

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### The impact of self-care education on awareness, attitude and quality of life in patients with asthma referred Shahid Beheshti hospital to clinic of Hamedan university of medical sciences

#### Protocol summary

##### Study aim

Determining the effect of self-care education on knowledge, attitude and quality of life in asthmatic patients

##### Design

A randomized, controlled clinical trial of 104 patients

##### Settings and conduct

The purpose of this study was to determine the effect of self-care education on knowledge, attitude and quality of life of asthmatic patients referred to Shahid Beheshti hospital of Hamedan University of Medical Sciences. The number of samples in this study is 104 patients. In this study, patients were randomly divided into two groups of intervention and control. In the intervention group, educational intervention will be performed in 4 sessions, but in the control group, except for routine care, no action will be taken. 8 weeks after the end of the intervention, the questionnaires will be completed by the two groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 20 and 65 years, Suffering from asthma, Not having other chronic diseases. Exclusion criteria: Exit for any reason during the study, such as death, dissatisfaction to continue participating in the study

##### Intervention groups

In the intervention group, self-care education will be given in four sessions. The first session includes anatomy and physiology training, the second session includes how to adhere to the proper diet, how to adhere to the prescribed regimen, the third session includes daily activities, exercise, stress-avoidance education. The fourth session involves training skills such as the use of respiratory sprays. Then, 8 weeks after the completion of the interventions, the questionnaires are given to two groups.

##### Main outcome variables

Quality of life

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160110025929N7**

Registration date: **2018-02-06, 1396/11/17**

Registration timing: **prospective**

Last update: **2018-02-23, 1396/12/04**

Update count: **1**

##### Registration date

2018-02-06, 1396/11/17

##### Registrant information

##### Name

Mehdi Molavi Vardanjani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 3422 5056

##### Email address

m.molavi@umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-02-09, 1396/11/20

##### Expected recruitment end date

2019-02-09, 1397/11/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

The impact of self-care education on awareness, attitude and quality of life in patients with asthma referred Shahid Beheshti hospital to clinic of Hamedan university of medical sciences

**Public title**

Impact of self-care education on awareness, attitude and quality of life in patients with asthma

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age between 20 and 65 years Suffering from asthma Not having other chronic diseases

**Exclusion criteria:**

Dissatisfaction to continue participating in the study Exit for any reason during the study, such as death

**Age**

From **20 years** old to **65 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **104**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomly, 104 patients are selected. Then, using random blocks, they will be divided equally in to two groups of intervention and control

**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 Hamedan University of Medical Sciences

**Street address**

Shahid Fahmideh St, Hamadan University of Medical Sciences, Hamadan

**City**

Hamadan

**Province**

Hamadan

**Postal code**

38698-65178

**Approval date**

2018-01-13, 1396/10/23

**Ethics committee reference number**

IR.UMSHA.REC.1396.725

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

Asthma

**ICD-10 code**

J45

**ICD-10 code description**

Asthma

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

Quality of life

**Timepoint**

Before and after intervention

**Method of measurement**

Questionnaire

**Secondary outcomes**

empty

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

Intervention group: Self-care education will be given in four sessions. The first session includes anatomy and physiology training, the second session includes how to adhere to the proper diet, how to adhere to the prescribed regimen, the third session includes daily activities, exercise, stress-avoidance education. The fourth session involves training skills such as the use of respiratory sprays

**Category**

Lifestyle

**2****Description**

Control group: Except for routine care, no action will be taken.

**Category**

Lifestyle

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Beheshti hospital

**Full name of responsible person**

Amir Sadeghi

**Street address**

Shahid Fahmideh St, Hamadan University of Medical Sciences, Hamadan

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**Email**

sadeghi@umsha.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Saeed Bashirian

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s-bashirian@umsha.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Hamedan 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**

Hamedan University of Medical Sciences

**Full name of responsible person**

Amir Sadeghi

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Amir Sadeghi

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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## Person responsible for updating data

#### Contact

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Somayeh Kokabi

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

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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**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available