

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

The effect of pulmonary rehabilitation application on care burden, psychological distress and quality of life of caregivers of patients with chronic obstructive pulmonary disease

Protocol summary

Study aim

Determining the effect of pulmonary rehabilitation application on care burden, psychological distress and quality of life of caregivers of patients with chronic obstructive pulmonary disease

Design

A clinical trial with a control group, with parallel groups, without blinding, randomized, on 70 observers. Randomization with Mineralization software.

Settings and conduct

Samples are selected at a comprehensive hospital respiration clinic in Isfahan, according to the criteria of entry. Then they are divided into two groups (intervention and control) with minimization software. The control group is also trained at the clinic.

Participants/Inclusion and exclusion criteria

1. age aged 18 - 60 for caregivers 2. Access to the Internet and smartphone 3. Lack of psychiatric disorders in caregivers and patients 4. Having a minimum reading and writing literacy among controllers 5. The primary responsibility for caring for the patient is by caregivers. 6. caregivers have a history of care more than 6 months 7. Patients are based on the global initiative scale of chronic lung obstruction (2 to 4 disease). Non - entry conditions: 1. Lack of willingness to work in research

Intervention groups

This intervention includes a mobile-based pulmonary rehabilitation program that runs for 6 weeks. The application will include educational content in the pulmonary Rehabilitation area, the guide to using types of respiratory spray, Exercises improve lung function, question and response, ability to record sign, Relaxation and Send reminder messages.

Main outcome variables

Care burden; Quality of Life; Psychological distress

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161203031200N3**

Registration date: **2022-06-29, 1401/04/08**

Registration timing: **prospective**

Last update: **2022-06-29, 1401/04/08**

Update count: **0**

Registration date

2022-06-29, 1401/04/08

Registrant information

Name

Vajihe Atashi

Name of organization / entity

Nursing Faculty of Isfahan University

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-23, 1401/05/01

Expected recruitment end date

2022-11-22, 1401/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of pulmonary rehabilitation application on care burden, psychological distress and quality of life of caregivers of patients with chronic obstructive pulmonary disease

Public title

The effect of pulmonary rehabilitation application on caregivers of patients with chronic obstructive pulmonary disease

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients should be in grades 2 to 4 on the Global Initiative Scale for Obstructive Pulmonary Disease. Patients and caregivers have no history of cognitive or mental disorders. The age category of caregivers is 18-60 years. Caregivers have access to the Internet and smartphones to use the app. The primary responsibility for patient care lies with the caregiver. The caregiver has more than 6 months of patient care history. Caregivers have a minimum reading literacy and Mobile literacy.

Exclusion criteria:

Samples are reluctant to participate in the study.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Caregivers are selected according to the inclusion criteria by available sampling method and are divided into two groups of intervention and control by simple randomization method individually and based on minimizing software. This software divides people into two groups during the study based on the background variables and the number required for each group. In order to conceal random allocation, the decision to accept or reject participation in the study was made from the beginning and the informed consent form was completed, and then participants were randomly assigned to each group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Esfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hazar, Azadi Square. Jerib St,

City

Esfahan

Province

Isfahan

Postal code

73461-81746

Approval date

2021-10-02, 1400/07/10

Ethics committee reference number

IR.MUI.NUREMA.REC.1400.152

Health conditions studied

1

Description of health condition studied

Chronic obstructive pulmonary disease

ICD-10 code

Z82.5

ICD-10 code description

Family history of asthma and other chronic lower respiratory diseases

Primary outcomes

1

Description

The burden of care, quality of life and psychological distress

Timepoint

Measuring the burden of care, quality of life and psychological distress at the beginning of the study and 6 weeks after starting to use the pulmonary rehabilitation application

Method of measurement

Kessler Psychological Distress Questionnaire, Zarit Care Load Questionnaire, SF12 Quality of Life Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention is a mobile-based pulmonary rehabilitation application that was prepared based on current world sources and approved by experts. This application has two main panels of patient management and education. Patient panel capabilities include educational content in the field of pulmonary rehabilitation in the form of video and text, guidance on the use of respiratory sprays, training in lung function-enhancing exercises, the ability to ask and answer questions, the ability to record symptoms daily, relaxation and daily reminder messages . This application will be provided to the intervention group for 6 weeks and the samples will be taught how to use it. After that, people can access educational content without any time limit by connecting to the Internet and through their mobile phones.

Category

Rehabilitation

2

Description

Control group: People in the control group are present to face - to - face lung rehabilitation training sessions. The pulmonary rehabilitation program provided for the patients involves a combination of lung performance enhancing exercises and providing the necessary training on the disease. People are trained in groups of five and are trained for two times a week. It goes on to train 12 sessions that will take about an hour each of the controllers training sessions. The training content included in the sessions included materials needed in the field of lung and rehabilitation. It is also called on to remind people twice a week to be involved in training sessions.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Khurshid hospital

Full name of responsible person

Vajihe Atashi

Street address

Khurshid Hospital, Governorate Street, Isfahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Siavash Dastjerdi

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Vajihe Atashi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

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Vajihe Atashi

Position

Associate professor

Latest degree

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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

Due to ethical considerations, no publication takes place.

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

No - There is not a plan to make this available

Clinical Study Report

No - There is not 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