

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

The effect of Implementation of Multidisciplinary Program via Telecare on The Level of Quality of Life on of Children in School-age Involved with Cystic Fibrosis and Their Parents

Protocol summary

Study aim

Determining the effect of Implementation of Multidisciplinary Program via Telecare on The Level of Quality of Life on of Children in School-age Involved with Cystic Fibrosis and Their Parents

Design

A clinical trial with a control group, with parallel-group design, without blindness, randomized through a throw Coins

Settings and conduct

This study was conducted in the respiratory ward of mofid Hospitals and Children's Medical Center in Tehran. Samples randomly assigned to intervention and control groups. The samples of both groups completed the Revised Quality of Life cystic fibrosis questionnaire for parents and children. For the intervention group, the educational program was implemented through the application. The post-test was taken immediately and one month after the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: consent to participate in research and having cooperation; children must be at least 12 and up to 18 years of age; ability to read and write; ability to work with smartphones and applications; access to android with mobile phones; no other child with cystic fibrosis and other diseases; parental physical and mental health. Exclusion criteria: participation in previous same care program in Last three months; not wanting to continue treatment in the middle of it.

Intervention groups

Intervention group: in the intervention group, the educational program include:1. Understanding cystic fibrosis: defining the disease, the cause and how to diagnose the disease 2. Treatment and care: Including two parts lung and nutrition 3. Daycare focused care training Respiratory (respiratory physiotherapy, daily exercise, medications) and gastrointestinal care (diet,

supplemental enzymes, and antibiotics) 4. How to communicate with the social worker (counseling) will be implemented. control group receives routine care.

Main outcome variables

Quality of Life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190805044443N1**

Registration date: **2019-09-28, 1398/07/06**

Registration timing: **retrospective**

Last update: **2019-09-28, 1398/07/06**

Update count: **0**

Registration date

2019-09-28, 1398/07/06

Registrant information

Name

Maryam Alibakhshi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6640 6886

Email address

m_alibakhshi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-22, 1398/04/01

Expected recruitment end date

2019-09-22, 1398/06/31

Actual recruitment start date

2019-06-22, 1398/04/01

Actual recruitment end date

2019-09-19, 1398/06/28

Trial completion date

2019-09-19, 1398/06/28

Scientific title

The effect of Implementation of Multidisciplinary Program via Telecare on The Level of Quality of Life on of Children in School-age Involved with Cystic Fibrosis and Their Parents

Public title

The effect of Implementation of Multidisciplinary Program via Telecare on The Level of Quality of Life

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Children and parent with school-age children (6-12 years) with cystic fibrosis Parent with ability to read and write At least 6 months have passed since the definitive diagnosis of the disease Mobile phone access with Android OS Ability to work with smartphones and app Parents should have physical and mental health based on self-expression

Exclusion criteria:

Unwillingness to continue caring in the middle Participation in previous same care program in Last three months

AgeFrom **6 years** old to **12 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **25**Actual sample size reached: **25****Randomization (investigator's opinion)**

Randomized

Randomization description

Simple randomization method was used for randomization. Firstly, all eligible patients were selected based on the criteria of entry and assigned a special code. Then, according to the sample size and the same number, the coin was thrown, and the heads subjects in the intervention group and the tails subjects in the 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

in front of Shahid Rajaei Heart Hospital, Intersection of Niayesh, Valiasr S

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2019-05-13, 1398/02/23

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1398.052

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**

Quality of Life

Timepoint

Before, immediately after and one month after intervention

Method of measurement

Revised Quality of Life cystic fibrosis questionnaire

Secondary outcomes

empty

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

Intervention group: in the intervention group, the educational program include: 1. Understanding cystic fibrosis: defining the disease, the cause and how to diagnose the disease 2. Treatment and care: Including

two parts lung and nutrition 3. Daycare focused care training Respiratory (respiratory physiotherapy, daily exercise, medications) and gastrointestinal care (diet, supplemental enzymes, and antibiotics) 4. How to communicate with the social worker (counseling) will be implemented

Category

Rehabilitation

2

Description

Control group: the control group will receive routine care

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Mofid children's Hospital

Full name of responsible person

Maryam Alibakhshi

Street address

Shariati Street, Mofid children's Hospital

City

Tehran

Province

Tehran

Postal code

1546815514

Phone

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Email

info-mch@sbmu.ac.ir

Web page address

<http://www.mch.sbm.ac.ir/>

2

Recruitment center

Name of recruitment center

Children's Medical Center

Full name of responsible person

Maryam Alibakhshi

Street address

Dr. mohammad gharib Street, Children's Medical Center

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Province

Tehran

Postal code

1419733151

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cmc.tums@gmail.com

Web page address

<http://chmc.tums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Shahid Aarabi St, Yaman St, Shahid Chamran Highway

City

Tehran

Province

Tehran

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1983963113

Phone

+98 21 2243 9781

Email

zarghi@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

Maryam Alibakhshi

Position

Nurse

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

in front of Shahid Rajaee Heart Hospital, Intersection of Niayesh, Valiasr St

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Tehran

Postal code

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Phone

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Email

m_alibakhhi@sbm.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Maryam Alibakhshi

Position

Nurse

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Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Maryam Alibakhshi

Position

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Email

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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