

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of family-centered empowerment pattern on nutrition style and physical activity in patients with asthma

Protocol summary

Summary

The main objective of this study is to determine the effect of Family-Centered Empowerment Model on feeding style and physical activity in patients with asthma. This is a randomized clinical trial study. The sample size consists of 70 patients with asthma admitted to Amiralmomenin Hospital of Zabol. All patients were selected on available method and were randomly divided to intervention (35 patients) and control groups (35 patients). The inclusion criteria include: suffering with asthma, experiencing asthma attack at least once in the last six months; literacy; lack of other chronic diseases. In addition, exclusion criteria include: lack of participation in all meetings of the intervention. Intervention will be carried out as implementation of the empowerment program on four steps (increased perceived threat, problem solving, educational participation, and evaluation) for samples of the study consisting of five 45-minute sessions of group counseling within two days a week. Participants in the control group received no intervention and are only subject to typical trainings. Information is collected in the intervention and control groups using a demographic questionnaire, feeding style self-made questionnaire and Beck standard questionnaire in four phases of before the intervention and one week, one month and three months after intervention. The main outcome variables are to examine the effects of implementing empowerment program on the feeding style and physical activity in patients with asthma.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016071428927N1**

Registration date: **2016-09-04, 1395/06/14**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-09-04, 1395/06/14

Registrant information

Name

Fatemeh Khajehmahmoud

Name of organization / entity

Birjand University of Medical Sciences

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Iran (Islamic Republic of)

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+98 56 3238 1400

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Birjand University of Medical Sciences

Expected recruitment start date

2016-07-22, 1395/05/01

Expected recruitment end date

2016-08-22, 1395/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of family-centered empowerment pattern on nutrition style and physical activity in patients with asthma

Public title

Effect of family-centered empowerment pattern on nutrition style and physical activity in patients with

asthma

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion Criteria: Suffering from asthma; experiencing asthma attack at least once in the last six months; literacy; lack of other chronic diseases; patients aged 18-60 years. Exclusion Criteria: Suffering with known physical and mental illnesses; lack of participation in all meetings of the intervention.

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: **70**

Randomization (investigator's opinion)
Randomized

Randomization description

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

Birjand University of Medical Sciences

Street address

Ghaffari Street, Birjand University of Medical Sciences, Birjand

City

Birjand

Postal code

9717853577

Approval date

2016-03-12, 1394/12/22

Ethics committee reference number

lr.bums.1394.367

Health conditions studied

1

Description of health condition studied

Asthma

ICD-10 code

J45

ICD-10 code description

Mixed asthma Combination of conditions listed in J45.0 and J45.1

Primary outcomes

1

Description

Nutrition Style

Timepoint

Before the intervention and one week, one month, and three months after the intervention

Method of measurement

questionnaire

2

Description

Physical Activity

Timepoint

Before the intervention and one week, one month, and three months after the intervention

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention will implement as a discussion group of 6-8 people over 3-5 meetings (maximum 45 minutes) as follows: The first step in Family-Centered Empowerment Model is increasing the threat perceived by the patient in relation to the nature of the disease and the potential side effects of the disease and treatment using discussion groups. The second phase is to use problem-solving skills in groups of 6-8 persons in which the patients are faced with problems and problem-solving process. Patients express their problems in this phase and discuss on how to solve them according to their viewpoints and subsequently participate in selecting the best solution. In the third phase, patients are required to transfer the contents discussed in training sessions to their active family member through flash cards using educational participation to promote self-esteem. In the fourth stage, process evaluation will be done with special tools to measure empowerment and the patients' empowerment and their active family member are studied in about 7-10 days after the intervention.

Category

Lifestyle

2

Description

In the control group did not perform certain actions

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali Hospital

Full name of responsible person

Fatemeh Khajehmahmoud

Street address

3 Kms away from Zabol- Zahedan road

City

Zabol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Birjand University of Medical Sciences

Full name of responsible person

Dr. Tooba Kazemi

Street address

3th floor, Birjand University of Medical Sciences, Ayatollah Ghaffari Street, Birjand

City

Birjand

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Birjand University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Fatemeh Khajehmahmoud

Position

MSc Student in Nursing

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Web page address	<i>empty</i>
Sharing plan	Informed Consent Form
	<i>empty</i>
Deidentified Individual Participant Data Set (IPD)	Clinical Study Report
<i>empty</i>	<i>empty</i>
Study Protocol	Analytic Code
<i>empty</i>	<i>empty</i>
Statistical Analysis Plan	Data Dictionary
	<i>empty</i>