

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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		Tehran
Public title		Postal code
Design, Implementation and Evaluation of Care Program Adherence to Treatment in Patients with Asthma		1985717443
Purpose		Approval date
Education/Guidance		2022-08-09, 1401/05/18
Inclusion/Exclusion criteria		Ethics committee reference number
Inclusion criteria:		IR.SBMU.PHARMACY.REC.1401.099
- 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		Health conditions studied
Exclusion criteria:		<u>1</u>
Age		Description of health condition studied
From 18 years old to 60 years old		Asthma
Gender		ICD-10 code
Both		ICD-10 code description
Phase		Primary outcomes
N/A		<u>1</u>
Groups that have been masked		Description
No information		The effect of treatment adherence program on adherence to treatment regimen
Sample size		Timepoint
Target sample size: 94		After the implementation of the care program, 2 months later, the effectiveness of this care program will be checked
Randomization (investigator's opinion)		Method of measurement
Randomized		by questionnaire
Randomization description		Secondary outcomes
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.		empty
Blinding (investigator's opinion)		Intervention groups
Not blinded		<u>1</u>
Blinding description		Description
Placebo		Intervention group: Asthma patients who receive care plan
Not used		Category
Assignment		Other
Parallel		2
Other design features		Description
Secondary Ids		Control group: Asthma patients who do not receive a care plan
empty		Category
Ethics committees		Other
<u>1</u>		Recruitment centers
Ethics committee		<u>1</u>
Name of ethics committee		Recruitment center
Research Ethics Committees of School of Pharmacy and Nursing & Midwifery- Shahid Beheshti University		Name of recruitment center
Street address		Affiliated Hospitals of Shahid Beheshti University of Medical Sciences and Health Services - Faculty
Tehran, intersection of Valiasr and Ayatollah Rafsanjani, Beheshti Nursing and Midwifery Faculty		Full name of responsible person
City		
tehran		
Province		

foroza atashzade

Street address

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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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Faculty of Nursing and Midwifery

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Email

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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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Tehran, the intersection of Valiasr and Ayatollah
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Person responsible for scientific inquiries

Contact

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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