

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

The effect of education-modificational intervention on psychosocial factors and asthma control among adolescents with asthma in respiratory speciality clinics of Tabriz -2011

Protocol summary

Summary

The purpose of this study is to assess the effect of education-modificational intervention on psychosocial factors (attitude, self-efficacy, quality of life) and asthma control. The research is experimental study and based on pretest-posttest control group design. A sample of 60 adolescents with asthma from 12 thru 18 years of age in respiratory speciality clinics participate in the study. Groups will be assigned randomly to intervention and control groups. Measurements of attitudes, quality of life, self- efficacy, and asthma control. Questionnaires will be collected prior intervention and five week post intervention in both groups. Intervention group receive the asthma face to face education program from asthma booklet and telephone follow up. Asthma education program is designed as four session, with emphasize on triggers of asthma and how to modification and control these triggers. Each session will take 20-30 min and trigger modification individually plan will be perform at last session.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201112078315N1**

Registration date: **2012-05-06, 1391/02/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-05-06, 1391/02/17

Registrant information

Name

Leila Valizadeh

Name of organization / entity

Tabriz University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2012-01-21, 1390/11/01

Expected recruitment end date

2012-03-19, 1390/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of education-modificational intervention on psychosocial factors and asthma control among adolescents with asthma in respiratory speciality clinics of Tabriz -2011

Public title

The effect of education-modificational intervention on psychosocial factors and asthma control among adolescents with asthma

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: age between 12-18 years old; Asthma diagnosis $\geq$ 1 year ; having moderate or severe

persistent asthma had physician-diagnosed; live in Tabriz and suburb; being able to read and write; being satisfied to participate in the study and no mental disability. Exclusion criteria: having other acute diseases and esophageal reflux, sinusitis, rhinitis ; change the location of Tabriz and suburb and incomplete participated in educational sessions.

Age

From **12 years** old to **18 years** old

Gender

Both

Phase

2-3

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

Tabriz Medical Sciences Ethic Commette

Street address

Tabriz University of Medical Sciences, Golgasht Street

City

Tabriz

Postal code

Approval date

2011-11-21, 1390/08/30

Ethics committee reference number

9051

Health conditions studied

1

Description of health condition studied

asthma

ICD-10 code

J45

ICD-10 code description

Mixed asthma

Primary outcomes

1

Description

Attitude

Timepoint

prior intervention and five week post intervention

Method of measurement

Child Attitude Toward Illness Scale

2

Description

Self-Efficacy

Timepoint

prior intervention and five week post intervention

Method of measurement

Child Asthma Self-Efficacy scale

3

Description

Quality of Life

Timepoint

prior intervention and five week post intervention

Method of measurement

Mini Pediatric Asthma Quality of Life Questionnaire (Mini PAQLQ)

Secondary outcomes

1

Description

Asthma control

Timepoint

prior intervention and five week post intervention

Method of measurement

Asthma Control Diary Questionnaire (modified)

Intervention groups

1

Description

Asthma education program is designed as four face to face sessions,with emphasize on triggers of asthma and how to modification and control these triggers. An individual modificational planning for identify and modify asthma triggers will perform last session. Each session will take 20-30 min.

Category

Behavior

2

Description

control group: routine care

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Sheikhalraeis speciality clinic

Full name of responsible person

Soheila Zarei

Street address

Maralan Square, Azady street

City

Tabriz

2

Recruitment center

Name of recruitment center

Pediatric Respiratory speciality clinic

Full name of responsible person

Soheila Zarei

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Maralan Squire, Azady Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz International University of Medical Sciences
(Aras)

Full name of responsible person

Mahmood Nazarpour

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Imam khomeini Street

City

Jolfa

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz International University of Medical Sciences (Aras)

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

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Soheila Zarei

Position

MS nursing Student

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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