Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of Mobile Application Effectiveness on Self-care of Children with Cystic Fibrosis

Protocol summary

Study aim
Designing, applying, and evaluating the effectiveness of using a self-care application in children with cystic fibrosis

Design
Two arm parallel group randomized trial, on 88 patients, simple randomization using coins

Settings and conduct
Design phase: In the first step, the researcher will determine the validity of its scientific content. Implementation phase: In the intervention group, the desired application is installed on the smartphone of children with CF. Before the installation, the self-care questionnaire for patients with Baker's cystic fibrosis and the demographic characteristics questionnaire are completed by the participants. Evaluation phase: After one month, the self-care questionnaire for patients with Baker's cystic fibrosis is completed by the control and intervention groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: - Children aged 11 to 20 willing to participate in the study - Membership in CF Iran Foundation - Access to a mobile phone and ability to use the Android operating system - Ability to read and write Exclusion criteria: - Having hearing, touch, and vision disorders - Simultaneous participation in another similar training program

Intervention groups
The research was conducted on 88 people with cystic fibrosis between the ages of 11 and 20 who were assigned to two age-matched intervention and control groups of 44 people, and the trial intervention, the use of a mobile application designed for self-care training, in the intervention group for one month will be done. The control group was age-matched with the intervention group.

Main outcome variables
improve self-care; increased life expectancy; increase life expectancy; Increase the quality of life

General information

Reason for update

Acronym
CFA

IRCT registration information
IRCT registration number: **IRCT20230717058812N1**
Registration date: **2023-09-11, 1402/06/20**
Registration timing: **prospective**

Last update: **2023-09-11, 1402/06/20**
Update count: **0**

Registration date
2023-09-11, 1402/06/20

Registrant information

Name
Mahtab Yousefian

Name of organization / entity

Country
Iran (Islamic Republic of)

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mahtabusefian95@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-09-23, 1402/07/01

Expected recruitment end date
2023-10-23, 1402/08/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of Mobile Application Effectiveness on Self-care of Children with Cystic Fibrosis

Public title
Effect of Using Mobile Application on Improving Self-care of Children with Cystic Fibrosis
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
People aged 11 to 20 who want to participate in the study Membership in Iran CF Foundation Access to a mobile phone and the ability to use the Android or IOS operating system Ability to read and write
Exclusion criteria:
Having hearing, touch and vision disorders that make it impossible to gather information Simultaneous participation in another similar training program
Age
From **11 years** old to **20 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **88**
Randomization (investigator's opinion)
Randomized
Randomization description
The research units were patients who were matched in pairs in terms of age. Then, each pair was assigned to two intervention and control groups by a simple random allocation method with a coin.
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 children's medical center-Tehran university of medical sciences
Street address
School of Nursing and Midwifery, Tehran University of Medical Sciences, Nosrat St., Tohid Sq., Tehran Town
City
Tehran
Province
Tehran
Postal code
1419733171
Approval date
2022-10-19, 1401/07/27
Ethics committee reference number
IR.TUMS.CHMC.REC.1401.136

Health conditions studied

1

Description of health condition studied
Cystic fibrosis
ICD-10 code
E84.9
ICD-10 code description
Cystic fibrosis, unspecified

Primary outcomes

1

Description
Baker's Cystic Fibrosis Self-care Practice Instrument score
Timepoint
Before intervention and one month after intervention
Method of measurement
Baker's Cystic Fibrosis Self-care Practice Instrument

Secondary outcomes

1

Description
Baker's Cystic Fibrosis Self-care Practice Instrument score
Timepoint
Before intervention and one month after intervention
Method of measurement
Baker cystic fibrosis self-care practice questionnaire

Intervention groups

1

Description
Intervention group: using the self-care application for cystic fibrosis children, after the entry of people who meet the entry criteria and obtaining written informed consent, with the help of a random number table, these people are divided into two intervention and control groups. In the intervention group, the desired application is installed on the smartphone of children with CF. Before the installation, the self-care questionnaire for patients with Baker's cystic fibrosis and the demographic characteristics questionnaire are completed by the participants. Then this application is used by this group for one month. Before the test of the written informed

consent form, the demographic information questionnaire will be provided to the control and intervention groups. After one month, a self-care questionnaire for patients with Baker's Cystic Fibrosis is completed by the control and intervention groups, and the data collected in the pre-test and post-test stages are entered into the SPSS version 22 software and using descriptive and inferential statistics of the case The analysis will be placed.

Category

Treatment - Devices

2

Description

Control group: not using the self-care application of cystic fibrosis children, the control group will also receive the usual training. It should be noted for to prevent the contamination of the control group samples, the desired application will be installed by the researcher and specifically with the help of each person's code on the phones of the intervention group. In order to comply with the ethical principles, after the end of the study, the application will be given to the people of the control group.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Iran CF foundation

Full name of responsible person

Mohamadreza Modaresi

Street address

Iran cf foundation, Forsate-Shirazi St.,Tehran Town

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Email

modaresipul@gmail.com

Web page address

http://cfiran.com/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Shahrazad Ghiathundian

Street address

School of Nursing and Midwifery, Tehran University of Medical Sciences, Nosrat St., Tohid Sq., Tehran Town

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Email

fnm@tums.ac.ir

Web page address

http://fnm.tums.ac.ir/

Grant name

Grant code / Reference number

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

No

Title of funding source

Iran CF Foundation

Proportion provided by this source

80

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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Batool Pouraboli

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Ph.D.

Other areas of specialty/work
Nursery

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Person responsible for updating data

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Assistant Professor

Latest degree
Ph.D.

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
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

Title and more details about the data/document
Only a part of the data, such as the information related to the main result or the like, can be shared.

When the data will become available and for how long
Year 1402-1403

To whom data/document is available
Doctors, nurses and specialists in the field of cystic fibrosis

Under which criteria data/document could be used
For more comprehensive studies, obtain permission from the responsible person

From where data/document is obtainable
Tehran University of Medical Sciences Faculty of Nursing and Midwifery Library

What processes are involved for a request to access data/document
Membership in the library of the Faculty of Nursing and Midwifery of Tehran University of Medical Sciences

Comments
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