Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effect of Applying the Transtheoretical Model of Behavior Change on Self-Care Status of Adults with Chronic Obstructive Pulmonary Disease (COPD)

Protocol summary

Study aim
To evaluate the effect of a transtheoretical model-based educational intervention on self-care in adults with chronic obstructive pulmonary disease (COPD).

Design
Randomized, parallel-group, controlled clinical trial with two study arms (intervention and control). A total of 40 participants will be randomly allocated to the intervention and control groups in a 1:1 ratio using a random number table.

Settings and conduct
The study will be conducted at Khatam al-Anbia Hospital in Abarkooh. A total of 40 eligible participants will be recruited through convenience sampling and randomly allocated to the intervention and control groups (20 participants per group) in a 1:1 ratio using a random number table. Outcomes will be assessed at baseline, immediately after the intervention, and at 3-month follow-up.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Adults with confirmed COPD, in the precontemplation, contemplation, or preparation stage of behavior change, able to provide written informed consent, and without asthma, pneumonia, active malignancy, or immunodeficiency. Exclusion criteria: Development of dementia, uncontrolled psychiatric or serious cardiopulmonary disease during the study, or withdrawal of informed consent.

Intervention groups
Intervention group: Participants will receive a transtheoretical model (TTM)-based educational intervention according to their stage of behavior change (precontemplation, contemplation, preparation, action, and maintenance). The intervention will be delivered through face-to-face training sessions lasting 45–60 minutes. Control group: Participants will receive routine care without the TTM-based educational intervention during the study period.

Main outcome variables
Self-care status Stage of behavior change Self-efficacy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260804070529N1**
Registration date: **2026-08-19, 1405/05/28**
Registration timing: **prospective**

Last update: **2026-08-19, 1405/05/28**
Update count: **0**

Registration date
2026-08-19, 1405/05/28

Registrant information
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Marzieh Sattar
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-09-11, 1405/06/20

Expected recruitment end date
2026-11-01, 1405/08/10

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effect of Applying the Transtheoretical Model of Behavior Change on Self-Care Status of Adults with Chronic Obstructive Pulmonary Disease (COPD)

Public title
The Effect of Applying the Transtheoretical Model of Behavior Change on Self-Care Status of Adults with Chronic Obstructive Pulmonary Disease (COPD)
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Confirmed diagnosis of chronic obstructive pulmonary disease (COPD) based on physician diagnosis or post-bronchodilator spirometry ($FEV_1/FVC < 0.70$). Willingness to participate and provision of written informed consent. Being in the precontemplation, contemplation, or preparation stage of behavior change. No history of asthma, pneumonia, active malignancy, or immunodeficiency.
Exclusion criteria:
Development of dementia or an uncontrolled psychiatric disorder during the study. Development of unstable heart disease, heart failure, bronchiectasis, bronchial carcinoma, or interstitial lung disease during the study. Withdrawal of informed consent or voluntary withdrawal from the study at any time.
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Eligible adults with chronic obstructive pulmonary disease (COPD) will be recruited through convenience sampling after meeting the inclusion criteria and providing written informed consent. Participants will then be randomly allocated to the intervention or control group in a 1:1 ratio using a random number table (simple randomization).
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
Research Ethics Committee, Islamic Azad University, Isfahan Branch (Khorasgan)
Street address
Jey Sharqi Street, Arghavanieh, Daneshgah Boulevard, Islamic Azad University, Isfahan Branch (Khorasgan), Isfahan.
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Province
Isfehan
Postal code
39998-81551
Approval date
2026-03-08, 1404/12/17
Ethics committee reference number
IR.IAU.KHUISF.REC.1404.667

Health conditions studied

1

Description of health condition studied
Chronic Obstructive Pulmonary Disease; COPD
ICD-10 code
J44.9
ICD-10 code description
Chronic obstructive pulmonary disease, unspecified

Primary outcomes

1

Description
Self-care status
Timepoint
Self-care will be measured at baseline (pre-intervention), immediately after the intervention (post-intervention), and 1 month after the intervention (follow-up).
Method of measurement
Self-care will be assessed using the Miller Self-Care Questionnaire. This 20-item instrument evaluates self-care behaviors, including adherence to prescribed diet, smoking avoidance, physical activity, medication adherence, and stress management. Items are rated on a 5-point Likert scale, with higher scores indicating better self-care status.

2

Description
Stage of behavior change
Timepoint

Stage of behavior change will be measured at baseline, immediately after the intervention, and 1 month after the intervention.

Method of measurement

The stage of behavior change will be assessed using the University of Rhode Island Change Assessment (URICA) Questionnaire, which evaluates participants' readiness for behavior change based on the transtheoretical model.

3

Description

Self-efficacy

Timepoint

Self-efficacy will be measured at baseline, immediately after the intervention, and 1 month after the intervention.

Method of measurement

Self-efficacy will be assessed using the Sherer General Self-Efficacy Scale. This instrument evaluates individuals' perceived ability to perform and maintain health-related behaviors.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Participants will receive a transtheoretical model (TTM)-based educational intervention according to their stage of behavior change (precontemplation, contemplation, preparation, action, and maintenance). The intervention will be delivered through face-to-face training sessions lasting 45–60 minutes. Outcomes will be assessed at baseline, immediately after the intervention, and one month after completion of the intervention.

Category

Behavior

2

Description

Control group: Participants will receive routine care without the TTM-based educational intervention during the study period. They will complete the same assessments at baseline, immediately after the intervention period, and one month later.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Khatam Al-Anbiya Hospital, Abarkooh

Full name of responsible person

Dr. Hassanieh Nematizadeh

Street address

Khatam Al-Anbia Hospital, Imam Ali Boulevard, Velayat Town, Abarkouh, Yazd Province, Iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University, Isfahan Branch (Khorasgan)

Full name of responsible person

Dr. Gholamreza Talebi

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Jey Sharqi Street, Arghavanieh, Daneshgah Boulevard, Islamic Azad University, Isfahan Branch (Khorasgan), Isfahan.

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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

Islamic Azad University, Isfahan Branch (Khorasgan)

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
Islamic Azad University, Isfahan Branch (Khorasgan)
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Dr. Shayesteh Salehi
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
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
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
Undecided - It is not yet known if there will be a plan to make this available