

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Effectiveness of partnership educational method on decreasing anxiety and stress in mothers of children with cystic fibrosis

Protocol summary

Summary

The aim of the study: Effectiveness of partnership educational method on decreasing anxiety and stress in mothers of children with cystic fibrosis. Type of study: This study is a quasi-experimental study with two groups. Research environment: Children's hospitals affiliated with the Tehran University of Medical Sciences (Children's Medical Center, Valiasr and Bahrami), Shahid Beheshti (Mofid) and Iran (Ali Asghar and Shahid Fahmideh). Research community: All mothers of hospitalized children with Cystic Fibrosis. Sampling : The convenience sampling. Entry criteria: The definitive diagnosis of CF; Able to read and write Persian; Housewife; Absence of congenital anomalies in children; The absence of stressful events in the family, such as having a child who has a serious illness and the married mothers. Exclusion criteria: Unwillingness to participate in research. Sample size: Test and control groups of 44 each. The intervention: In the first day, mothers will sign the informed consent form. Before the intervention, mothers will complete Spielberger anxiety questionnaire, parental stress and demographic information. Mothers will receive a booklet. In the second and third days, mothers will study the booklet and will discuss with each other. In the Seventh day, questionnaires will be completed by the mothers again. The control group will receive the usual medical care. The results of the questionnaires will be compared

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201501296316N4**

Registration date: **2017-01-06, 1395/10/17**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-01-06, 1395/10/17

Registrant information

Name

Zahra Daneshvar Ameri

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6692 7171

Email address

daneshvz@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Science

Expected recruitment start date

2016-10-21, 1395/07/30

Expected recruitment end date

2017-03-05, 1395/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of partnership educational method on decreasing anxiety and stress in mothers of children with cystic fibrosis

Public title

Clinical trials of Effectiveness of partnership educational method on decreasing anxiety and stress in mothers of children with cystic fibrosis

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: The definitive diagnosis of CF; Able to read and write Persian; Housewife; Absence of congenital anomalies in children; The absence of stressful events in the family; such as having a child who has a serious illness; The married mothers. Exclusion criteria: Unwillingness to participate in research.

Age

From **1 month** old to **18 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)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Names are marking and odd numbers will enter in the experimental group and even numbers in the control group.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran university of medical science School of Nursing and Midwifery

Street address

Tehran - tohid Square

City

tehran

Postal code**Approval date**

2015-11-03, 1394/08/12

Ethics committee reference number

IR.TUMS.REC.1394.2096

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

cystic fibrosis

ICD-10 code

E84

ICD-10 code description

Cystic fibrosis, unspecified

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

Anxiety

Timepoint

before and after intervention

Method of measurement

spilberger questionnaire

2**Description**

stress

Timepoint

before and after intervention

Method of measurement

Parenting Stress Index—Short Form

Secondary outcomes

empty

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

Intervention group: In the first day, mothers will sign the informed consent form. Before the intervention, mothers will complete Spielberger anxiety questionnaire, parental stress and demographic information. Mothers will receive a booklet. In the second and third days, mothers will study the booklet and will discuss with each other. In the Seventh day, questionnaires will be completed by the mothers again.

Category

Other

2**Description**

Control group: In the first day, mothers will sign the informed consent form. Mothers will complete Spielberger anxiety questionnaire, parental stress and demographic information. The control group will receive the usual medical care. In the Seventh day, questionnaires will be completed by the mothers again.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Children's hospitals of Tehran University of Medical Science (Children Center, Valiasr and Bahrami h

Full name of responsible person

Soraya Jafari

Street address

Children Medical Center, Valiasr and Bahrami hospitals, Tehran

City

Tehran

2

Recruitment center

Name of recruitment center

Children's hospitals of Iran University of Medical Science (Ali Asgar and Shahid Fahmide hospitals)

Full name of responsible person

Soraya Jafari

Street address

Ali asgar and Shahid Fahmide hospitals, Tehran

City

Tehran

3

Recruitment center

Name of recruitment center

Children's hospital of Shahid Beheshti University of Medical Science (Mofid hospital)

Full name of responsible person

Soraya Jafari

Street address

Mofid hospital, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Dr Masoud Yunesian

Street address

Building 43, Quds Street, Keshavarz Boulevard, Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Tehran University of Medical Sciences

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**

School of Nursing and Midwifery, Tehran University of Medical Sciences

Full name of responsible person

Zahra Daneshva Ameri

Position

Faculty member

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

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

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Full name of responsible person

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Position

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Person responsible for updating data

Contact

Name of organization / entity

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Medical Sciences

Full name of responsible person

Soraya Jafari

Position

Graduate student at the Pediatric nursing

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pleiades611@gmail.com

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