

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Studying the effect of telenursing-based family empowerment program on self-efficacy and treatment adherence in children with cystic fibrosis

Protocol summary

Study aim

Determining the Effect of telenursing-based family empowerment program on self-efficacy and treatment adherence in children with cystic fibrosis

Design

A RCT with an intervention and control group & sample size of 50 people.

Settings and conduct

Sampling will be done based on the inclusion criteria after obtaining the relevant permits from Shahid Beheshti University of Medical Sciences and coordinating with the relevant officials in the hospital. Participants will be randomly assigned to the intervention and control groups based on the case number (Even numbers in intervention group/odd numbers in control group). The objectives and method of the research will be explained to participants and the consent form will be completed by them. For the intervention group, content presentation and follow-up have been planned twice a week for a period of 12 weeks. In the control group, there will be no intervention. The research environment is the lung department and Cystic fibrosis clinic of Mofid Hospital in Tehran.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Access of a child or teenager to a smartphone. The child should be literate. The caregiver must be at least 18 years old. The caregiver is not part of the medical staff. Exit criteria: Reluctance and refusal to continue participating study.

Intervention groups

For the intervention group, providing content and remote follow-up have been planned twice a week on the Skype platform for a period of 12 weeks in the form of sending an audio-video file or a training text (5-10 minutes) through the content link (Send Big website) to the mobile number of the teenager or home caregiver of children with Cystic fibrosis. Patients in the control group will have routine treatment and follow-up (monthly visits to the cystic fibrosis clinic, taking prescribed medications).

Main outcome variables

Self-efficacy, Treatment adherence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230717058822N1**

Registration date: **2023-07-19, 1402/04/28**

Registration timing: **registered_while_recruiting**

Last update: **2023-07-19, 1402/04/28**

Update count: **0**

Registration date

2023-07-19, 1402/04/28

Registrant information

Name

Fatemeh Rameh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8865 5366

Email address

fatemerame1999@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-20, 1402/02/30

Expected recruitment end date

2023-09-21, 1402/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Studying the effect of telenursing-based family empowerment program on self-efficacy and treatment adherence in children with cystic fibrosis

Public title

the effect of telenursing-based family empowerment program on self-efficacy and treatment adherence in children with cystic fibrosis

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

The child or teenager has access to a smartphone. The child does not suffer from mental, cognitive or any other chronic diseases. The child should be able to speak Persian and be literate in reading and writing. The child should live with both parents. The home caregiver must be at least 18 years old. The home caregiver should have at least a bachelor's degree, be fluent in the Persian language, and can answer questionnaires. The mother is not part of the medical staff The child's caregiver does not participate in a training course or class related to the child's illness before.

Exclusion criteria:

Reluctance and refusal to continue participating in the study Inability to communicate due to reasons such as internet disconnection during at least two sessions Failure to follow up on educational materials and lack of feedback in virtual question-and-answer sessions at least twice Adverse complications during research for the child

Age

From **9 years** old to **17 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

In the current study, sampling will be done based on the inclusion criteria, and then the random allocation of the samples will be done using the simple randomization method to intervention and control group.

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 Shahid Beheshti University of Medical Sciences

Street address

Faculty of Nursing and Midwifery, Niayesh Intersection, Valiasr St., Tehran

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2023-03-07, 1401/12/16

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1401.280

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

Self-efficacy, Treatment adherence, Cystic fibrosis, Telenursing

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Self-efficacy

Timepoint

Before the intervention, immediately after and one month after the intervention

Method of measurement

Pediatric Rating of Chronic Illness Self-efficacy (PRCISE)

2**Description**

Treatment Adherence

Timepoint

Before the intervention, immediately after and one month after the intervention

Method of measurement

Measurement of adherence to treatment in chronic patients questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: interventional content with educational-practical and care-support model is in the form of an audio-visual file or an educational text (5-10 minutes) within a period of three months and through the content link (Send Big website) to the email address or number. It will be sent to teenager or caregiver of children with Cystic fibrosis, and after observation, remote follow-up will be done twice a week on the Skype platform, and the researcher will answer All of the questions that relate to contents. The content includes items related to the definition of chronic respiratory diseases and cystic fibrosis in children, the impact of the disease on the development of the child and family, the importance of receiving and implementing a therapeutic regimen, the importance of physical activity, types of respiratory exercises, management of respiratory symptoms, and training to clean the airways. performing creative games, performing drugs and oxygen therapy, exacerbation management and prevention, nutritional support, sleep challenges, stress and anxiety management, frequently asked questions session and create motivation in the implementation of the treatment regimen.

Category

Other

2

Description

Control group: Control group: No intervention will take place and the patients will receive their routine treatment plan.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mofid Children Hospital

Full name of responsible person

Fatemeh Rameh

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Shariati St., above Hosseiniyeh Irshad, before Mirdamad St.

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1551415468

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Afshin Zarghi

Street address

School of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences, Niyayesh Cross-Section, ValiAsr St.

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sbnmf@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Fatemeh Rameh

Position

MSc Nursing Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

There is no further information.

When the data will become available and for how long

The access is possible 6 months after the results are published.

To whom data/document is available

Researchers, students, hospital staff

Under which criteria data/document could be used

For the purpose of study and research by referring to this study

From where data/document is obtainable

Contacting with: fateme.rame@yahoo.com

What processes are involved for a request to access data/document

After sending an e-mail to the above-mentioned address, the maximum period of 1 month

Comments