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

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Iran (Islamic Republic of)

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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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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
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Person responsible for updating data

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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