

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

Investigating the impact of continuous care model on lifestyle and self-care of patients with chronic obstructive pulmonary disease(COPD)

Protocol summary

Study aim

Investigating the impact of continuous care model on lifestyle and self-care of patients with chronic obstructive pulmonary disease

Design

The clinical trial is a blind and has a control and intervention group for 70 patients. A table of random numbers was used for randomization.

Settings and conduct

The study is carried out in the respiratory departments of Amir al-Mominin Hospital in Zabul and then in the patients' homes. Initial sampling is done from the hospital departments, and if the patient is discharged, the follow-up is done at home, and the intervention is implemented for three months.

Participants/Inclusion and exclusion criteria

Over 40 years old Suffering from chronic obstructive pulmonary disease, diagnosis confirmed by a specialist doctor Availability of the patient for a period of 3 months and obtaining informed consent to participate in the study Having a history of more than one year of illness Being literate in reading and writing

Intervention groups

In this study, the continuous care model, which is an Iranian model, is implemented for three months in the intervention group, and the control group receives routine care.

Main outcome variables

lifestyle, self-care

General information

Reason for update

Acronym

chronic obstructive pulmonary disease(COPD)

IRCT registration information

IRCT registration number: **IRCT20230711058740N1**

Registration date: **2023-09-02, 1402/06/11**

Registration timing: **prospective**

Last update: **2023-09-02, 1402/06/11**

Update count: **0**

Registration date

2023-09-02, 1402/06/11

Registrant information

Name

Tayebe Sargazi shad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3223 7998

Email address

t.sargazi.shad@zbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-06, 1402/06/15

Expected recruitment end date

2023-09-23, 1402/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the impact of continuous care model on lifestyle and self-care of patients with chronic obstructive pulmonary disease(COPD)

Public title

Investigating the impact of continuous care model on lifestyle and self-care of patients with chronic obstructive pulmonary disease

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 40 years Having chronic obstructive pulmonary disease and confirming diagnosis by a doctor A history of more than one year of illness Being literate in reading and writing Availability of the patient for 3 months and obtaining informed consent to participate in the study

Exclusion criteria:

Age

From 40 years old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: 70

Randomization (investigator's opinion)

Randomized

Randomization description

After checking the conditions for entering the study and selecting the eligible patients, they are classified into two intervention and control groups using a random number table.

Blinding (investigator's opinion)

Single blinded

Blinding description

After checking the conditions for entering the study and obtaining informed consent, patients are classified into intervention and control groups using a random number table, and the participants do not know which group they are in, and the intervention group receives care related to the study. and the control group receives routine care.

Placebo

Not used

Assignment

Other

Other design features

After checking the conditions of entry into the study and obtaining informed consent, the patients are randomly divided into two intervention and control groups, and the intervention group receives the follow-up care model, and the control group receives routine care. Then the results of the two groups are compared.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Zabul University of Medical Sciences

Street address

Deputy of research and technology; first floor., Zabul

University of Medical Sciences educational complex., health intersection., Shahid Rajae St.

City

Zabol

Province

Sistan-va-Balouchestan

Postal code

9861615881

Approval date

2023-06-07, 1402/03/17

Ethics committee reference number

IR.ZBMU.REC.1402.047

Health conditions studied

1

Description of health condition studied

Chronic obstructive pulmonary disease

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Lifestyle

Timepoint

Before the intervention, three months after the intervention

Method of measurement

Miller-Smith Lifestyle Questionnaire 1988

2

Description

Self care

Timepoint

Before the intervention and three months after the intervention

Method of measurement

Miller 1982 self-care behavior questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The continuous care model is an Iranian model that is implemented for three months for the intervention group and includes three stages. In the first phase, one face-to-face training session every week for a month, and in the second phase, four calls per week for consultation and follow-up, and in the third phase, for a month, the patient implements the provided care and training, and if needed, in all The researcher will be contacted for consultation.

Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir al-Mominin Hospital, Zabul

Full name of responsible person

Dr. Abili

Street address

Respiratory department., Amiral Mominin hospital.,
Parastar St., Zabul city

City

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9861979917

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Email

t.sargazishad@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zabol University of Medical Sciences

Full name of responsible person

Dr. Hadi Mirzaei

Street address

Deputy of research and technology; first floor., Zabul
University of Medical Sciences educational complex.,
health intersection., Shahid Rajaei St.

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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

Zabol University of Medical Sciences

Proportion provided by this source

80

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

Zabol University of Medical Sciences

Full name of responsible person

Tayebe sargazi shad

Position

Lecturer of clinical education

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

6th door on the left., 13th alley., South Imam
Khomeini street

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Zabol University of Medical Sciences

Full name of responsible person

Tayebe sargazi shad

Position

Lecturer of clinical education

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Other areas of specialty/work

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Person responsible for updating data

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Contact

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Email

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

Not applicable