

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

The Impact of Motivational Interview on Self-Efficacy, Beliefs Medicines and Medication Adherence among Adolescents with Asthma

Protocol summary

Study aim

Determining the Impact of Interview on Drug Belief, Self-Efficiency and Adherence to Drug Adolescents with Asthma

Design

The research method is block random assignment in two groups of intervention and control. For this purpose blocks of size 4 will be used. To create a random sequence, the randomizer.org website will be used to hide the random allocation, and the numbered dark envelopes will be used, in which the group name is specified in the random sequence generated. Then, according to the order of entering samples, the sample for the first sample of the envelope number one is opened and the group will be identified until the end.

Settings and conduct

Patients in the intervention group will receive motivational interviews in three sessions of 40 to 60 minutes, individually per week based on the protocol described (for each motivational interview session). Session 1: Patient Assessment, Environmental and External Barriers to Drug Abuse, second Session: Interview with Patient in Connection with Individual and Internal Barriers to Drug Abuse, Session third: Promoting Self-Efficacy Levels The client All interviews are conducted by a qualified person who has received the necessary training in this regard. The interviewer will use books, articles and CDs to improve his skill and experience in the field of motivational interviewing, but if the sample is in the control group, it will only run a pre-test and clinical routine care for the sample. Became Forty days after the end of the post-test intervention.

Participants/Inclusion and exclusion criteria

ages 10 to 18 years old, asthma diagnosis in the past year by the physician, Unwillingness to participate in the follow-up of the study also considered as exclusion criteria

Intervention groups

intervention group (20 people), in the control group (26)

Main outcome variables

Self-Efficacy, Beliefs Medicines and Medication Adherence

General information

Reason for update

Changes in volume, sample age and study completion

Acronym

IRCT registration information

IRCT registration number: **IRCT20180217038766N1**

Registration date: **2018-03-04, 1396/12/13**

Registration timing: **registered_while_recruiting**

Last update: **2020-02-02, 1398/11/13**

Update count: **1**

Registration date

2018-03-04, 1396/12/13

Registrant information

Name

Atefeh Barikani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

a-barikani@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-14, 1396/11/25

Expected recruitment end date

2019-04-09, 1398/01/20

Actual recruitment start date

2018-02-14, 1396/11/25

Actual recruitment end date

2019-04-09, 1398/01/20

Trial completion date

2019-04-09, 1398/01/20

Scientific title

The Impact of Motivational Interview on Self-Efficacy, Beliefs Medicines and Medication Adherence among Adolescents with Asthma

Public title

"Impact of Motivational Interview on Self-Efficacy",
"Impact of Motivational Interview on Beliefs Medicines "
"Impact of Motivational Interview on Medication Adherence"

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

The criteria for entering the study include: ages 10 to 18 years, asthma diagnosis in the past year by the physician, the occurrence of moderate and severe persistent asthma, daily use of asthma prevention by corticosteroids, non-use of the drug for problems other than illness Asthma is the ability to speak Persian and desire to communicate with scholars.

Exclusion criteria:

Unwillingness to participate in the study, hospitalization during the study period, incidents and unrelated stressful experiences during the study, absence from the motivational interview in two consecutive sessions, attendance in other educational and counseling programs during the study Are also considered as exclusion criteria.

Age

From **10 years** old to **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **52**

Actual sample size reached: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

The research method is block random assignment in two groups of intervention and control. For this purpose blocks of size 4 will be used. To create a random sequence, the randomizer.org website will be used to hide the random allocation, and the numbered dark envelopes will be used, in which the group name will be specified in the random sequence generated. Then, according to the order of entering samples, the sample for the first sample of the envelope number one is opened and the group will be identified until the end.

Blinding (investigator's opinion)

Double blinded

Blinding description

Bilingual blindness was conducted in participants and researchers in a way that the participants received the questionnaire after hearing the study objectives and the willingness of the company to study and sign the written consent, without the participants being aware that In the intervention group, or in the control group. The researcher also does not know that the participant is in the control group or the intervention, since after completing the questionnaire, the researcher opens the packet based on the random block and then realizes that the sample is in the control group or Intervention If the sample is in the control group, the researcher determines the post-test time for the sample and if the sample is in the intervention group, the researcher talks about setting the time for the intervention to be performed.

Placebo

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Tehran University of Medical Sciences

Street address

Ghods. Keshavarz Blvd, Tehran Town

City

Tehran

Province

Tehran

Postal code

3361648783

Approval date

2018-02-04, 1396/11/15

Ethics committee reference number

IR.TUMS.VCR.REC.1396.4439

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

Adolescents with Asthma

ICD-10 code

J45

ICD-10 code description

Asthma

Primary outcomes

1

Description

Drug Compliance (MARS's 10-item questionnaire) was conducted to measure drug compliance, the grading rate was never = 5, rarely = 4, sometimes = 3, most often = 2, always = 1. The scores obtained from this The questionnaire is divided into 10, and thus the range of scores to be obtained in a questionnaire is from 1 to 5. A score of more than 4.5 indicates good drug compliance and a score of less than 4.5 indicates poor drug compliance.)

Timepoint

Before intervention and 1 month after the last intervention session

Method of measurement

questionnaire Medication Adherence (MARS)

2

Description

Belief in the questionnaire was a questionnaire consisting of two dimensions of the necessity of drug use and concerns about drug issues. The method of scoring based on Likert scale was totally opposite = 1, opposed = 2, No matter = 3 I agree = 4 I totally agree = 5. Out of the 11 items, the BMQ 5 questionnaire is followed by concerns about drug issues and 6 afterwards on the need for drug use. The next scores for drug issues concern The sum of these is divided into 5, and the 6th grade points of the next need for drug use are combined and divided into six. The scores that can be obtained from the two dimensions mentioned above can be summarized. Dentistry varies between 1 and 5. Higher score = 5 in the dimension of concerns Concerns about drug issues The BMQ questionnaire indicates more concern about long-term use of the drug and a lower score of 1 indicates a lower concern regarding the long-term use of Medication. But in the case of the need for drug use, a higher score of 5 indicates a greater belief in the necessity of taking the drug for health and a lower score of 1 indicates a lower belief in the necessity of taking the drug to provide health.

Timepoint

Before intervention and 1 month after the last intervention session

Method of measurement

questionnaire Beliefs Medicines (BMQ)

3

Description

Self-efficacy (CASES 14-item questionnaire for measuring self-efficacy in adolescents), this questionnaire consists of two dimensions of prevention of asthmatic attacks (Gove1-8) and management of asthmatic attacks (Clause 9-14). The scoring method is not at all safe. = 1, I'm pretty sure = 2, I'm fairly sure = 3, I'm pretty sure = 4, I'm pretty sure = 5. Of the 14 items in the CASES 8 questionnaire, the item is dedicated to preventing asthma attacks and 6 items for management of asthma attacks. The scoring criteria available in the prevention of asthma attacks range from 40-40% and in the

management of asthmatic attacks is 6-30. A score of more than 40 in the prevention of asthma attacks indicates better prevention than H Asthma mortality and score less than 8 indicate a weakness in the prevention of asthma attacks and a greater score of 30 in the management of asthma attacks suggests better management of asthmatic attacks and a score of less than 6 indicates a weakness in the management of asthma attacks.)

Timepoint

Before intervention and 1 month after the last intervention session

Method of measurement

questionnaire Self-efficacy of childhood with asthma (CASES)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: There is only one intervention group. In the intervention group, motivational interviewing takes place in four sessions of 40 to 60 minutes, individually per week based on the protocol described (for each motivational interview session). Session 1: Patient Assessment, Second Session: Interview with Patient in Connection with Environmental and External Barriers to Drug Abuse, Third Session: Interview with Patient in Connection with Individual and Internal Barriers to Drug Abuse, Session Four: Promoting Self-Efficacy Levels The client

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Respiratory Clinic of Children's Medical Center in Imam Khomeini Hospital

Full name of responsible person

Atefeh Barikani

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Imam Khomeini Children's Medical Center, Keshavarz Blvd, Tehran Town

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Deputy of Research and Technology of Tehran
University of Medical Sciences

Street address

Ghods Ave, Keshavarz Blvd, Tehran Town

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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

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

atefeh barikani

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

reza negarandeh

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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atefeh barikani

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

A portion of the information, such as information on the main outcome or the like, can be shared.

When the data will become available and for how long

"Starting the access period 12 months after printing results"

To whom data/document is available

Researchers working in academia and academia

Under which criteria data/document could be used

Only the results of the study are to be used and, except for this case, there is no right in the analysis or other matters.

From where data/document is obtainable

atefeh barikani .by email barikani2000@gmail.com

What processes are involved for a request to access data/document

Whoever wants the study information should contact Atefeh Barikani by email. And if he accepts the terms from his / her side, the respondent will be informed as soon as possible.

Comments