

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

Comparison the effect of receiving and not receiving self-care education on the function and quality of respiration in patients with chronic obstructive pulmonary disease

Protocol summary

Study aim

Comparison the effect of receiving and not receiving self-care education on the function and quality of respiration in patients with chronic obstructive pulmonary disease

Design

A clinical trial has two parallel groups of control and intervention, with a sample size of 70. The allocation of samples to the groups will be randomly using the random numbers table.

Settings and conduct

After receiving written permission from the Research and Technology Department and the Ethics Committee of Zahedan University of Medical Sciences, patients are enrolled according to inclusion criteria. They are randomly assigned to control and intervention groups. And their quality and respiratory function are measured , subsequently they receive the necessary training based on need.They are followed for 45 days and their quality and respiratory function are re-measured.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 40-65 years, Ability to read and write, History of hospitalization, Residence in Zahedan City, Not having formal education about chronic obstructive pulmonary disease, Satisfaction to participate in the study, Possibility to make a phone call, Known Case Of Chronic Obstructive Pulmonary Disease. Non inclusion criteria: psychological and cognitive disorders, vision and hearing impairment that makes communication with the patient impossible, education in medical and para-medicine groups, drug addiction

Intervention groups

In the intervention group, 8 sessions and in control group one session about chronic obstructive pulmonary disease and complications will be held.

Main outcome variables

Respiratory function; respiratory quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181028041484N1**

Registration date: **2019-07-19, 1398/04/28**

Registration timing: **retrospective**

Last update: **2019-07-19, 1398/04/28**

Update count: **0**

Registration date

2019-07-19, 1398/04/28

Registrant information

Name

Aliakbar Keykha

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 54 3344 2481

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-05, 1397/07/13

Expected recruitment end date

2019-04-03, 1398/01/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of receiving and not receiving self-care education on the function and quality of respiration in patients with chronic obstructive pulmonary disease

Public title

The effect of self-care education on the quality and Function of Respiration

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Age Between 40-65 years old Ability to read and write A previous history of chronic obstructive pulmonary disease hospitalization Living in Zahedan Consent to participate in the study Have telephone access to patients A known case of chronic obstructive pulmonary disease

Exclusion criteria:

formal education about chronic obstructive pulmonary disease Cognitive and psychological diseases Hearing and vision disturbances Medical and paramedical professions

Age

From **40 years** old to **64 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling method with convenience sampling is done and for the randomization of patients in the intervention and control groups, the first patient is selected using drawing numbers and allocated into one of the groups. Then patients will alternately be allocated into the intervention and control groups.

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 Zahedan University of Medical

Sciences

Street address

Hesabi square, Zahedan university and medical science

City

zahedan

Province

Sistan-va-Balouchestan

Postal code

78591-71155

Approval date

2018-10-05, 1397/07/13

Ethics committee reference number

IR.ZAUMS.REC.1397.259

Health conditions studied

1

Description of health condition studied

Chronic obstructive pulmonary disease

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Forced expiratory volume in first second(FEV1),Forced vital capacity(FVC)

Timepoint

At the beginning of the patient's entry to the study and 45 days after end of the study

Method of measurement

Respiratory volumes are measured by spirometers.

Secondary outcomes

1

Description

Quality of respiration

Timepoint

45 days after the end of the intervention

Method of measurement

Quality of respiration measured by Saint George Respiratory Questionnaire

Intervention groups

1

Description

Intervention group:in the intervention group at baseline, Forced Expiratory Volume (FEV1) and Forced Vital Capacity (FVC) are measured by spirometers and quality of respiration is measured by St. George's breathing questionnaire,Then based on the educational needs of each patient, Face-to-face training in relation to deep breathing, diaphragmatic breathing, puffy breathing,

proper diets, Using proper from respiratory inhaler sprays and medications, oxygen therapy, prevention of infection and avoidance of environmental stimuli are done. Training sessions are 8 that will be held during four weeks (two days in each week). Saturday and Tuesday, started at 10 am and continue for 30 minutes. Educational content is provided as a manual booklet for study at home. Patients spend 45 days on the educational program. After this period, respiratory volume is measured by spirometry and quality of respiration is measured by St. George's Respiratory Quality Questionnaire.

Category

Treatment - Devices

2

Description

Control group: In this group, only one training session is conducted on brief introduction to the disease and its complications, And the usual process of treatment without intervention is done. After 45 days, respiratory volume is measured by spirometry and quality of respiration is measured with the St. George's Respiratory Quality Questionnaire. At the end of the study the training manual booklet prepared for the intervention group also will be given to the control group.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali ibn Abitaleb Hospital (Zahedan)

Full name of responsible person

Aliakbar Keykha

Street address

Ali ibn Abitaleb Hospital, KHalige Fars Blvd, Zahedan

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aliakbar.keykha@zaums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

aliakbar keykha

Street address

mashahir square,college of nursing and midwifery

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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

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

aliakbar Keykha

Position

instructor

Latest degree

Master

Other areas of specialty/work

Nursery

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Mashahir square, College of nursing and midwifery

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Person responsible for scientific inquiries

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Person responsible for updating data**Contact****Name of organization / entity**

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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

One of the ethical principles is the confidentiality 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

No - There is not 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