

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 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

###### Name

Masumeh Zarei

###### Name of organization / entity

Shiraz University Medical of Sciences

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Iran (Islamic Republic of)

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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

**City**

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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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**City**

Shiraz

**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**

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Zahra Molazem

**Position**

PHD in nursing

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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*