Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Jul 2026

Effect of pulmonary rehabilitation program on respiratory disorders and quality of life in chemical victims, Sardasht

Protocol summary

Study aim

Identify effect of pulmonary rehabilitation program on respiratory disorders and quality of life in chemical victims, Sardasht, Iran

Design

After random allocation, the researcher in the intervention group will need an assessment based on the health status forms from the intervention group. Then, based on the problems with nutritional reform, activities, the correct use of medication, respiratory physiotherapy and rehabilitation exercises will be taught to them. Trained athletic exercises will be conducted daily for two months at home and with researcher follow up. In the control group, quality of life questionnaire and visual instrumentation, the severity of shortness of breath will be completed concurrently with the intervention group.

Settings and conduct

Khatam Al Anbia Sardasht Clinic of Chemical Injuries is affiliated with the Martyr Foundation and the Affaires. The city's chemical casualties are referred to as the first line of health care services.

Participants/Inclusion and exclusion criteria

Chemical injuries suffered from chronic pulmonary insufficiency referring to Sardasht chemical injury clinic

Intervention groups

After random allocation, the researcher in the intervention group will need an assessment based on the health status forms from the intervention group. Then, based on the problems with nutritional reform, activities, the correct use of medication, respiratory physiotherapy and rehabilitation exercises will be taught to them. Trained athletic exercises will be conducted daily for two months at home and with researcher follow up.

Main outcome variables

With the implementation of the pulmonary rehab program, the participants' respiratory problems have been reduced and quality of life related to health has been improved.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141124020064N2**
Registration date: **2019-01-28, 1397/11/08**
Registration timing: **retrospective**

Last update: **2019-01-28, 1397/11/08**
Update count: **0**

Registration date

2019-01-28, 1397/11/08

Registrant information

Name

Fereydoon Khayeri

Name of organization / entity

Iran University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-05-22, 1396/03/01

Expected recruitment end date

2017-06-21, 1396/03/31

Actual recruitment start date

2017-05-22, 1396/03/01

Actual recruitment end date

2017-06-21, 1396/03/31

Trial completion date

2017-11-13, 1396/08/22

Scientific title
Effect of pulmonary rehabilitation program on respiratory disorders and quality of life in chemical victims, Sardasht

Public title
Effect of pulmonary rehabilitation program on respiratory disorders and quality of life in chemical victims, Sardasht, Iran

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Moderate to severe COPD Able to cooperate in pulmonary rehabilitation program Writing and reading ability Not having mental or psychological illness No history of pulmonary disease before mustard exposure Non smoker

Exclusion criteria:
Exit from study No cooperation in 1 of education class Increase of pulmonary disorders or decrease of FEV1 less than 30%

Age
From **30 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**
Actual sample size reached: **76**

Randomization (investigator's opinion)
Randomized

Randomization description
The allocation of people in the two groups will be randomly based on a random selection of random numbers. In this way, before and after the study, AB and AB randomized permutations are defined as control (A) and intervention (B) groups. Using a random number table of half the sample size, the single digit number is selected between zero and nine. The odd number will be the selection of two people in the AB group and the pair number will mean two people in the BA groups. In this way, a sequence of AB and BA will be selected, which will be the same for the two groups. On the other hand, the layout will be completely random and it will not be easy to determine which group to be grouped into.

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
Iran University of Medical Sciences Ethical Committee

Street address
Rashid Yasemi St., Vali-e-Asr St.

City
Tehran

Province
Tehran

Postal code
1996713883

Approval date
2019-01-21, 1397/11/01

Ethics committee reference number
IR.IUMS.REC.1397.878

Health conditions studied

1

Description of health condition studied
Respiratory Disorders

ICD-10 code
j44

ICD-10 code description
COPD

Primary outcomes

1

Description
Reducing respiratory problems means that pulmonary volumes increase and dyspnea is reduced. An increase in the quality of life score that reflects its improvement.

Timepoint
2 month

Method of measurement
St George Respiratory Questionnaire, Spirometery, 6 Minute Walking Test, Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
First, after obtaining the consent and willingness of the injured to participate in the research, the questionnaires are completed and the preliminary data are collected. For each Individuals in the intervention group, the informed consent form will be filled out. Each participant first completed a demographic questionnaire form including the name (optional), age, gender, injury history, marital status, smoking and tobacco, education,

job status, and income, and then a form of review of the quality of life of the St George will fill out a quality of life questionnaire for respiratory diseases.Self-reporting questionnaire for chronic lung patients is standardized and the time required to complete 10 minute. This questionnaire has 50 questions and 3 distentions. The sections include symptoms, activity, and impact on daily life. Questions are scanned from 0 to 100 and expressed as percentages. The higher the score, the worse the quality of life. The questionnaire will be completed again two months after the intervention.Participants are also asked to record their shortness of breath. The intensity of shortness of breath is measured by the Visual Analog Scale instrument once a month. This instrument is a visual instrument for measuring the degree of shortness of breath in the range of 0 to 100 mm. The zero number indicates that there is no shortness of breath and the number of 100 represents the maximum severity of the breathlessness. This tool will be completed again two months after the intervention. Then, from each of the Individuals in the intervention group, spirometery will be performed to determine the pulmonary function. Spirometry will be re-sampled two months later. Each participant is then asked to complete the six minute gap test. In this test, each sample is asked to walk for six minutes and the area traveled by each person will be recorded.The distance traveled will be measured again after two months And increasing the distance up to 54 meter will be a significant change.

Category

Rehabilitation

2

Description

Control group: After receiving the consent and willingness of the injured to participate in the research, the questionnaires are completed and the preliminary data are collected. For each research unit, the informed consent form will be filled out. Each person in the control group first completed a demographic questionnaire containing the name (optional), age, sex, injury history, marital status, smoking and tobacco, education, job status and income, and then a quality of life assessment form St. George fill in. The questionnaire will be completed again two months later.Participants are also asked to record their shortness of breath. The intensity of shortness of breath is measured by the VAS tool once a month. The tool will be completed again two months later. Then, each spirometric control group will be assigned to determine pulmonary function. Spirometery will be re-sampled two months later. Then, each of the control group samples are asked to complete the six minute interval test. In this test, each specimen is asked to walk for six minutes and the area traveled by each person will be recorded.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of chemical victims Khatam-ol-Anbia Sardasht

Full name of responsible person

Mostafa Omari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Iran 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
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Full name of responsible person
Fereydoun Khayyeri
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Assistant Professor
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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
Not applicable
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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
The results of the research will be published as a scientific paper. The results will be announced to the beneficiary organizations.
When the data will become available and for how long
1 year
To whom data/document is available
Vice-Chancellor's Office for Research
Under which criteria data/document could be used
evaluation
From where data/document is obtainable
Vice-Chancellor's Office for Research
What processes are involved for a request to access data/document
Request from the research vice president
Comments