

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of family-centered empowerment model (FCEM) on the coping strategies of parents of children with cystic fibrosis

Protocol summary

Study aim

Determining the effect of family-centered empowerment model on coping strategies of parents of children with cystic fibrosis

Design

Clinical trial with control group

Settings and conduct

The study includes two groups of intervention and control. The intervention group in the family-centered empowerment project will use the family-based empowerment model to examine the impact of the model on parenting coping strategies. This template will be presented in four steps: perceived threat, increased self-efficacy, increased self-esteem and process evaluation, and six educational sessions will be provided for 6 weeks at the Cystic Fibrosis Clinic of the Children's Medical Center. Before the intervention and one month after it is completed, parents will be asked to complete the coping strategies questionnaire. In the control group the training will not be given. The parents of this group are requested to complete the questionnaire two months after completion of the coping strategies.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Passed at least six months from the diagnosis of childhood cystic fibrosis, Having the least literacy of parents to read and write, The child has a medical record in the clinic. Exclusion criteria: The child is involved in other chronic illness, in addition to cystic fibrosis, the occurrence of any unexpected incident affecting life from two months before entering the study, Parental involvement in physical and psychological illness.

Intervention groups

In intervention group (one group), family-centered empowerment model in four steps including perceived threat, increasing self-efficacy in child care, increasing self-esteem in child care and process evaluation in six training sessions from 20 to 40 minutes for 6 week will be held. The control group receives the routine training.

Main outcome variables

Coping Strategies score in Lazarus Questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180501039489N2**

Registration date: **2019-01-09, 1397/10/19**

Registration timing: **prospective**

Last update: **2019-01-09, 1397/10/19**

Update count: **0**

Registration date

2019-01-09, 1397/10/19

Registrant information

Name

Fahimeh Sabeti

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8888 2885

Email address

sabeti.f@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-10, 1397/10/20

Expected recruitment end date

2019-05-10, 1398/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of family-centered empowerment model (FCEM) on the coping strategies of parents of children with cystic fibrosis

Public title

The effect of family empowerment on the coping strategies of parents of children with cystic fibrosis

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Passed at Least Six Months of Diagnosis of Childhood Cystic Fibrosis parents' low literacy The Child has a Medical Record in the Clinic

Exclusion criteria:

The child is involved in other chronic illness, in addition to cystic fibrosis The occurrence of any unexpected incident affecting life from two months before entering the study Parental involvement in physical and psychological illness

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **78**

Randomization (investigator's opinion)

Not 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**

Ethics Committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, 1449614535, IRAN

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2018-09-03, 1397/06/12

Ethics committee reference number

IR.IUMS.REC.1397.187

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

Cystic Fibrosis

ICD-10 code

E84

ICD-10 code description

Cystic fibrosis

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

Coping Strategies score in Lazarus Questionnaire

Timepoint

before the intervention and one month after the end of empowerment training

Method of measurement

Lazarus Folkman Coping Strategies Questionnaire

Secondary outcomes

empty

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

Intervention group: After completing the coping strategies questionnaire and demographic information, parents of children referred to the cystic fibrosis clinic in the parental intervention group will be included in the family-centered empowerment design using the family-centered empowerment model of Dr. Alhani. This pattern is based on four steps: perceived threats including perceived severity and perceived sensitivity, increased self-efficacy, increased self-esteem and process evaluation, and by holding six training sessions of 20 to 40 minutes on Thursdays at the Cystic Fibrosis clinic of Medical Center will be provided. Meetings will be held in groups of 4 to 6 for parents. One month after the completion of the empowerment plan, parents will be asked to complete the coping strategies questionnaire.

Category

Prevention

2

Description

Control group: Parents referring to the cystic fibrosis clinic of the Children's Medical Center Hospital in the control group will be provided with demographic information and coping strategies. Once completed, parents will routinely take care of their children. Two months after the completion of the questionnaire, Parents will be asked to complete the coping strategies questionnaire.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Cystic Fibrosis Clinic, Children's Medical Center Hospital, Tehran, Iran

Full name of responsible person

Somayeh Kiani

Street address

Children's Medical Center, Qarib St, Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1419733151

Phone

+98 21 6147 9123

Email

cmc.tums@gmail.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Seyyed Kazem Malekoti

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran 1449614535, IRAN

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Phone

+98 21 86701

Email

malakoutik@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Fahimeh Sabeti

Position

Instructor

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

School of Nursing & Midwifery, Rashid Yasemi Street, Vanak Square, Vali-e Asr Street

City

Tehran

Province

Tehran

Postal code

1919816766

Phone

+98 21 2304 6253

Email

sabeti.f@iums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Fahimeh Sabeti

Position

Faculty member

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

School of Nursing & Midwifery, Rashid Yasemi Street, Vanak Square, Vali-e Asr Street

City

Tehran
Province
Tehran
Postal code
1919816766
Phone
+98 21 8888 2885
Fax
Email
Sabeti.f@iums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Fahimeh Sabeti
Position
Faculty member
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
School of Nursing & Midwifery, Rashid Yasemi Street,
Vanak Square, Vali-e Asr Street
City
Tehran
Province
Tehran

Postal code
1919816766
Phone
+98 21 8888 2885
Fax
Email
Sabeti.f@iums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available