

# 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

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##### 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

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Iran University of Medical Sciences

#### Full name of responsible person

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#### Position

Faculty member

#### Latest degree

Master

#### Other areas of specialty/work

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## Person responsible for updating data

### Contact

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**Full name of responsible person**  
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**Latest degree**  
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**Other areas of specialty/work**  
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## 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