

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Evaluation the effect of jujube and lemon balm extract accompanying anxiety symptoms and respiratory symptoms in patients with chronic obstructive pulmonary disease (COPD)

Protocol summary

Study aim

Evaluation the effect of jujube and lemon balm extract accompanying anxiety symptoms and respiratory symptoms in patients with chronic obstructive pulmonary disease

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 60 patients. Randomization with a table of random numbers and Random Allocation Software.

Settings and conduct

60 patients with chronic obstructive pulmonary disease referred to Imam Reza Hospital's lung clinic, treated with standard drugs, with anxiety without the need for drug treatment, were selected. In the intervention group, 750 mg capsules containing hydroalcoholic extract of jujube and lemon balm are added to the treatment regimen twice a day for 6 weeks; In the control group, capsules containing Avicel are added. First, the level of anxiety will be checked with hospital anxiety questionnaire (HADS) and Spielberger (STAI), respiratory status with physical tests and breathing questionnaire. Questionnaires and tests will be repeated in the 3rd and 6th week. The quality of life questionnaire will be done at the beginning and end of the study. The study is double-blind (researcher and patients) and patients are divided into intervention and control groups by randomization.

Participants/Inclusion and exclusion criteria

Inclusion criteria: People aged 40 to 70 years with confirmed COPD without known anxiety disorder, who have a score of 8 and above based on the HADS questionnaire; exclusion criteria: pregnancy and breastfeeding severe anxiety requiring classical treatment Known anxiety or mood disorder requiring psychiatric treatment

Intervention groups

Intervention group: Adding jujube and lemonbalm extract

in the form of 750 mg capsules twice a day for 6 weeks to medicines. Control group: adding a placebo capsule (Avisel) for 6 weeks.

Main outcome variables

Anxiety, respiratory symptoms (cough, shortness of breath, sputum)

General information

Reason for update

Modifying the start time of patient admission

Acronym

IRCT registration information

IRCT registration number: **IRCT20220628055302N1**

Registration date: **2022-07-23, 1401/05/01**

Registration timing: **prospective**

Last update: **2023-02-14, 1401/11/25**

Update count: **1**

Registration date

2022-07-23, 1401/05/01

Registrant information

Name

samane mousapour

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-28, 1401/11/08

Expected recruitment end date

2024-01-28, 1402/11/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of jujube and lemon balm extract accompanying anxiety symptoms and respiratory symptoms in patients with chronic obstructive pulmonary disease (COPD)

Public title

Evaluation the effect of jujube and lemon balm extracts in patients with chronic obstructive pulmonary disease

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

People aged 40 to 70 with COPD, whose disease has been confirmed by a lung specialist COPD patients who did not have a known anxiety disorder and were not under standard psychiatric treatment, but had a score of 8 or higher based on the HADS questionnaire People who are satisfied with traditional treatment

Exclusion criteria:

Pregnancy and breastfeeding A history of severe anxiety that requires classical medical treatment People who are under the supervision of a psychiatrist or take psychiatric medication due to a known anxiety or mood disorder People who have severe anxiety in the screening tests will be referred to a psychiatrist for diagnostic evaluation and standard treatment Suffering from other medical diseases including hypothyroidism

Age

From **40 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly divided into Intervention and control groups in blocked randomization model by using the random numbers table and Random Allocation Software. 16 blocks of 4 will be produced and the sequence produced by the design statistician will be placed in opaque sealed envelopes and numbered, respectively.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, researcher and outcome assessor are unaware of the individuals assigned to the intervention and control group. Clinical supervisor and sample allocator to the groups are aware of the control and intervention group. The drug used in both intervention and control groups will be similar in terms of shape and appearance.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

The Ethics Committee of Mashhad University of Medical Sciences

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Mashhad University Of Medical Sciences, University Street
The Ethics Committee of Mashhad University of Medical Sciences

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Province

Razavi Khorasan

Postal code

13944-91388

Approval date

2022-06-11, 1401/03/21

Ethics committee reference number

IR.MUMS.REC.1401.076

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**

Anxiety score in HADS anxiety subscale questionnaire

Timepoint

At the beginning of the study (before the intervention) and the 3rd and 6th week

Method of measurement

HADS anxiety subscale questionnaire

2

Description

Anxiety score in Spielberger's Clear and Hidden Anxiety Questionnaire (STAI)

Timepoint

At the beginning of the study (before the intervention) and the 3rd and 6th week

Method of measurement

Spielberger state anxiety questionnaire

3

Description

CAT score

Timepoint

At the beginning of the study (before the intervention) and the 3rd and 6th week

Method of measurement

CAT test

Secondary outcomes

1

Description

distance traveled in the 6MWT

Timepoint

At the beginning of the study (before the intervention) and the 3rd and 6th

Method of measurement

6-minute walk test (6MWT)

2

Description

Number of times sitting and getting up in the chair

Timepoint

At the beginning of the study (before the intervention) and the 3rd and 6th

Method of measurement

1-min sit-to-stand test (STST)

3

Description

Blood oxygen saturation (SaO2)

Timepoint

At the beginning and end of each round of the (STST) and (6MWT)

Method of measurement

Pulse oximeter device

4

Description

Pulse rate

Timepoint

At the beginning and end of each round of the (STST) and (6MWT)

Method of measurement

Pulse oximeter device

5

Description

Quality of Life score on WHO Quality of Life Questionnaire (Bref-WHOQoL)

Timepoint

Before and after intervention

Method of measurement

WHO Quality of Life Questionnaire

Intervention groups

1

Description

Intervention group: Hydroalcoholic extract of jujube and lemonbalm in the form of capsules 750 mg twice a day for 6 weeks

Category

Treatment - Drugs

2

Description

Control group: placebo(Avisel) capsule for 6 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Lung Clinic of Imam Reza Hospital

Full name of responsible person

Mahnaz Mozdurian Mahdi Abad

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Imam Reza Hospital, Imam Reza Square, Mashhad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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http://v-research.mums.ac.ir

Grant name**Grant code / Reference number**

4001898

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

Samane Mousapoor

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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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