Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of follow-up nurse plan and its effect on disease severity and dyspnea in patients with chronic obstructive pulmonary disease (COPD)

Protocol summary

Study aim
Evaluation of follow-up nurse plan and its effect on disease severity and dyspnea in patients with COPD

Design
A randomized, parallel- group controlled clinical trial on 88 patients. The randomization list will determine using a web-based randomization program.

Settings and conduct
The study location: Allameh Bohlool Hospital The Intervention group: The frequency of follow-up of patients is determined based on the severity of the disease and the symptoms from three days to three months after discharge as follows: 1. The "Green area": once a month; 2. The "Yellow area": once a week; 3. The "Red area": Advising to go to the hospital emergency department immediately; follow-up by phone up to 6 hours later; follow-up twice a week after discharge from the hospital until they will be set at the "Green area". Note: The frequency of follow-up could be determined by the relevant doctor's order. The control group will receive routine hospital training and follow-up. In order to preserve ethics, at least one routine follow-up will be done in the control group.

Participants/Inclusion and exclusion criteria
Definitive diagnosis of COPD; referring to the hospital's self-care and follow-up unit after discharge; being conscious; shortness of breath score more than 3 on the Borg scale; informed consent; resident of Gonabad city; access to landline or mobile; no speech, hearing and vision disorders and the ability to understand and answer questions; no history of mental illness

Intervention groups
This study has two intervention and control groups. In the intervention group, the frequency of follow-up of patients is determined from three days to three months after discharge based on the severity of the disease and the symptoms, or based on the relevant doctor's order. The control group will receive routine hospital training and follow-up.

Main outcome variables
Disease severity; dyspnea

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191223045868N2**
Registration date: **2022-05-27, 1401/03/06**
Registration timing: **prospective**

Last update: **2022-05-27, 1401/03/06**
Update count: **0**

Registration date
2022-05-27, 1401/03/06

Registrant information

Name
Fatemeh Mohammadzadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 5722 5213

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-06-10, 1401/03/20

Expected recruitment end date
2022-12-11, 1401/09/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of follow-up nurse plan and its effect on disease severity and dyspnea in patients with chronic obstructive pulmonary disease (COPD)

Public title
Evaluation of follow-up nurse plan and its effect on disease severity and dyspnea in patients with chronic obstructive pulmonary disease (COPD)

Purpose
Health service research

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with definitive diagnosis of COPD by a specialist Referring to the hospital's self-care and follow-up unit after discharge Being conscious Moderate to severe shortness of breath (Shortness of breath score more than 3 on the Borg scale) Informed consent Resident of Gonabad city Access to landline or mobile

Exclusion criteria:
Speech, hearing, and vision disorders and the disability to understand and answer questions History of mental illness based on self-reporting or patient records data

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **88**

Randomization (investigator's opinion)
Randomized

Randomization description
Random permutation blocks of sizes 2 and 4 will be used for randomization. The analyzer will determine the randomization list based on a web-based randomization program. The allocation will be concealed using opaque sealed envelopes with a random sequence.

Blinding (investigator's opinion)
Single blinded

Blinding description
Blinding will be done for the data analyzer. For the study groups, A and B codes are considered, and the data analyzer is not told the type of intervention.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee of Gonabad University of Medical Sciences

Street address
Gonabad University of Medical Sciences, Asian Road Border

City
Gonabad

Province
Razavi Khorasan

Postal code
9691793718

Approval date
2022-04-11, 1401/01/22

Ethics committee reference number
IR.GMU.REC.1401.006

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
Disease severity

Timepoint
Before and three months after intervention

Method of measurement
COPD Assessment Test (CAT)

2

Description
Dyspnea

Timepoint
Before and three months after intervention

Method of measurement
Borg scale

Secondary outcomes

1

Description
Satisfaction of patients

Timepoint
Three months after intervention

Method of measurement
percentage- questionnaire

2

Description
Percentage of unscheduled referrals of discharged patients to hospital emergencies
Timepoint
Three months after intervention
Method of measurement
Hospital file

3

Description
Physical complications after discharge in relation to self-care at home
Timepoint
Three months after intervention
Method of measurement
Percentage of physical complications-questionnaire

4

Description
Re-hospitalization after discharge
Timepoint
Three months after intervention
Method of measurement
Percentage of Re-hospitalization after discharge-questionnaire

Intervention groups

1

Description
The intervention group: The follow-up nurse care plan for the intervention group includes: 1- Safe discharge procedures; 2- Introduce the patient to the follow-up nurse and send a summary of the patient history; 3- Initial evaluation of the patient by the nurse to continue the necessary training after discharge and 4- The main phase of follow-up, which will be called to the patient by phone 3 to 7 days after discharge according on the checklist. Then the nurse introduces him/herself, the appropriate follow-up is performed based on the relevant checklist, and recommendations are offered if the patient requires additional training. Also, if the patient needs support resources such as outpatient clinics, hospital self-care clinics, health centers, psychologists, addiction and smoking cessation centers, nutrition counselors, and home care centers, will refer the patient to the mentioned institutions. The frequency of follow-up of patients is determined based on the severity of the disease and the symptoms from three days to three months after discharge as follows: 1. The "Green area": once a month; 2. The "Yellow area": once a week; 3. The "Red area": Advising to go to the hospital emergency department immediately; follow-up by phone up to 6 hours later; follow-up twice a week after discharge from the hospital until they will be set at the "Green area". Note: The relevant doctor's order could determine the frequency of follow-up.
Category
Rehabilitation

2

Description
Control group: The control group will receive routine hospital training and follow-up. In order to preserve ethics, at least one routine follow-up will be done in the control group.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Allameh Bohlool Hospital-Gonabad
Full name of responsible person
Elham Saberi Noghabi
Street address
Parstar Ave., Gonabad University of Medical Sciences
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
Leila Sadegh Moghadam
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is_moghadam@yahoo.com
Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Gonabad 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
Gonabad University of Medical Sciences
Full name of responsible person
Elham Saberi Noghabi
Position
Faculty instructor
Latest degree
Master
Other areas of specialty/work
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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
There is no more information
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
Yes - There is 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
Title and more details about the data/document
There is no more information.
When the data will become available and for how long
There is no more information.

To whom data/document is available

There is no more information.

Under which criteria data/document could be used

There is no more information.

From where data/document is obtainable

There is no more information.

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

There is no more information.

Comments