

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of continuous care model and routine care on self-efficacy of patients with chronic obstructive pulmonary disease

Protocol summary

Study aim

To determine the effect of using the contentious care model on the self-efficacy of patients with COPD

Design

Randomized double blind clinical trial with control group and parallel group design, on 84 patients. For randomization, Randomizer will be used.

Settings and conduct

Research environment: Internal ward of all educational and medical centers of Gorgan, includes 5Azar and Sayyad Medical and Educational Centers; Study population: All patients with chronic obstructive pulmonary disease; Type of blinding: Double blind; Method of blinding: Blinding will be done for patients. Also the researcher and the outcome assessor will be also unaware of the allocation of patients into the groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Able to write and read; ability to communicate; confirmation of the diagnosis of COPD by a physician; ability to perform the daily activities: history of hospitalization at least once with a diagnosis of COPD; having a smart phone. Non-inclusion criteria: Having malignant disease and psychiatric disorders; history of participating in educational program with similar content

Intervention groups

Intervention group: Patients with chronic obstructive pulmonary disease under follow-up care; Control group: Patients with chronic obstructive pulmonary disease under routine care

Main outcome variables

Self-Efficacy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140412017237N13**

Registration date: **2021-09-24, 1400/07/02**

Registration timing: **registered_while_recruiting**

Last update: **2021-09-24, 1400/07/02**

Update count: **0**

Registration date

2021-09-24, 1400/07/02

Registrant information

Name

Mahnaz Modanloo

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

2021-09-21, 1400/06/30

Expected recruitment end date

2022-05-22, 1401/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of continuous care model and routine care on self-efficacy of patients with chronic obstructive pulmonary disease

Public title

Continuous care and self-efficacy of patients with COPD

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Ability to write and read Ability to communicate Ability to perform the daily activities Having a smart phone
Obtaining low and medium scores from the self-efficacy questionnaire

Exclusion criteria:

Lack of known psychiatric disorder History of participation in an educational course with the same content

AgeFrom **18 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample sizeTarget sample size: **84****Randomization (investigator's opinion)**

Randomized

Randomization description

By referring to the Randomization.com website and using the block randomization method (block of size 4), a list of random numbers is produced by one of the members of the research team who will not aware of the process of entering the groups (sample size of 84 people, in two groups A - B). Then the letters A and B will be written on the cards and placed in the sequentially numbered, sealed, opaque envelopes (1 to 84). After checking the inclusion criteria, the participants will receive the relevant envelope, respectively, and they will be allocated into two intervention (A) and control (B) groups according to the card in the envelopes.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is a double blind trial. Blinding will be done for patients. Also the researcher and the outcome assessor will be also unaware of the allocation of patients into the groups. In this study for random sequence generation, 84 eligible patients will be recruit using Permuted Block Randomization (25 blocks of size 4) through Randomization.com. in order to conceal of sequence of randomization, based on a created list, A (for intervention group) and B (for control group) letter will be written on cards and the they will put in the sequentially numbered, sealed, opaque envelopes. Then the envelopes will be numbered from 1 to 84 and will consider for eligible patients sequentially that they will be close till applying intervention.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Golestan University of Medical Sciences

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Deputy of Research and Technology, Golestan University of Medical Sciences, Hirkan Boulevard

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Approval date

2021-07-18, 1400/04/27

Ethics committee reference number

IR.GOUMS.REC.1400.101

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**

The level of Self-efficacy

Timepoint

Before intervention, immediately after intervention and one months after intervention

Method of measurement

COPD Self-Efficacy Scale

Secondary outcomes**1****Description**

Number of rehospitalization

Timepoint

Record the number of readmissions of patients two and

three months after discharge
Method of measurement
Patient clinical information registration form

Intervention groups

1

Description

Intervention group: The patients in intervention group will access to the Link of educational content in the developed site. The educational content consists of a lung rehabilitation program for patients with chronic obstructive pulmonary disease that will be implemented face-to-face for 2 months based on 4 steps of continuous care model including Orientation, Sensitization, Control and Evaluation. The follow up will be done weekly for 5 weeks.

Category

Behavior

2

Description

Control group: Patients in control group will receive routine care without any intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

5 Azar Medical and Educational Center

Full name of responsible person

Ali Ariannia

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2

Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

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Grant name

Grant code / Reference number

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

Person responsible for general inquiries

Contact

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Mahnaz Modanloo

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

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inquiries.

What processes are involved for a request to access data/document

The data will be available through email.

Comments

Please contact to both email address:
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