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
Shahrekord

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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Shahrekord
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Chahar-Mahal-va-Bakhtiari
Postal code
8816758915
Phone
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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
Street address
Hajar hospital, nurse ave
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Web page address
https://hajarhp.skums.ac.ir/

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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Person responsible for scientific inquiries

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Person responsible for updating data

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Other areas of specialty/work
Nursery

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Email
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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