

# 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 Rajaei 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**

زابل

**Province**

Sistan-va-Balouchestan

**Postal code**

9861979917

**Phone**

+98 54 3421 1300

**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.

**City**

Zabol

**Province**

Sistan-va-Balouchestan

**Postal code**

9861615881

**Phone**

+98 54 3223 0768

**Email**

pr@zbmu.ac.ir

**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

**City**

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**Province**

Sistan-va-Balouchestan

**Postal code**

9861868447

**Phone**

+98 54 3223 7998

**Email**

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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**

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## Person responsible for updating data

t.sargazishad@gmail.com

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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