

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 2026

### The Study of the Impact of Self- Management Education on 7-12 years old children's 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

###### Name of organization / entity

Islamic Azad University Sari Branch

###### Country

Iran (Islamic Republic of)

###### Phone

+98 11 3472 4813

###### Email address

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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 children's Asthma Control

###### Public title

Self- Management in Children 7-12 aged with Asthma

###### Purpose

Supportive

###### Inclusion/Exclusion criteria

Inclusion: A definitive diagnosis of Asthma by pulmonary specialist : 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 University 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 intervention

#### Method of measurement

percent spirometry

### 2

#### Description

Days of Absence from School

#### Timepoint

Before and 3 months after intervention

#### Method of measurement

Questionnaire

### 3

#### Description

the number of referrals to emergency room

#### Timepoint

Before and 3 months after intervention

#### Method of measurement

Questionnaire

### 4

#### Description

Asthma control

#### Timepoint

After Intervention

#### 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 Asthma attack 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 child 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

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**Web page address**

## **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*