Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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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

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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

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Sponsors / Funding sources

1

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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

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

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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
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