Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Assessment the effect of a comprehensive care program on quality of life and respiratory symptoms in patients with cystic fibrosis

Protocol summary

Study aim

Determining the effect of a comprehensive care program on quality of life and respiratory symptoms in patients with cystic fibrosis

Design

Clinical trial with control group, pre- and post-test, members of two randomized groups, without blinding, on 80 patients

Settings and conduct

The research environment will be the Iranian CF Association. The entire work will be done in a virtual environment. To prevent data contamination, sampling will be done first from the control group. After sampling from the control group, gradually and based on the designed comprehensive care program, the training will be provided to the intervention group for practice and repetition virtually every week. The intervention (a comprehensive care program that includes nutrition, exercise and breathing exercises, psychological and social care) will be implemented for 8 weeks.

Participants/Inclusion and exclusion criteria

Inclusion: Age ≥ 18 years; Confirmed diagnosis of CF by a physician; Fluency in Persian and literacy; Owning a smartphone and being able to use it; Not participating in similar care programs in the past 6 months; Providing written informed consent to participate in the study. Exclusion: Having a diagnosed severe psychiatric illness (such as schizophrenia or active bipolar disorder); Having severe chronic illnesses (severe organ failure and active cancer); History of lung transplantation.

Intervention groups

Control group, intervention group: comprehensive care program

Main outcome variables

Quality of life, respiratory symptoms, self-management

General information

Reason for update

Residence in Tehran was removed from the inclusion criteria because the number of patients was limited, and to ensure sufficient sampling, samples from each city were included in the study. The start and end times of sampling were changed because sampling was not performed before receiving the code from the system, and after receiving the code, sampling began several months later due to a change in one of the secondary outcome measurement tools. The license for the clinical symptom measurement tool was revoked due to sanctions, and based on the suggestion of the tool's designer, it was replaced with an older and similar tool. The method of randomizing the groups was also changed due to the small sample size available, and the previous randomization method is discussed below. The implementation method of planner was changed to checklists due to the lack of in-person access to some patients. Each of the items mentioned was edited in the relevant section.

Acronym

IRCT registration information

IRCT registration number: **IRCT20250727066652N1**
Registration date: **2025-11-13, 1404/08/22**
Registration timing: **prospective**

Last update: **2026-07-20, 1405/04/29**
Update count: **1**

Registration date

2025-11-13, 1404/08/22

Registrant information

Name

Zahra Mansoor Samaei

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-11-22, 1404/09/01
Expected recruitment end date
2026-10-22, 1405/07/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Assessment the effect of a comprehensive care program on quality of life and respiratory symptoms in patients with cystic fibrosis

Public title
Assessment the effect of a comprehensive care program on quality of life and respiratory symptoms in patients with cystic fibrosis
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
- Greater age equal to 18 years; - A confirmed diagnosis of CF by a physician; - Fluency in Persian and ability to read and write; - The patient resides in Tehran; - Having a smartphone and being able to use it; - Not participating in similar care programs in the past 6 months; - Giving written informed consent to participate in the study.
Exclusion criteria:
- Having a diagnosed severe psychiatric illness (such as schizophrenia or active bipolar disorder); - Having severe chronic diseases (severe vital organ failure and active cancer); - History of lung transplantation.
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
In the first stage, patients will be selected from among those who refer to the Cystic Fibrosis (CF) Association who meet the inclusion criteria. Then, participants will be divided into two control and intervention groups using a block randomization method, such that the number of people in both groups will be equal. For this purpose, blocks of four will be used; so that the letter A will represent the intervention group and the letter B will represent the control group. In each block, two people will be assigned to group A and two people to group B. All possible combinations of the sequence of letters A, A, B, and B, which includes the following six cases, will be considered. 1. AABB 2. ABBA 3. ABAB 4. BBAA 5. BAAB 6. BABA Then, the numbers 1 to 6 will be written on cards and placed in a container. To determine the order of allocation, one number will be randomly removed from the container each time. For example, if the number 2 is chosen, the order of sample allocation will be according to the second combination, i.e. (ABBA); that is, the first and fourth people will be in the intervention group and the second and third people will be in the control group. This process will continue until the required number of samples is completed. To ensure randomization of allocation and eliminate bias, numbered cards will be placed in sealed envelopes so that the researcher does not know their order. After each withdrawal, the card will be returned to the container. In total, 18 numbers will be randomly drawn from the container and the resulting sequence of numbers will determine the final order of the blocks. Considering the conditions in the clinic, the random sampling method was changed as follows: The allocation of participants to study groups was done using the even and odd-numbered allocation method, so that people with even numbers on the patient list were placed in the intervention group and people with odd numbers were placed 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
Research Ethics Committee of School of Nursing and midwifery And Rehabilitation- Tehran University
Street address
6th floor. Central Headquarters of Tehran University of Medical Sciences, at the corner of Ghods Street, Keshavarz Boulevard
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1419733171
Approval date
2025-09-17, 1404/06/26
Ethics committee reference number
IR.TUMS.FNM.REC.1404.121

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
Determining and comparing the average quality of life score of adult patients with cystic fibrosis in the intervention and control groups, before and after implementing a comprehensive care program.
Timepoint
At the beginning of the study and 8 weeks after the intervention
Method of measurement
Persian version of the standard and validated Cystic Fibrosis Questionnaire-Revised for ages 14 and older (CFQ-R +14)

Secondary outcomes

1

Description
Determining and comparing the mean clinical symptom scores of adult patients with cystic fibrosis in the intervention and control groups, before and after implementing a comprehensive care program.
Timepoint
At the beginning of the study and 8 weeks after the end of the intervention
Method of measurement
Persian version of the standard questionnaire for total symptom score

2

Description
Determining and comparing the average self-management score of adult patients with cystic fibrosis in the intervention and control groups, before and after implementing a comprehensive care program.
Timepoint
At the beginning of the study and 8 weeks after the end of the intervention
Method of measurement
Persian version of the Partners in Health (PIH) questionnaire

Intervention groups

1

Description
Control group: Control group: Members of the Iranian CF Association have a channel and information group on the ETA messenger; in this environment, patients and CF specialists are members; patients visit online and ask their questions to specialists or other members of the organization; for this purpose, to prevent data contamination, sampling is first done for the control group and then for the intervention group. Sampling and intervention are carried out virtually on a shared domestic messenger (due to restrictions on international Internet access). In order to facilitate the work for patients, to consider respiratory problems and limitations resulting from the disease in their daily activity, to save time, and to prevent the imposition of travel costs on patients, the plan is implemented virtually. On the other hand, the intervention content is located on a special channel for the intervention group, and there is continuous access to the channel content and training for members of the intervention group. After obtaining informed consent from the control group, they fill out four electronic questionnaires (demographic information, quality of life, respiratory symptoms, and self-management) in two stages with an 8-week interval; the control group receives routine care during this period, and after the sampling from the control group is completed, the sampling from the intervention group begins.
Category
N/A

2

Description
Intervention group: After obtaining informed consent, all members of the intervention group become members of a shared messenger between members in the "information channel" that the research team has designed for the explanations of the intervention group; the channel settings are such that participants cannot see the channel members; only the channel admin, i.e. the researcher, has the ability to send messages in the channel, and if participants have any questions, they should ask the channel admin privately. The above is done to maintain the confidentiality of the sample information and to avoid influencing each other and the results of the research. Pre-prepared introductory messages, which include introducing the plan, goals, and how the intervention group members will cooperate, are placed in the channel. After that, four electronic questionnaires (demographic information, quality of life, respiratory symptoms, and self-management) are filled out by the intervention group members before the intervention. The intervention (comprehensive care program) is implemented for 8 weeks. Gradually and based on the designed comprehensive care program, training is placed in the channel every week in the form of PDFs, infographics, text messages, etc. for practice and repetition. Participants in the intervention group are asked to record all their activities in daily checklists with details such as the type of activity, date, and time. The

format of the checklists is designed in advance by the research team and is placed in the channel step by step. During this period, individuals are continuously in touch with the project implementer to ask their questions and ambiguities through messengers; to ensure the correct implementation of the intervention, the researcher contacts all samples every week and, on the other hand, planning checklists are provided to the patients so that the patients can continuously complete it step by step along with the comprehensive care plan. After 8 weeks from the start of the program, four more questionnaires are filled out by the intervention group members and planning booklets are collected from them. In this study, the comprehensive care plan intervention will include four main parts: 1. Nutrition: Teaching the principles of proper nutrition for cystic fibrosis patients with an emphasis on the specific needs of these patients (such as calories, protein, vitamins); 2. Exercise and breathing exercises: Providing an exercise program including aerobic exercises and special breathing exercises to improve lung function and increase tolerance to daily activities; 3. Psychological care: Teaching stress management methods, psychological support, and coping strategies for anxiety and depression related to the disease; 4. Social care: Providing guidance for social support, increasing social interactions, and using support resources in the community. The content of this program will be developed based on a systematic review of current scientific literature, internationally recognized guidelines, and in consultation with several experts in the field of cystic fibrosis. To confirm the validity of the content, the draft of the program will be reviewed by 5 to 7 experts and the CVR and CVI indices will be calculated. Also, a small pilot test will be conducted with the presence of 5 to 10 patients to assess the understandability, acceptability, and applicability of the program, and necessary modifications will be made based on feedback. The data from this pilot will not be used in the final analysis.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Iranian CF Association

Full name of responsible person
Zahra Mansoor Samaei

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81, Unit 2, 1st Floor, Left Side, Intersection of Gharib St. and Forsat Shirazi St., Gharib St., Western End of Keshavarz Blvd., Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Grant name

Grant code / Reference number

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

Title of funding source
Tehran 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
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Full name of responsible person
Haleh Jafari

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Assistant Professor

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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
All data is potentially shareable after anonymizing individuals.
When the data will become available and for how long
The access period will begin 6 months after the publication of the results.
To whom data/document is available
The data will not only be available to researchers working at academic and scientific institutions, but individuals employed in industry can also apply to access them.
Under which criteria data/document could be used
No other specific condition is required.
From where data/document is obtainable
They can refer to the person who is conducting the sampling.
What processes are involved for a request to access data/document
They can send a message to the mentioned number, and it will be sent to them within a week.
Comments