

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effect of multidisciplinary support package on burden and patient interaction with family caregivers of patients with chronic obstructive pulmonary disease(COPD).

Protocol summary

Study aim

Determining the effect of multidisciplinary support package on burden and patient interaction with family caregivers of patients with chronic obstructive pulmonary disease(COPD).

Design

A randomized controlled trial clinical trial with parallel, single blinded groups. Phase 2-3.

Settings and conduct

Caregivers bear a high burden for patients with COPD. Therefore, interventions to reduce the burden appear to be necessary. The research will be conducted in Birjand Pulmonary Disease Clinic in three phases. In the first phase training sessions will be held by specialists. In the second phase will be conducted by a psychiatric nurse. The data analyzer will not know the intervention type.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Ability to read and write, Caregivers of patients with severe or very severe chronic obstructive pulmonary disease according to a lung specialist, Physical ability in patient care, Absence of other life-threatening diseases in the patient except COPD. Exclusion criteria: Absent caregiver in more than two sessions of intervention, patient death during the intervention, Affecting a COPD caregiver with a debilitating diseases.

Intervention groups

Intervention group: The support package will be offered in three main phases. In the first phase, 3 training sessions will be held by the lung disease specialist and the COPD specialist nurse. Each session will be 60 minutes. At the end of each session, the content will be delivered as a pamphlet to caregivers. In Phase II, two 60-minute training sessions will be conducted by an experienced Psychiatric nurse. In the third phase, peer support and training sessions will be held in 3 sessions. Control group: Caregivers in the control group will receive the

routine services provided by the health centers.

Main outcome variables

Burden of care; Caregiver-patient communications

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190515043601N4**

Registration date: **2020-03-29, 1399/01/10**

Registration timing: **registered_while_recruiting**

Last update: **2020-03-29, 1399/01/10**

Update count: **0**

Registration date

2020-03-29, 1399/01/10

Registrant information

Name

Hossein Rahimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 56 3238 1427

Email address

hosseinrahimi92@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-23, 1398/06/01

Expected recruitment end date

2020-05-21, 1399/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of multidisciplinary support package on burden and patient interaction with family caregivers of patients with chronic obstructive pulmonary disease(COPD).

Public title

Investigating the effect of multidisciplinary support package on burden and patient interaction with family caregivers of patients with chronic obstructive pulmonary disease(COPD).

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Ability to read and write. Caregivers of patients with severe or very severe chronic obstructive pulmonary disease, according to a lung specialist Physical ability in patient care Absence of other life-threatening diseases in the patient except COPD Ages 18 to 60 yearsold

Exclusion criteria:

Absent caregiver in more than two sessions of intervention Patient death at time of intervention Affecting a COPD caregiver with a debilitating diseases.

AgeFrom **18 years** old to **60 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample sizeTarget sample size: **92****Randomization (investigator's opinion)**

Randomized

Randomization description

Participants were divided into control and intervention groups using blocking method.The blocks size will be 4.The random split action will proceed until the second participant is randomly assigned to a group.Afterwards, participants will be automatically assigned to another group, Until block 4 is completed. This process will continue evenly until the groups are completed.

Blinding (investigator's opinion)

Single blinded

Blinding description

The data analyst will be unaware of the type of intervention for each group.Pre-intervention questionnaires will be coded in the intervention group with the letter M and the control group with N. Questionnaires will be coded after intervention in intervention group with letter G and control group with H.The coding will be done by the researcher.No one other than the researcher will know about coding.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Birjand University of Medical Sciences

Street address

Ayatollah Ghafari Street

City

Birjand

Province

South Khorasan

Postal code

9717853577

Approval date

2019-02-25, 1397/12/06

Ethics committee reference number

IR.BUMS.REC.1397.360

Health conditions studied**1****Description of health condition studied**

Burden of care

ICD-10 code**ICD-10 code description****2****Description of health condition studied**

Patient-Caregiver communication

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Relationship scores from the Dyadic Relationship Scale(DRS)

Timepoint

Before, immediately and two months after the end of the intervention

Method of measurement

Dyadic Relationship Scale

2**Description**

Burden of care scores from the Zarit Burden Interview(ZBI)

Timepoint
Before, immediately and two months after the end of the intervention

Method of measurement
Zarit Burden Interview(ZBI)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:In the first phase, 3 training sessions will be held by the lung disease specialist and the COPD specialist nurse. Each session will be 60 minutes.At the end of each session, the content will be delivered as a pamphlet to caregivers.In Phase II, two 60-minute training sessions will be conducted by an experienced Psychiatric nurse.n the third phase, peer support and training sessions will be held in 3 sessions.

Category

Other

2

Description

Control group: Caregivers in the control group will receive the routine services provided by the health centers.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr hospital

Full name of responsible person

Dr Alireza Mahmoudirad

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Ayatollah Ghafari Street

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+98 56 3204 1088

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dr_mahmoodi_rad@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Tuba Kazemi

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Email

drtooba.kazemi@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Birjand 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

Birjand University of Medical Sciences

Full name of responsible person

Hossein Rahimi

Position

Faculty member of Birjand university of medical science

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

Hossein Rahimi

Position

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Person responsible for updating data

Contact

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Hossein Rahimi

Position

Faculty member of Birjand university of medical science

Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

All potential data can be shared after unidentifiable participants

When the data will become available and for how long

Start of access period 12 months after publishing results

To whom data/document is available

It will only be available to researchers working in academic and scientific institutions

Under which criteria data/document could be used

In order to access the data, researchers can request access to the information 12 months after the results are published. Within two weeks, the information will be sent to them. It should be noted that applicants must be faculty members of the Ministry of Health.

From where data/document is obtainable

Applicants can apply to the Birjand University of Medical Sciences School of Nursing and Midwifery for information.

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

After verifying the identity of the applicant, the data will be submitted to the researcher within 2 weeks.

Comments