

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparing the effect of a designed care program by cases without intervention on control of asthma and quality of life in 60 patients with asthma referring to selected clinics of Shiraz university of medical sciences

Protocol summary

Summary

This study is a randomized clinical trial on 60 patients with asthma in selected clinics in Shiraz (Faghihi and Motahary) was performed to evaluate the effect of designed care program on control of asthma and quality of life in patient with asthma. 2) Design: After obtaining informed consent, eligible patients were randomly assigned to two groups: education with rehabilitation and control groups. Methods: before intervention we measured basic test with asthma Control Questionnaire, Quality of Life Questionnaire and peak flow meter in two groups. The interventional group received care programs that include education about asthma and its treatment and rehabilitation was done during one month. Then, immediately and two months after the intervention, two groups were evaluated. During this period, the control group received no intervention. Inclusion criteria: patients with asthma, age range 19 -65 years, Failure to participate in similar programs in the past 6 months, Absence of other known chronic condition that requires special care and different programs. Exclusion criteria were: having muscle problems-bone defects, heart disease-cardiovascular diseases, pregnancy or acute diseases that may be incompatible with the exercise, lack of cooperation and participation in the study and absence of two or more training sessions 6) Interventions: asthma education, rehabilitation and exercise techniques under the expert supervision.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014041617299N1**

Registration date: **2014-12-19, 1393/09/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-12-19, 1393/09/28

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shiraz University of Medical Sciences

Expected recruitment start date

2014-01-21, 1392/11/01

Expected recruitment end date

2014-06-21, 1393/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of a designed care program by cases without intervention on control of asthma and quality of life in 60 patients with asthma referring to selected clinics of Shiraz university of medical sciences

Public title

Effect of care program on Asthma control and quality of life

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: 1) patients with asthma disease after approval by the relevant specialist. 2) In asthmatic patients, age range 19 -65 years. 3) they wish to participate in the study. 4) Failure to participate in similar programs in the past 6 months. 5) absence of other known chronic condition that requires special care and different programs. Exclusion criteria were: 1) having muscle problems, bone defects, heart disease - cardiovascular diseases, pregnancy or acute diseases that may be incompatible with the exercise. 2) lack of cooperation and participation in the study. 3) absence of two or more training sessions.

Age

From **19 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Block randomization method is presented.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Shiraz University of Medical Sciences Ethics Committee

Street address

Vice Chancellor for Research, 7th floor, Central Building of Shiraz University of Medical Sciences, Zand Street, Shiraz.

City

Shiraz

Postal code

1978-71345

Approval date

2014-01-15, 1392/10/25

Ethics committee reference number
6851

Health conditions studied**1****Description of health condition studied**

Asthma

ICD-10 code

j45

ICD-10 code description

asthma

Primary outcomes**1****Description**

Asthma Control

Timepoint

Before the intervention, immediately after intervention, two Months after treatment

Method of measurement

Peak flow meter, Asthma Control Test

2**Description**

Quality of life

Timepoint

Before the intervention, immediately after intervention and two months after treatment

Method of measurement

Asthma Quality of Life Questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: The rehabilitation-educational classes were held according to pre-recorded training schedule for the intervention group as 4-6 sessions of 60 minutes for one month (depending on training needs, understanding of each individual and their educational level, the length of the class time may increase). Educational items include: understanding the disease and its pathophysiology, allergens, drug treatments and their side effects, using spray correctly and teaching effective coughing, effective exercise techniques, and self-care. In addition, pulmonary rehabilitation was provided under the supervision of a specialist in physical medicine as moderate-intensity aerobic exercise 6-5 days per week, each time 30 minutes for large muscle groups and correct posture and contraction of the shoulder, shrugging and rotating of shoulders, stretching

the shoulder girdle, spinal cord, and intercostals muscles, exercising deep breath and holding it, along with relaxation training. The participants were given pamphlets. Follow-up phone calls were conducted by the researcher to control their abeyance from the care program.

Category

Other

2

Description

The control group received routine care and education. Also at the end of the study, the control group also runs a training program and manual were awarded to them.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz Motahari Clinic

Full name of responsible person

Masum Masumpoor

Street address

Namazi Square, Shiraz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Shiraz University of Medical Sciences

Full name of responsible person

Gholamreza Hatam

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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

Vice Chancellor for Research, Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Zahra Molazem

Position

PHD in nursing

Other areas of specialty/work

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty