

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Jun 2026

### The effect of self care program education on the quality of life of school-age children with asthma

#### Protocol summary

##### Summary

Aims: 1. Determine and compare the quality of life of school-age children with asthma in the intervention and control groups before intervention 2. Determine and compare the quality of life of school-age children with asthma in the intervention and control groups after the intervention. 3. Determine and compare the quality of life of school-age children with asthma in the intervention and control groups after the intervention, physical symptoms 4. Determine and compare the quality of life of school-age children with asthma in the emotional aspect of the intervention and control groups after the intervention. 5. Determine and compare the quality of life of school-age children with asthma in the active and control groups after the intervention After approval of the Ethics Committee of the University Asthma and Allergy Center, hospital officials will attend and introduce themselves to the subjects that are eligible for inclusion and cooperation after the description, written informed consent was taken The samples of 88 children of school age (12-7 years) referred to the Asthma and Allergy Center, Tehran Children make up at random (n = 6 blocks) were selected and divided into two groups. Inclusion criteria being age 12-7 years, asthma confirmed by a physician, child and family desire, not suffering from a mental disability and exclusion criteria of having missed training sessions, an incident which affect the quality of life of subjects disease Asthma and other chronic participate in research programs is similar. Data Inventory underlying demographic information (age, sex, education, duration of disease, family history, etc.) will record and quality of life in children with asthma (PedAQLQ) is appropriate for this group age and have physical, emotional, and activities for children. The routine will be performed in the control group interventions. The curriculum within 5 to 6 sessions (45-30 minutes) once a week for 8-6 persons and researcher in the group runs at the end of each question and answer session and will be

summarized. It is a way of teaching is adjusted according to age. So that children in classes I, II and III levels, and a fourth to sixth grade level are considered. To increase the attractiveness of images and videos related to education for children is used.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201306271788N7**

Registration date: **2013-07-06, 1392/04/15**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2013-07-06, 1392/04/15

##### Registrant information

##### Name

Leili Borimnejad

##### Name of organization / entity

Iran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6150 4212

##### Email address

borimnej@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

centre of Nursing Care Research

##### Expected recruitment start date

2013-07-23, 1392/05/01

##### Expected recruitment end date

2013-11-22, 1392/09/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of self care program education on the quality of life of school-age children with asthma

**Public title**

The effect of self care program education on the quality of life

**Purpose**

Supportive

**Inclusion/Exclusion criteria**

Inclusion criteria: Age between 12-7 years with asthma confirmed by a physician, child and family desire, not suffering from mental disabilities Exclusion criteria: having missed training sessions, an incident that may affect the quality of life of subjects, other chronic diseases like asthma and participate in research programs

**Age**

From **7 years** old to **12 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **88**

**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**

Tehran University of Medical Sciences

**Street address**

Ghods Street

**City**

Tehran

**Postal code****Approval date**

2013-03-11, 1391/12/21

**Ethics committee reference number**

3292/130/91/3

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

Asthma

**ICD-10 code**

J45.0

**ICD-10 code description**

Predominantly allergic asthma

**Primary outcomes****1****Description**

Quality of Life

**Timepoint**

eight week

**Method of measurement**

Pediatric asthmatic quality of Life Questionnaire

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention: Curriculum within 5 to 6 sessions (45-30 minutes) once a week for In groups of 8-6 persons and researcher runs at the end of each question and answer session will be summarized. It is a way of teaching is adjusted according to age. So that children in classes I, II and III levels, and a fourth to sixth grade level are considered. To increase the attractiveness of images and videos related to the education of children used

**Category**

Other

**2****Description**

Control: Routine care provided by the Asthma and Allergy Association will receive

**Category**

Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Pediatric Medical Centre

**Full name of responsible person**

Tahmineh Naji

**Street address**

Gharib Street

**City**

Tehran

Tehran

**Postal code****Phone**

+98 21 8867 1613

**Fax****Email**

l.borimnejad@gmail.comlborimnejad@tums.ac.ir

**Web page address****Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Centre of Nursing Care Research

**Full name of responsible person**

Seyede Fatemeh Haghdoost Osquee

**Street address**

Yasemi Street

**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Centre of Nursing Care Research

**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**

Nursing and Midwifery School

**Full name of responsible person**

Leili Borimnejad

**Position**

Ph.D

**Other areas of specialty/work****Street address**

Yasemi Street

**City****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Nursing And Midwifry School

**Full name of responsible person**

Leili Borimnejad

**Position**

Ph.D

**Other areas of specialty/work****Street address**

Yasemi Street

**City**

Tehran

**Postal code****Phone**

+98 21 8867 1613

**Fax****Email**

l.borimnejad@gmail.com

**Web page address****Person responsible for updating data****Contact****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*