

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

The effectiveness of respiratory training interventions based on teach back method on the level of the dyspnea, 6-minutes walking test and FEV1% in patients with chronic obstructive pulmonary disease (COPD).

Protocol summary

Study aim

Determining the effectiveness of the program of respiratory training programs based on the teach back method on the level of dyspnea, activity tolerance and FEV1 in chronic obstructive pulmonary patients

Design

A clinical trial with a sample size of 80 and control and test groups were randomly divided into two groups

Settings and conduct

The research population is patients with chronic pulmonary obstruction, which will be selected by simple sampling. The location of the intervention is Kashani and Hajar hospitals in Shahrekord. The number of patients in each group is 40. The intervention group will develop a respiratory training program based on the pattern of rejection and follow up for the test group three months.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Diagnosis of chronic obstructive pulmonary disease by specialized doctors and recorded in the patient's case 2- Hospitalization in one of the internal departments of Hajar and Kashani hospitals 3. Age under 60 years 4. Lack of cognitive impairment 5- Stability of physical conditions and the ability to attend training sessions 6. Spirometry in the case and FEV1 level greater than 30% 7. No other underlying illness 8. The desire to participate in the training program 9. Minimum reading and writing literacy Exit criteria: 1. Unwilling to continue the program 2. Exacerbation of the condition for any reason

Intervention groups

Intervention group: The respiratory training will be conducted for the test group and three months follow up will be done for the group. The venue for these sessions will be in the patient's bedside

Main outcome variables

Improvement of patients' respiration, increased activity of patients, improvement of FEV1 in patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181024041449N5**

Registration date: **2019-05-27, 1398/03/06**

Registration timing: **retrospective**

Last update: **2019-05-27, 1398/03/06**

Update count: **0**

Registration date

2019-05-27, 1398/03/06

Registrant information

Name

ali hassanpourdehkordi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3334 6720

Email address

alihassanpourdehkordi@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-11, 1397/12/20

Expected recruitment end date

2019-05-10, 1398/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of respiratory training interventions based on teach back method on the level of the dyspnea, 6-minutes walking test and FEV1% in patients with chronic obstructive pulmonary disease (COPD).

Public title

Investigation of respiratory exercises in patients with chronic obstructive pulmonary disease

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

1- Diagnosis of chronic obstructive pulmonary disease by specialized doctors and recorded in the patient's case 2- Hospitalization in one of the internal departments of Hajar and Kashani hospitals 3. Age under 60 years 4. Lack of cognitive impairment 5- Stability of physical conditions and the ability to attend training sessions 6. Spirometry in the case and FEV1 level greater than 30% 7. No other underlying illness 8. The desire to participate in the training program 9. Minimum reading and writing literacy

Exclusion criteria:

1. Failure to continue the program. 2. Exacerbate the condition for any reason

Age

To 60 years old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 80

Randomization (investigator's opinion)

Randomized

Randomization description

Considering the fact that the samples are gradually entered into the study, the researcher will use the available method to obtain the samples. Therefore, all patients admitted to the internal departments of Hajar and Kashani Hospitals of Shahr-e-Kord, who have been admitted to study, were selected by the researcher And will enter the study. Since the entry of patients to the study environment is gradual, the researcher will then enter randomly selected patients in the case and control group after selecting the patients with the condition using the Random Allocation Rule method. In this method, according to the sample size, two colors of the card (red and blue) With the same number and total volume of the sample is placed inside the pot. Then, the qualified individuals entered the study randomly remove one of the cards from the pot and enter the research group according to the definition of the researcher.

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 Shahrkord University Of Medical Sciences

Street address

University Of Medical Sciences, Rahmatie, Shahrkord Town

City

ShahreCORD

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815713471

Approval date

2019-03-10, 1397/12/19

Ethics committee reference number

IR.SKUMS.REC.1397.299

Health conditions studied

1

Description of health condition studied

chronic obstructive pulmonary disease

ICD-10 code

J44.9

ICD-10 code description

Chronic obstructive pulmonary disease, unspecified

Primary outcomes

1

Description

Dyspnea

Timepoint

The beginning of the study, immediately after and three months after the intervention

Method of measurement

Borg Disease Questionnaire

2

Description

6 Minute Walking Test

Timepoint

The beginning of the study, immediately after and three months after the intervention

Method of measurement

Walk within six minutes

3

Description

FEV1(force expiratory volume in second 1)

Timepoint

The beginning of the study, immediately after and three months after the intervention

Method of measurement

Espiratory

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For the intervention group, training of breathing exercises based on the teachback model with 3-5, 45-minute training sessions In addition to medical treatments and then three months of follow up, will be conducted individually for each of the participants in the group. The venue for these sessions will be in the patient's bedside

Category

Rehabilitation

2

Description

Control group: The control group only receives routine care and treatment.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashani hospital

Full name of responsible person

Ali Hassanpour Dehkordi

Street address

ayatollah kashani hospital, nurse ave

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8816758915

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Email

Kashani@skums.ac.ir

Web page address

http://sapp.ir/kashani_hospital_sh

2

Recruitment center

Name of recruitment center

Hajar hospital

Full name of responsible person

Ali Hassanpour Dehkordi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Dr Kamal Solati

Street address

Shahrekord University Of Medical Sciences, Rahmatie, Shahrkord..

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Email

Kamal_Solati@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

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

Full name of responsible person

Ali Hassanpour Dehkordi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Contact

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Person responsible for scientific inquiries

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Name of organization / entity

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Other areas of specialty/work

Nursery

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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

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

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

Not applicable

Data Dictionary

Not applicable