Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Study of the Impact of Self- Management Education on 7-12 years old childrenś Asthma Control

Protocol summary

Summary

The purpose of this study was to determine the effect of self-management on the number of referrals to emergency, absence from school and the 7-12 years old children's FEV1(Forced Expiratory Volume in One Second). This is a randomized clinical trial that would be done for 2 weeks on 60 children with Asthma in 1394-95. 7-12 years old children should not suffer from Asthma and systemic diseases and if they do not wish, they should not be studied. The sample would be randomly divided into control and experimental groups. For each child, FEV1(Forced Expiratory Volume in One Second) should be measured before and after 12 weeks. In the group under WAP(Written Action Program) based on the symptoms, the demographic information and Asthma control questionnaires would be distributed, and in the control group the same questionnaires would be distributed. The data would be collected after 12 weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016011626043N1**
Registration date: **2016-08-11, 1395/05/21**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-08-11, 1395/05/21

Registrant information

Name
Soghra Hasani Narenjbaghi
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Islamic Azad University Sari Branch
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Recruitment status

Recruitment complete

Funding source

Islamic Azad University Sari Branch

Expected recruitment start date

2016-07-19, 1395/04/29

Expected recruitment end date

2017-03-19, 1395/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Study of the Impact of Self- Management Education on 7-12 years old childrenś Asthma Control

Public title

Self- Management in Children 7-12 aged with Asthma

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion:ˊA definitive diagnosis of Asthma by pulmonory spesialist ؛ ages 7 to 12 ؛The absence of serious systematic disease Exclusion: Unwillingness to cooperate during the investigation

Age

From **6 years** old to **11 years** old

Gender

Both

Phase

N/A

Groups that have been masked
No information
Sample size
Target sample size: **60**
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
Mazandaran University of Medical Sciences
Street address
Department of Research and Technology of Mazandran Universitu of Medical Sciences Moalem square Moalem street
City
Sari
Postal code
Approval date
2016-04-11, 1395/01/23
Ethics committee reference number
IR.MAZums.Rec.95-A102

Health conditions studied

1

Description of health condition studied
Asthma
ICD-10 code
j45.8
ICD-10 code description
Mixed Asthma

Primary outcomes

1

Description
FEV1(Forced Expiratory Volume in One Second)
Timepoint
Before and 3 months after intervation
Method of measurement
percent espirometery

2

Description
Days of Absence from School
Timepoint
Before and 3 months after intervation
Method of measurement
Questionnaire

3

Description
the number of referrals to emergency room
Timepoint
Before and 3 months after intervation
Method of measurement
Questionnaire

4

Description
Asthma contorol
Timepoint
After Intervantion
Method of measurement
Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Experimental (treatment) Group: For each child before treatment, FEV1 (Forced Expiratory Volume in One Second)would be measured using Spirometry. Then, the child would be asked to complete the demographic information and a written Action program (WAP) would be completed by the sensitivity and asthma specialist on the required orders in normal situation, before exercise and Asthmaattack that the child will act upon it during the following three months. The questionnaire on asthma control would be completed by the child weekly for the 12 weeks and the number of referrals to emergency and the days of absence from school would be recorded in the questionnaire by the child and 12 weeks after treatment FEV1(Forced Expiratory Volume in One Second) would be re- measured using Spirometry
Category
Lifestyle

2

Description
Control Group: For each child FEV1 (Forced Expiratory Volume in One Second)would be done using Spirometry before any treatment and 12 weeks after that. Then the child would be asked to complete the demographic information. The questionnaire on asthma control would be completed by the child weekly for the 12 weeks and

the number of referrals to emergency and the days of absence from school would be recorded in the questionnaire by the chil and 12 weeks after treatment FEV1(Forced Expiratory Volume in One Second) would be re- measured using Spirometry

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Bu Ali Sina Educational medical center sari

Full name of responsible person

Javad Ghaffari

Street address

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University Sari Bbranch

Full name of responsible person

Mohammad Farsi

Street address

7 km Sea Road Complex Islamic Azad University Sari Branch

City

Sari

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad University Sari Bbranch

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

Islamic Azad University Sari Brabnch

Full name of responsible person

Soghra Hasani Narenjbaghi

Position

Master Science Faculty Member

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty