Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The assessment of effectiveness of respiratory muscle training (I M T)and aerobic training on quality of life in patients with chronic obstructive pulmonary disease(C O P D)

Protocol summary

Study aim
Comparison of the Effect of Two Methods of Dementia Respiratory Muscle Exercise and Aerobic Exercise in Patients with C.O.P.D in Imam Hussein Hospital in 2016

Design
The first group (n = 16) treated with the I.M.T method in the second group (n = 14) received the aerobic exercise method in the third group (n = 15) in the fourth group (n = 15) (control group)

Settings and conduct
Hospital but Hussein Department of Physiotherapy

Participants/Inclusion and exclusion criteria
Satisfaction to participate in the study, Getting Grade 2 or 3 Based on GOLD Criteria, Age 40 to 70 years, Lack of other pulmonary diseases, Lack of severe limb limbs, Lack of pulmonary surgery in the last 12 months, Recent fracture failure at the level of ribs (6 months), No history of psychotropic disease and related drugs and alcohol and psychotropic substances.

Intervention groups
The first group (n = 16) was treated by IMT: the intensity of training was 40-60% (S-Index 40-60%), 2 days per week, and 5 sessions of dermal muscle training with repeat 50 (5 Repeat 10) for about 15 minutes per session. The second group (n = 14) was treated with aerobic exercise method: with a treadmill and foot pedometer, 2 times a week, with 40 to 60% HRR for 40 minutes per session. The third group (n = 15) received combined therapy (in each session, breathing exercises were performed first and then aerobic exercises were performed on the lower extremities) The fourth group (n = 15) did not take any special intervention other than the usual treatments (control group)

Main outcome variables
Evaluation of pulmonary function according to spirometry (FEV1); Testing of respiratory muscles with the IMT Test Power Breath device to determine the S-index; Dyspnea severity: based on the MMRC classification; 6-minute walk test (6MWD); The severity of COPD was assessed by two methods: A-GOLD BODE INDEX. Health-related quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180205038633N1**
Registration date: **2019-03-17, 1397/12/26**
Registration timing: **retrospective**

Last update: **2019-03-17, 1397/12/26**
Update count: **0**

Registration date
2019-03-17, 1397/12/26

Registrant information

Name
Saeid Rezaei

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-03-21, 1396/01/01

Expected recruitment end date
2017-05-21, 1396/02/31

Actual recruitment start date

2017-05-22, 1396/03/01

Actual recruitment end date

2017-07-23, 1396/05/01

Trial completion date

empty

Scientific title

The assessment of effectiveness of respiratory muscle training (I M T)and aerobic training on quality of life in patients with chronic obstructive pulmonary disease(C O P D)

Public title

The assessment of effectiveness of respiratory muscle training (I M T)and aerobic training in patients with pulmonary disease

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Satisfaction to participate in the study Getting Grade 2 or 3 Based on GOLD Criteria Age 40 to 70 years Failure to have previous known disease, such as heart disease (such as C.H.F and coronary artery disease), or disease of the lungs (E.S.R.D and C.R.F), and liver (cirrhosis of the liver, cancer, etc.) Lack of other pulmonary diseases, such as lung cancer, plural disease, or musculature involvement. The lack of extreme limbs that prevent aerobic exercise Lack of pulmonary surgery in the last 12 months Recent fracture failure at the level of ribs (6 months) No history of psychotropic disease and related drugs and alcohol and psychotropic substances

Exclusion criteria:

Failure to have previous known disease, such as heart disease (such as C.H.F and coronary artery disease), or disease of the lungs (E.S.R.D and C.R.F), and liver (cirrhosis of the liver, cancer, etc.)

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **68**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

block 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

Ethics committee of Shahid beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2016-06-21, 1395/04/01

Ethics committee reference number

IR.SBMU. MSP.REC.1395.146

Health conditions studied

1

Description of health condition studied

Chronic bronchitis-emphysema

ICD-10 code

J41-J43

ICD-10 code description

Emphysema Excl.: emphysema-Simple and mucopurulent chronic bronchitis

Primary outcomes

1

Description

Spirometric FEV 1 Index - Quality of Life Indicator score

Timepoint

Beginning of study - Week 4 - Week 8

Method of measurement

Lung Spirometry - St. George's Quality of Life Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: -

Category

Rehabilitation

2

Description
Exercise group and respiratory training
Category
Rehabilitation

3

Description
Intervention group: Respiratory training group
Category
Rehabilitation

4

Description
Control group: no intervention
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossein Hospital
Full name of responsible person
Saeed Razaei
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Shahid Madani Avenue Nizam Abad Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
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Grant name
Deputy of Research of Shahid Beheshti University of Medical Sciences
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
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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
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
No - There is not 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
Dissertation and some with information about the consequences of patients without mentioning patients' characteristics
When the data will become available and for how long
Possibility of post-publication of the article
To whom data/document is available
Researchers and students from all over the country
Under which criteria data/document could be used
Clinical research similar to the direction of relevant researchers
From where data/document is obtainable
Theses and articles of research deputy of Shahid Beheshti University of Medical Sciences
What processes are involved for a request to access data/document
Through a reputable service center at a different country and adhering to the principles of copyright
Comments