Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of educational pictogram-based training on sleep quality and activity tolerance in patients with chronic obstructive pulmonary disease.

Protocol summary

Study aim

The effect of educational pictogram-based training on sleep quality and activity tolerance in patients with chronic obstructive pulmonary disease.

Design

Sampling of patients with COPD will be done on a convenience basis. Patients will be randomly divided into two groups: experimental and control. Identical cards will be used to assign groups, and each patient will be placed in the corresponding group by drawing a card blind, and the researcher is unaware of the contents of the cards. Randomization is used to control for confounders and reduce background differences, including the exact entry and exit conditions of patients. The sample size is determined with 95% confidence and 80% power.

Settings and conduct

The study will be conducted in educational and medical centers affiliated with Shahrekord University of Medical Sciences (Hajar Hospital, Kashani Hospital, Vali Asr Hospital, Borujen (under the supervision of Borujen Faculty of Medical Sciences, a subsidiary of Shahrekord University of Medical Sciences)) during the year 1404.

Participants/Inclusion and exclusion criteria

Inclusion criteria included: COPD diagnosis - age 45-70 years - ability to understand pictograms - and stages 2 and 3 of the GOLD criteria -10 - voluntary consent - speaking Persian. Exclusion criteria included: non-participation - failure to complete the questionnaire - life-threatening diseases - obvious apathy and refusal - disease progression to stage 4 and patient death.

Intervention groups

In the intervention group, pictogram-based education included disease management, sleep improvement, and increased exercise tolerance, as well as information about COPD.Symptoms, breathing techniques, medications, symptom control, sleep pattern modification, and physical exercises are presented and educational pictograms are given to patients.

Main outcome variables

Sleep quality and activity tolerance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250803066745N1**
Registration date: **2025-08-07, 1404/05/16**
Registration timing: **prospective**

Last update: **2025-08-07, 1404/05/16**
Update count: **0**

Registration date

2025-08-07, 1404/05/16

Registrant information

Name

mohammad rafie boldaji

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3464 3751

Email address

m.rafie78@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-09-06, 1404/06/15

Expected recruitment end date

2025-12-06, 1404/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of educational pictogram-based training on sleep quality and activity tolerance in patients with chronic obstructive pulmonary disease.

Public title
The effect of educational pictograms on sleep quality and activity tolerance in patients with chronic obstructive pulmonary disease.

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
.Definite diagnosis of chronic obstructive pulmonary disease (COPD) by the treating physician. Ability to speak Persian Patients in stages 2 and 3 of the disease according to the GOLD classification Absence of life-threatening diseases Voluntary consent to participate in the study Age between 45 and 70 years Ability to understand and respond to educational pictograms Ability to understand pictograms through the Pictogram Comprehension Test: In this test, patients are presented with several standard pictograms and asked to explain the meaning and concept of each image. The patients' responses are compared with a standard checklist and if the individual correctly identifies at least 70% of the concepts, they are considered to have the ability to understand pictograms Not having mental, motor, visual, or hearing disabilities

Exclusion criteria:
History of psychological problems Blindness, deafness, or speechlessness Being in another clinical trial Isolated patients who are in quarantine conditions Patients with motor disabilities Unknown patients who do not have correct identification details Patients with drug addiction

Age
From **45 years** old to **75 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization using sealed envelopes A card-based randomization method was used to assign participants to the intervention and control groups. For this purpose, an equal number of cards were prepared as many as the number of subjects, half of which were labeled “intervention” and the other half “controlThese cards were completely identical, with no apparent differences in size, color, or material, and would be placed in a mixed box or envelope.For each eligible patient who enters the study, a card is randomly drawn from the envelope without prior review, and the patient is placed in the appropriate group based on the card's contents. It should be noted that the researcher was unaware of the contents of the card and the study was double-blind.

Blinding (investigator's opinion)
Single blinded

Blinding description
Participants in this study are blinded to either the intervention or control group. Participants are grouped after selecting cards with similar characteristics, one identifying the control group and the other identifying the intervention group.It should be noted that the control group was also provided with training with images other than the original pictograms, which meant that the person in the control group was unaware of which group they were in.

Placebo
Not used

Assignment
Parallel

Other design features
Educational pictogram design by a graphic designer and master's student under the supervision of experienced faculty members

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shahrekord University of Medical Sciences

Street address
Shahrekord-Headquarters, Kashani Blvd.,-Shahrekord University of Medical Sciences

City
Shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
۸۸۱۵۷۱۳۴۷۱

Approval date
2025-08-02, 1404/05/11

Ethics committee reference number
IR.SKUMS.REC.1404.062

Health conditions studied

1

Description of health condition studied
Chronic obstructive pulmonary disease

ICD-10 code
J44

ICD-10 code description
Other chronic obstructive pulmonary disease

Primary outcomes

1

Description
Sleep quality
Timepoint
Before the intervention_Immediately after the intervention_3 months after the intervention
Method of measurement
Pittsburgh Sleep Quality Questionnaire

2

Description
activity tolerance
Timepoint
Before the intervention_Immediately after the intervention_3 months after the intervention
Method of measurement
6-minute walk test

Secondary outcomes

1

Description
Decreased time to fall asleep
Timepoint
Before the start of the intervention - Immediately after the end of the intervention - 3 months after the end of the intervention
Method of measurement
Pittsburgh Sleep Quality Questionnaire

2

Description
Reduction in nighttime awakenings
Timepoint
Before the start of the intervention - Immediately after the end of the intervention - 3 months after the end of the intervention
Method of measurement
Pittsburgh Sleep Quality Questionnaire

3

Description
Feeling refreshed and energetic in the morning
Timepoint
Before the start of the intervention - Immediately after the end of the intervention - 3 months after the end of the intervention
Method of measurement
Pittsburgh Sleep Quality Questionnaire

4

Description
Increased distance covered in the 6-minute walk test
Timepoint
Before the start of the intervention - Immediately after the end of the intervention - 3 months after the end of the intervention
Method of measurement
6-minute walk test

5

Description
Improve activity time
Timepoint
Before the start of the intervention - Immediately after the end of the intervention - 3 months after the end of the intervention
Method of measurement
6-minute walk test

6

Description
Reduce the need to rest during walks
Timepoint
Before the start of the intervention - Immediately after the end of the intervention - 3 months after the end of the intervention
Method of measurement
6-minute walk test

Intervention groups

1

Description
Intervention group:In the intervention group, instruction based on educational pictograms, which included information related to disease management, improving sleep quality, and increasing activity tolerance, was provided during an individualized education session for each patient for 20 minutes.It will be conducted by attending each patient's bedside and providing verbal and face-to-face training using educational pictograms and providing information about the pictograms. In severely ill patients, these sessions will be held by the researcher in the patient's hospital room, accompanied by the patient's companion.The content of the sessions is designed so that patients can understand the main concepts related to their disease through simple visual images without the need for complex texts. During this session, in the first five minutes, patients will be provided with information about COPD, its symptoms and complications, and the impact of the disease on sleep quality and daily activities, and familiarization with pictograms.In the second five minutes, proper breathing techniques, use of medications, sprays, devices, symptom control, and sleep pattern modification will be taught with pictograms. In the third five minutes, appropriate physical exercises, methods for increasing activity tolerance and stress management, avoidances, warning signs, and follow-ups will be taughtIn the fourth five minutes, the content of the sessions will be reviewed, patients' questions will be answered, and supplementary points will be provided. Patients will be asked to ask questions or share their experiences. In

order to follow up and reinforce learning, patients in the intervention group will receive a set of educational pictogramsWhich includes demonstrating correct breathing techniques, proper sleeping positions, appropriate physical exercises, and care tips.

Category

Rehabilitation

2

Description

Control group: In the control group, routine medical care will continue and pictogram-based education will not be provided to these patients, but a series of educational brochures regarding the course of the disease and prevention of symptom exacerbation will be used for blinding.It should be noted that these brochures will not bear any resemblance to the designed pictograms.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Kashani Hospital, Shahrekord - Hajar Hospital, Shahrekord - Vay Asr Hospital, Borujen

Full name of responsible person

Mohammad Rafie Boldaji

Street address

No. 6-Akbar Boldaji Alley-Eastern Dolat Boulevard-Boldaji--Borujen

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8876149404

Phone

+98 991 964 0221

Fax

Email

m.rafie78@yahoo.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Dr.Akbar Soleimani

Street address

No. 6-Akbar Boldaji Alley-Eastern Dolat Boulevard-Boldaji-Borujen

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8876149404

Phone

+98 991 964 0221

Email

m.rafie78@yahoo.com

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

50

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

Full name of responsible person

Mohammad Rafi Boldaji

Position

Master's degree student in nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

No. 6-Akbar Baldaji Alley- East Dolat Boulevard-Baldaji

City

Shahrekord

Province

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Postal code

8876149404

Phone

+98 38 3464 3751

Email

m.rafie78@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Mohammad Rafie Boldaji

Position

Master's degree student in nursing

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Postal code
8876149404

Phone
+98 38 3464 3751

Email
m.rafie78@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Shahre-kord University of Medical Sciences

Full name of responsible person
Mohammad Rafie Boldaji

Position
Master's degree student in nursing

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Postal code
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Phone
+98 38 3464 3751

Email
m.rafie78@yahoo.com

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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
The data will be shared after collection and classification, with the names of the participants hidden.

When the data will become available and for how long
After completing the thesis writing process, approving the relevant references, extracting the article, and publishing it in reputable journals, access to the data is available.

To whom data/document is available
The collected data is visible to researchers working in medical and paramedical fields.

Under which criteria data/document could be used
The use of data is only available for research and further research in the current and related research field.

From where data/document is obtainable
To access the data, simply visit Mohammad Rafie's email address at m.rafie78@yahoo.com.

What processes are involved for a request to access data/document
Any researcher can obtain data after obtaining the Code of Ethics and the Code of Ethics in Biomedical Research and obtaining permission from Shahrekord University of Medical Sciences.

Comments