Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of self-management program on anxiety and depression of people with chronic obstructive pulmonary disease

Protocol summary

Study aim

The main goals of the project: Determining the effect of self-management program on anxiety and depression in people with chronic obstructive pulmonary disease objectives of the project: - Comparison of anxiety in control and intervention groups before the intervention - Comparison of depression in control and intervention groups before the intervention - Comparison of anxiety of control and intervention groups three months after the intervention - Comparison of depression of control and intervention groups three months after the intervention

Design

The present study is a double-blind randomized clinical trial study.

Settings and conduct

Participants will be selected from the hospitals of Hazrat Rasool Akram (PBUH) of Iran University of Medical Sciences and Imam Khomeini Hospital of Tehran University of Medical Sciences. Then, the questionnaires will be completed by the patients. Data collection tools include a demographic information questionnaire and a hospital anxiety and depression questionnaire. The researcher will then teach self-management skills to intervention group members. Three months after the intervention, the questionnaires will be completed again by the members of the control and testing group to examine the impact of the interventions in both groups.

Participants/Inclusion and exclusion criteria

Entry : Having chronic obstructive pulmonary disease Not Entry : having a life-threatening illness

Intervention groups

The researcher will educate the self-management skills to intervention group members, and control group members will receive only common training in the department. In the intervention group, face-to-face training will be given to individuals. Educational aids such as displaying images and videos on a laptop or mobile phone and various forms of pills and inhalers will also be used for training.

Main outcome variables

Depression and Anxiety

General information

Reason for update

Due to the termination of the study, the study information was updated. Due to the spread of corona disease and difficult access to respiratory patients, the start of the study and the first sampling was delayed by one year.

Acronym

IRCT registration information

IRCT registration number: **IRCT20160704028781N4**
Registration date: **2020-05-14, 1399/02/25**
Registration timing: **prospective**

Last update: **2023-02-15, 1401/11/26**
Update count: **1**

Registration date

2020-05-14, 1399/02/25

Registrant information

Name

Farshad Heidari Beni

Name of organization / entity

Iran Univercity of Medical Science

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-09, 1399/03/20

Expected recruitment end date
2022-08-11, 1401/05/20
Actual recruitment start date
2020-06-09, 1399/03/20
Actual recruitment end date
2022-08-11, 1401/05/20
Trial completion date
2022-08-11, 1401/05/20

Scientific title
The effect of self-management program on anxiety and depression of people with chronic obstructive pulmonary disease

Public title
The effect of self-management on anxiety and depression of people with chronic obstructive pulmonary disease
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Confirmation of the disease by the specialist physician having the ability to understand and speak and read and write in Persian having the physical ability to interview and complete the questionnaire not participating in previous self-management programs for chronic obstructive pulmonary disease lack of hearing problems and problems Disruption of communication non-use of anti-anxiety or anti-depressant drugs 45 to 70 years age
Exclusion criteria:
Having a life-threatening illness
Age
From **45 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **100**
Actual sample size reached: **91**
Randomization (investigator's opinion)
Randomized
Randomization description
Allocation of samples in groups will be by random blocks without being replaced in each center. For this purpose, first the letter A for the control group and the letter B for the intervention group are considered and different modes of the two groups are written on the cards and each of them is placed in a closed and opaque envelope. These envelopes are placed in a box and before selecting the card, the researcher does not know the participants will be palace in what group. The statistician (unaware of the study and the groups) with picking up one of the envelopes from the box, will determines the patients entering the study will be in which group, respectively. This process is continued until all the cards are taken out of the box and the cards are returned to the box again and this random selection is repeated to provide the desired sample size. To cover the random allocation, the blocks with different numbers will be used, ie six blocks and two blocks will be entered into the blocks. The six blocks can be a combination of ABBABA and so on. Double blocks can also include AB, BA.
Blinding (investigator's opinion)
Double blinded
Blinding description
Outcome evaluators and data analysts are unaware of the allocation of study groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of School of Nursing and Midwifery & Rehabilitation - Tehran University of Medical
Street address
School of Nursing Midwifery ,Tehran University of Medical Sciences, Nosrat st. Tohid sq. Tehran I.IRAN
City
Tehran
Province
Tehran
Postal code
141973317
Approval date
2019-12-05, 1398/09/14
Ethics committee reference number
IR.TUMS.FNM.REC.1398.155

Health conditions studied

1

Description of health condition studied
Chronic obstructive pulmonary disease
ICD-10 code
J44
ICD-10 code description
Other chronic obstructive pulmonary disease

Primary outcomes

1

Description
The level of depression
Timepoint
Before the intervention, Six months after the intervention

and Twelve months after the intervention

Method of measurement

Hospital Anxiety and Depression Questionnaire (HADS)

2

Description

The level of anxiety

Timepoint

Before the intervention, Six months after the intervention and Twelve months after the intervention

Method of measurement

Hospital Anxiety and Depression Questionnaire (HADS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The researcher will educates the self-management skills to the intervention group members. In this group, the education will be given face-to-face. Educational aids such as displaying images and videos on a laptop or mobile phone and various forms of pills and inhalers will also be used for training. Educational content includes self-management training for chronic obstructive pulmonary disease, which includes introducing the patient, introducing and expressing the importance of self-management, drug information required in this disease, prevention and management of relapses, exercise and physical activity in the disease, reduction methods. Shortness of breath, energy-saving techniques, airway cleansing techniques, and proper nutrition in chronic obstructive pulmonary disease. The content of the training program will be guided by the guidelines for patients with chronic lung obstruction written by the Australian Lung Association, which has been approved by faculty members of the Department of Surgery, School of Nursing and Midwifery, Iran. The number of education sessions will include four two-hour sessions on consecutive days. After the first session in each session, first, the contents of the previous session will be reviewed for 30 minutes and answer the patients' questions, and then new content will be presented. Intervention group members will be contacted every two weeks to ensure that they perform the self-management interventions correctly.

Category

Rehabilitation

2

Description

Control group: They will only receive routine care and will not receive any additional education.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Rasool Akram Hospital (PBUH) of Iran University of Medical Sciences and Imam Khomeini Hospita

Full name of responsible person

Farshad Heidari-Beni

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Nahid Dehghan Nayeri

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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

Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Farshad Heidari-Beni
Position
Student
Latest degree
Master
Other areas of specialty/work
Nursery
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Is confidential
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not 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

Trial results

Please tick if results have been published
Yes
Summary result posting date
2023-02-15, 1401/11/26

Table of baseline comparison

The mean age in the control group was 61.21 and in the intervention group was 60.11 years. The majority in both groups were male, in stage 3 of the disease, and ex-smoker. The mean pack/year in the control group was 33.14 and in the intervention group was 33.42. More than two-thirds of both groups have a comorbidity, and cardiovascular disease was the common comorbidity. There were no significant differences between groups in age, sex, BMI, smoking status, pack/year, stage, comorbidity, cardiovascular diseases, metabolic diseases, respiratory diseases, other diseases, CAT score, and mMRC Score.

The mean anxiety score in the control group was 10.17 ± 5.06 and in the intervention group was 9.66 ± 5.03. There were no significant differences between groups in the anxiety domain of HADS at baseline (p=630).

The mean depression score in the control group was 8.66 ± 4.76, and in the intervention group was 8.20 ± 4.67 at baseline; there was no significant difference between groups (p=0.647).

Participant flow diagram

CONSORT 2010 Flow Diagram

Enrollment

Assessed for eligibility (n=341)

Excluded (n=241)

Not meeting inclusion criteria (n=177)

Decline to participate (n=64)

Randomized (n=100)

Allocation

Allocated to control group (n=50)

Received routine care (n=50)

Allocated to intervention group (n=50)

Received routine care (n=50)

Received self-management education (n=50)

Follow-Up

Lost to follow-up (n=6)

Lost to follow-up (n=3)

Analysis

Analysed (n=44) ¨ Excluded from analysis (n=0)

Analysed (n=47) ¨ Excluded from analysis (n=0)

Table of variable outcomes' results

Six months later, the mean anxiety score in both groups decreased, and the control group was 9.85 ± 5.25. The intervention group was 7.14 ± 4.32, and there were significant differences between groups, and the intervention group was lower than the control group (p=0.009). Twelve months later, the mean anxiety domain score of HADS was 9.62 ± 4.93 in the control group and 7.89 ± 4.55 in the intervention group. Although the anxiety score was decreased in the intervention group than in the control group, there were no significant differences between anxiety score groups

(p=0.086).

The mean depression score was 8.91 ± 4.80 in control and 6.25 ± 3.76 in the intervention groups six months later and 9.04 ± 4.86 in the control group, and 6.23 ± 3.67 in the intervention group twelve months later. There were significant differences between groups at both times (p=0.004 and 0.002, respectively).

Table of adverse events

First publication date

empty

Abstract of published paper