Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

study of the effect of changes in medication regimen and patient education on treatment adherence andspirometry indices in patients with chronic obstructive pulmonary disease

Protocol summary

Study aim
Comparison of the Efficacy of Modifying the Medication Regimen and Educational Intervention on Treatment Adherence and Spirometric Indices in Patients with Chronic Obstructive Pulmonary Disease

Design
This study is designed as a three-arm, pre-post clinical trial. It aims to compare the effects of an educational intervention and a modification of the medication regimen on treatment adherence and spirometric indices in hospitalized patients with Chronic Obstructive Pulmonary Disease (COPD). The study will be conducted at the Hajar and Kashani teaching hospitals, which are affiliated with the Shahrekord University of Medical Sciences.

Settings and conduct
The study includes all patients with chronic obstructive pulmonary disease (COPD) who present to the educational centers affiliated with Shahrekord University of Medical Sciences.

Participants/Inclusion and exclusion criteria
Willingness to participate in the study Age between 40 and 65 years Ability to read and write Diagnosis of COPD by a medical specialist Hemodynamic stability Patients classified as being in Stage II of the disease according to the GOLD criteria: 1) Mild: FEV1 > 80% 2) Moderate: 50% ≤ FEV1 < 80% 3) Severe: 30% ≤ FEV1 < 50% 4) Very Severe: FEV1 < 30% Possession of a smartphone by the patient or their caregiver

Intervention groups
The first intervention group will receive an intervention involving changes to their medication regimen, the second intervention group will undergo an educational program, and the control group will receive routine care. Data regarding spirometry indices and medication adherence (assessed via a questionnaire) will be collected and compared for both groups before and after the interventions.

Main outcome variables
Treatment adherence, spirometry index, medication regimen complexity index,

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20261010071360N1**
Registration date: **2026-11-02, 1405/08/11**
Registration timing: **prospective**

Last update: **2026-11-02, 1405/08/11**
Update count: **0**

Registration date
2026-11-02, 1405/08/11

Registrant information

Name
MHRAB Sharifi sedeh

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 8896 5427

Email address
mehrabsharifi@gmail.com

Recruitment status
Not yet recruiting

Funding source

Expected recruitment start date
2026-12-21, 1405/09/30

Expected recruitment end date
2027-06-20, 1406/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

study of the effect of changes in medication regimen and patient education on treatment adherence andspirometry indices in patients with chronic obstructive pulmonary disease

Public title

Study of the effect of changes in medication regimen and patient education on treatment adherence andspirometry indices in patients with chronic obstructive pulmonary disease

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness to participate in the study Age between 40 and 65 years Ability to read and write Diagnosis of COPD by specialist physicians Hemodynamic stability Classification as GOLD stage II COPD Confirmed diagnosis of chronic obstructive pulmonary disease (COPD) and currently receiving pharmacological treatment

Exclusion criteria:

Exacerbation of COPD symptoms that prevents the delivery of an intervention or the implementation of an educational program Contracting illnesses that exacerbate COPD, such as pneumonia or COVID-19.

Age

From **45 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **108**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahrekord University of Medical Sciences

Street address

Rahmatiyeh Street

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

۸۸۱۵۷۱۳۴۷۱

Approval date

2026-05-25, 1405/03/04

Ethics committee reference number

IR.SKUMS.MED.REC.1405.052

Health conditions studied

1

Description of health condition studied

Lung Diseases

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Individuals with chronic lung diseases

Timepoint

Before education and pharmacological intervention

Method of measurement

Spirometer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Education and Medication Regimen Modification

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hajar and Kashani Hospitals

Full name of responsible person

Mehrab Sharifi sedeh

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Kashani Boulevard, University Central Headquarters
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
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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
Shahre-kord 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
Shahre-kord University of Medical Sciences
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Mehrab Sharifi sedeh
Position
Resident
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Person responsible for updating data

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Phone

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Email

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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

Presence of personal information

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

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

Clinical Study Report

When the data will become available and for how long

6 months after the publication of the results

To whom data/document is available

University students and researchers

Under which criteria data/document could be used

Development of treatment protocols

From where data/document is obtainable

Research Deputy of Shahrekord University of Medical Sciences

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

Visiting the Research Deputy’s office at Shahrekord University of Medical Sciences in person and submitting a request for access.

Comments