heel to the toes using 3 cc of lavender essence oil for 10 Minutes for every Foot. Intervention group2: Massage will be done with the Hand Thenar and Thumb Finger, start from the heel to the toes with use of 3 cc of orange essence oil for 10 Minutes brief pressure for every Foot. Intervention group 3: Massage will be done with the hand thenar and thumb Finger, start from the heel to the toes without use of oils for 10 Minutes brief pressure for every Foot.

Main outcome variables
Sleep Quality; Fatigue

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221005056098N1**
Registration date: **2022-10-23, 1401/08/01**
Registration timing: **prospective**

Last update: **2022-10-23, 1401/08/01**
Update count: **0**

Registration date
2022-10-23, 1401/08/01

Registrant information

Name
Reza Mohammadpourhodki

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 5542 1289

Email address
mohammadpourhr@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-11-16, 1401/08/25

Expected recruitment end date
2023-03-16, 1401/12/25

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of aromatherapy massage on fatigue and quality of sleep in Chronic Obstructive Pulmonary Disease patients

Public title

Effect of aromatherapy massage on fatigue and quality of sleep in Chronic Obstructive Pulmonary Disease patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Having chronic obstructive pulmonary disease Age 30 to 60 years old Having healthy feet Ability to tolerate foot massage Ability to tolerate massage

Exclusion criteria:

Specific disease (diabetes and stroke and asthma) Use sleeping pills and anti-anxiety drugs Infection of the respiratory system

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **105**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation sequences will be developed using the SPSS software by a statis- tician to select random permuted blocks (block size of 6). Then, samples were randomly assigned to three groups (aromatherapy massage with Lavender essential oil, aromatherapy massage with Citrus Aurantium essential oil, and control group).

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Knowledge and Health City – In the end of Shahid Fakouri Blvd (In front of Fakouri 94) – Mashhad - Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9716591778

Approval date

2022-06-11, 1401/03/21

Ethics committee reference number

IR.MUMS.REC.1401.055

Health conditions studied

1

Description of health condition studied

Chronic Obstructive Pulmonary Disease

ICD-10 code

J44.9

ICD-10 code description

Chronic obstructive pulmonary disease, unspecified

Primary outcomes

1

Description

Sleep Quality

Timepoint

Before the study (before the intervention) and five days after the intervention

Method of measurement

Pittsburgh Sleep Quality Index

2

Description

Fatigue

Timepoint

Before the study (before the intervention) and five days after the intervention

Method of measurement

With Use Of FSS Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group1: Massage will be done with the Hand Thenar and Thumb Finger, start from the heel to the toes using 3 cc of Noshad chamomile oil

for 10 Minutes for every Foot.

Category

Treatment - Other

2

Description

Intervention group: Intervention group2: Massage will be done with the Hand Thenar and Thumb Finger, start from the heel to the toes with use of 3 cc of Noshad Almond oil for 10 Minutes brief pressure for every Foot.

Category

Treatment - Other

3

Description

Control group: Intervention group 3: Massage will be done with the Hand Thenar and Thumb Finger, start from the heel to the toes without use of oils for 10 Minutes brief pressure for every Foot.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Modarres Hospital

Full name of responsible person
Reza Mohammadpourhodki

Street address
Shahid Modarres

City
Kashmar

Province
Razavi Khorasan

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+98 51 5522 1440

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rezamdpoor@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Majid Ghayour

Street address
Knowledge and Health City – In the end of Shahid Fakouri Blvd (In front of Fakouri 94) – Mashhad - Iran

City
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Email
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Reza Mohammadpourhodki

Position
Educator

Latest degree
Master

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Reza Mohammadpourhodki

Position
Educator

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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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