

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

Design, Implementation and Evaluation of Care Program Adherence to Treatment in Patients with Asthma

Protocol summary

Study aim

general purpose 1) Designing, implementing and evaluating the care program for adherence to treatment in patients with asthma who refer to the asthma clinic of hospitals affiliated to Shahid Beheshti University of Medical Sciences 1401

Design

The research population is the patients with asthma, which is done by the available sampling method and is divided into two intervention and control groups by random allocation method.

Settings and conduct

In this study, which will be conducted on patients with asthma in hospitals affiliated to Shahid Beheshti University of Medical Sciences, the level of adherence to treatment will be checked with a questionnaire whose validity and reliability have already been checked, and the needs of the patients will be extracted through it. And then based on that a care plan is prepared and based on that care plan is taught to the patients in 3 to 5 sessions and after two months the questionnaire is done again by the intervention and control group and the level of treatment compliance in these two groups is compared

Participants/Inclusion and exclusion criteria

Criteria for entering • Has asthma and at least 3 months have passed since the diagnosis • Frequent recurrence of the disease • Having a minimum education level of a diploma • Age 18 to 60 years Exclusion criteria • Incomplete completion of the questionnaire • Failure to accept the care plan • Foot

Intervention groups

The samples are 94 people, who are divided into two intervention and control groups, and for the intervention group, a care plan is implemented, and for the control group, they receive routine clinic treatments and are evaluated after 2 months.

Main outcome variables

Adherence to treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220815055708N1**

Registration date: **2022-09-21, 1401/06/30**

Registration timing: **registered_while_recruiting**

Last update: **2022-09-21, 1401/06/30**

Update count: **0**

Registration date

2022-09-21, 1401/06/30

Registrant information

Name

Faranak Ghorbanian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3653 7472

Email address

faranakghorbanian76@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-01, 1401/06/10

Expected recruitment end date

2023-03-01, 1401/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Design, Implementation and Evaluation of Care Program
Adherence to Treatment in Patients with Asthma

Public title

Design, Implementation and Evaluation of Care Program
Adherence to Treatment in Patients with Asthma

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

• Has asthma and at least 3 months have passed since the diagnosis • Frequent recurrence of the disease
Having a minimum education level of diploma Age 18 to 60 years

Exclusion criteria:**Age**

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **94**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the samples will be entered into the study using the available sampling method and based on the entry criteria, and in this study, random allocation will be done, for this purpose, the researcher will first determine a total sample size, and then randomly (by lottery method)) will assign groups of them to the intervention group and assign the rest to the control group.

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**

Research Ethics Committees of School of Pharmacy and Nursing & Midwifery- Shahid Beheshti University

Street address

Tehran, intersection of Valiasr and Ayatollah Rafsanjani, Beheshti Nursing and Midwifery Faculty

City

tehran

Province

Tehran

Postal code

1985717443

Approval date

2022-08-09, 1401/05/18

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1401.099

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

Asthma

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

The effect of treatment adherence program on adherence to treatment regimen

Timepoint

After the implementation of the care program, 2 months later, the effectiveness of this care program will be checked

Method of measurement

by questionnaire

Secondary outcomes

empty

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

Intervention group: Asthma patients who receive care plan

Category

Other

2**Description**

Control group: Asthma patients who do not receive a care plan

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Affiliated Hospitals of Shahid Beheshti University of Medical Sciences and Health Services - Faculty

Full name of responsible person

foroza atashzade

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sbnmf@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Foroza atashzade

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Grant name

Grant code / Reference number

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

No

Title of funding source

School of Nursing and Midwifery

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Faranak Ghorbanian

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Position

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Person responsible for updating data

Contact

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Fax**Email**

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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