

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Investigation of the effect of theory-based education on asthma control behaviors among women with asthma referred to Amir Al-Momenin Hospital in Arak

#### Protocol summary

##### Study aim

Determining the effect of theory-based training on asthma control behaviors in asthmatic women referred to Amirul Mominin Hospital in Arak

##### Design

The study population is 80 women with asthma, 40 of whom are randomly assigned to the intervention group and 40 to the control group.

##### Settings and conduct

This study is conducted in the city of Arak to educate women with asthma. In this study, it is a randomized controlled trial that is selected by simple random and placed in intervention and control groups.

##### Participants/Inclusion and exclusion criteria

1. A person suffering from asthma with a doctor's confirmation 2. Not suffering from other chronic diseases, such as chronic obstructive pulmonary disease (COPD), which includes chronic bronchitis, emphysema, and small airways disease. 3. Age 18 to 65 years 4. Not having communication problems such as deafness and being literate 5. Living in Arak for at least one year

##### Intervention groups

The desired training program is implemented in a combined way (direct training including group discussion, lectures, questions and answers, film showing and indirect training including distribution of pamphlets and educational booklets). Based on the needs assessment, the number of sessions and the method are determined. The training is based on the health belief model in the field of prevention of exposure to air pollution, medication compliance and dietary compliance in women with asthma for the intervention group.

##### Main outcome variables

The main outcome variable is performing asthma disease control behaviors (including medication adherence, avoiding exposure to air pollution, and following diet) in women with asthma.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20231126060178N1**

Registration date: **2023-12-06, 1402/09/15**

Registration timing: **prospective**

Last update: **2023-12-06, 1402/09/15**

Update count: **0**

##### Registration date

2023-12-06, 1402/09/15

##### Registrant information

##### Name

Fateme Bagheri

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 3465 4680

##### Email address

f.bagheri@arakmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-04-20, 1403/02/01

##### Expected recruitment end date

2024-05-21, 1403/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Investigation of the effect of theory-based education on asthma control behaviors among women with asthma referred to Amir Al-Momenin Hospital in Arak

## Public title

Investigation of the effect of theory-based education on asthma control behaviors among women with asthma referred to Amir Al-Momenin Hospital in Arak

## Purpose

Education/Guidance

## Inclusion/Exclusion criteria

### Inclusion criteria:

A person suffering from asthma with a doctor's confirmation Not suffering from other chronic diseases, such as chronic obstructive pulmonary disease (COPD), which includes chronic bronchitis, emphysema, and small airways disease. Not having communication problems such as deafness and being literate Living in Arak for at least one year Age: 18 to 65 years old

### Exclusion criteria:

Leaving for any reason during the study, such as death, relocation and unwillingness to continue participating in the study Patients with severe asthma are admitted to the ward Non-attendance of sick women in half of the training sessions Non-availability of female patients when completing the post-intervention questionnaire

## Age

From **18 years** old to **65 years** old

## Gender

Female

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **80**

## Randomization (investigator's opinion)

Randomized

## Randomization description

The patients are coded based on the list prepared by the hospital's information technology department and entered into the SPSS software, and they are divided into two groups. It will be divided by simple random with the above software. Finally, 40 people will be included in each of the groups under study.

## 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 Arak University of Medical Sciences

### Street address

Vice-Chancellor of Education and Research, Pardis Educational Complex, Basij Square, Sardasht

### City

Arak

### Province

Markazi

### Postal code

38481-7-6941

## Approval date

2022-12-05, 1401/09/14

## Ethics committee reference number

IR.ARAKMU.REC.1401.258

## Health conditions studied

## 1

## Description of health condition studied

Asthma

## ICD-10 code

J45

## ICD-10 code description

Asthma

## Primary outcomes

## 1

## Description

Improving the ability of asthmatic women in asthma control behaviors

## Timepoint

Before the intervention and three months after the intervention

## Method of measurement

In this study, two questionnaires are used: 1- Asthma control questionnaire 2- Theory-based questionnaire to measure the effect of the educational program on the constructs of the health belief model

## Secondary outcomes

empty

## Intervention groups

## 1

## Description

Intervention group: In this study, the group received the designed educational intervention test. The desired training program is implemented in a combined way (direct training including group discussion, lectures, questions and answers, film showing and indirect training including distribution of pamphlets and educational

booklets). Based on the needs assessment, the number of sessions and the method are determined. The training is based on the health belief model in the field of prevention of exposure to air pollution, medication compliance and dietary compliance in women with asthma for the intervention group.

**Category**

N/A

**2**

**Description**

Control group: without educational intervention and 3 months after the implementation of the intervention, the test groups will be checked and compared again through questionnaires.

**Category**

N/A

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Amir al-Mominin hospital in Arak city

**Full name of responsible person**

Dr. Mohsen Shamsi

**Street address**

AmirulMominin Medical Education Center, next to Medical Faculty, Basij Square

**City**

Arak

**Province**

Markazi

**Postal code**

3848176941

**Phone**

+98 86 3836 0000

**Fax**

+98 86 3417 3619

**Email**

it-amiralmomenin@arakmu.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Dr. Davoud Hekmat Po

**Street address**

Research Assistant, Arak University of Medical Sciences, Pardis Educational Complex, Basij Square, Sardasht

**City**

Arak

**Province**

Markazi

**Postal code**

3848176941

**Phone**

+98 86 6368 4615

**Fax**

+98 86 6443 3368

**Email**

dr\_hekmat@arakmu.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Arak 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**

Arak University of Medical Sciences

**Full name of responsible person**

Fateme Bagheri

**Position**

Master's student in health education

**Latest degree**

Bachelor

**Other areas of specialty/work**

Health Promotion

**Street address**

Arak Faculty of Health, Golestan, Mustafa Khomeini

**City**

Arak

**Province**

Markazi

**Postal code**

3818146851

**Phone**

+98 66 4342 1995

**Email**

f97bagheri@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

dr.mohsen shamsi

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Health Promotion

**Street address**

Arak Faculty of Health, Golestan, Mustafa Khomeini

**City**

Arak

**Province**

Markazi

**Postal code**

3818146851

**Phone**

+98 86 3368 4615

**Email**

dr.shamsi@arakmu.ac.ir

**City**

Arak

**Province**

Markazi

**Postal code**

3818146851

**Phone**

+98 86 3342 1995

**Email**

f97bagheri@gmail.com

**Person responsible for updating data****Contact****Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Fateme bagheri

**Position**

Master's student in health education

**Latest degree**

Bachelor

**Other areas of specialty/work**

Health Promotion

**Street address**

Arak Faculty of Health, Golestan, Mustafa Khomeini

**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**

Not applicable

**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