

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### The Effectiveness Of Health Literacy Promotion Based On Family-Centered Empowerment Model On Common Delayed Outcomes Of Patients With Covid 19

#### Protocol summary

##### Study aim

Determining the effectiveness of promoting health literacy based on the family-centered empowerment model on the common delayed outcomes of patients with Covid-19

##### Design

The clinical trial has a control group on 70 discharged patients along with their caregivers, blinded by random allocation with A and B blocks.

##### Settings and conduct

Corona ward of Chamran hospital. One side blind. Participants

##### Participants/Inclusion and exclusion criteria

People with COVID 19 who have been admitted to hospital wards and have been diagnosed with COVID 19 through a positive PCR and CT Scan report. Willingness to participate in the study Having at least reading and writing literacy Patients should not have fever for 3 consecutive days at the time of discharge. Include level 2 and 3 patients of the classification of Covid 19 patients based on the instructions issued by the Ministry of Health. The patient's spo2 should be between 85 and 93 during discharge. have more than 50% involvement in lung CT scan. During the clearance of inflammatory markers, the proportion of early stages has decreased. The patient must be at least 18 years old. The patient should have the ability to learn and communicate effectively.. The health literacy level of the patient's family member (participant) should be less than 66 based on the health literacy questionnaire. Having minimum literacy in reading and writing Non-entry criteria History of underlying disease such as lung disease, cardiac disorders, and skeletal-muscular disorders

##### Intervention groups

Intervention group: Teaching diet and breathing technique Control group: Department routine training

#### Main outcome variables

In this study, the main outcome variables of delayed complications including the two complications of shortness of breath and fatigue are measured according to Borg and FSS questionnaires respectively.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20221006056103N1**  
Registration date: **2022-11-22, 1401/09/01**  
Registration timing: **registered\_while\_recruiting**

Last update: **2022-11-22, 1401/09/01**

Update count: **0**

##### Registration date

2022-11-22, 1401/09/01

##### Registrant information

##### Name

Nasim Abbaszadeh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2296 7062

##### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-10-20, 1401/07/28

##### Expected recruitment end date

2023-01-18, 1401/10/28

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The Effectiveness Of Health Literacy Promotion Based On Family-Centered Empowerment Model On Common Delayed Outcomes Of Patients With Covid 19

**Public title**

The effect of family health literacy in controlling delayed complications of covid-19

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

Criteria for inclusion in the study are patients with COVID-19 who have been admitted to hospital wards and have been diagnosed with COVID-19 through a positive PCR and CT Scan report. Patients should not have fever for 3 consecutive days at the time of discharge Include level 2 and 3 patients of the classification of Covid 19 patients based on the instructions issued by the Ministry of Health The patient's spo2 should be between 85 and 93 during discharge Involvement of more than 50% in lung CT scan During the clearance of inflammatory markers, the proportion of early stages has decreased COVID 19 through positive PCR and CT Scan report..Patient caregiver inclusion criteria The patient's caregiver is the person with whom the patient lives and is responsible for taking care of the patient The health literacy level of the patient's family member (participant) should be less than 66 based on the health literacy Willingness to participate in the study Having minimum literacy in reading and writing The patient's caregiver should have the ability to learn and communicate effectively

**Exclusion criteria:**

History of underlying disease such as lung disease, cardiac disorders, and skeletal-muscular disorders

**Age**

From **18 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Care provider

**Sample size**

Target sample size: **70**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this research, at the beginning, sampling will be done as available. The samples included in the study will be placed into two groups, test and control, through random allocation with classified blocks. The blocks used in this

research are four blocks in It is considered that the houses of each block are marked with Latin letters A (test) and B (control group). All the possible possibilities regarding the arrangement of the blocks are determined and placed in the basket, and randomly the blocks are taken out and based on that, the samples are placed in two control and test groups. This process continues until we reach the desired sample size.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

In this research, the participants in the control and intervention groups receive both interventions and routine trainings, but the intervention group samples are also trained by the researcher in addition to receiving routine trainings, and each of the participants from They do not know whether they are in the intervention group or the control group.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Baqiyatullah University of Medical Sciences

**Street address**

Ba'ath Township, Fakhrizadeh Street, Nobonyad Square

**City**

Tehran

**Province**

Tehran

**Postal code**

1693716563

**Approval date**

2022-08-14, 1401/05/23

**Ethics committee reference number**

IR.BMSU.BAQ.REC.1401.037

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

Covid19

**ICD-10 code**

U07.1

**ICD-10 code description**

COVID-19, virus identified

## Primary outcomes

### 1

#### Description

Tiredness

#### Timepoint

7 and 42 days

#### Method of measurement

Fatigue Severity Scale Questionnaire

### 2

#### Description

Shortness of breath

#### Timepoint

7 and 42 days

#### Method of measurement

Borg scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: After people are placed in the control and test groups, a demographic questionnaire is given to the samples of the test group using random allocation, and then after the first-degree family member who was responsible for taking care of the patient, it is determined that Using a health literacy questionnaire, the level of family health literacy in the test group is examined, and in the next step, using questionnaires to measure the delayed complications of Covid-19 patients, which includes the assessment of the patients' fatigue and shortness of breath, the basic condition of the test group samples. After the discharge of the patients in the test group, the care package according to the latest standard recipes and approved by the experts in this field is given to the same person from the family who takes care of the patient in a group method based on A family-oriented model will be presented. In the first step, meetings (usually the first and second meeting) with the aim of the perceived threat through increasing the level of knowledge and understanding about the problems threatening the patient, as well as the nature, complications, process, prognosis and symptoms of the disease will be held face to face and in person. At the end of the session, educational cards containing a summary of the topics raised in the sessions will be given to the participants to review the material. In the second step of the session, to solve the problems and problems of the patients, training on functional matters such as how to perform effective breathing, planning activity and rest periods, methods Correctly performing the activities and movements by the method of problem solving and group discussion and transfer of experiences will be done in the form of virtual video call with the

members, and the goal is to identify the issues and problems by the research units and provide solutions on their behalf and improve self-efficacy. In the third step, the participants teach the patient about the issues raised and participate as a health liaison in patient care, which increases self-confidence. In the last step, the evaluation will be done one week as a process evaluation and 6 weeks later as a brain evaluation by questionnaire. In total, 30-40 minutes of time will be considered for 3-5 sessions. After 1 week (process evaluation) and 6 weeks (brain evaluation), the level of shortness of breath and fatigue will be checked again.

#### Category

Prevention

### 2

#### Description

Control group: The working method is that after selecting the samples of the participants in the study and after placing the people in the control groups using random allocation, a demographic questionnaire is given to the samples of both groups, and then Since the first degree family member who was responsible for the patient's care, it was determined that the level of family health literacy in the control group was investigated using the health literacy questionnaire, and in the next step, using questionnaires to measure the delayed complications of Covid-19 patients. It includes checking the level of fatigue and shortness of breath of the patients. The basic condition of the control group samples is checked. The control group is also trained with the routine training of the department. Braindy's evaluation) again, the degree of shortness of breath and fatigue will be examined.

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Chamran hospital

##### Full name of responsible person

Nasim Abbaszadeh

##### Street address

Fakhrizadeh St

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Tehran

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##### Phone

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## Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Bagheiat-allah University of Medical Sciences

**Full name of responsible person**

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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**

Bagheiat-allah 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**

Bagheiat-allah University of Medical Sciences

**Full name of responsible person**

Dr.Rababe Khalili

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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### Person responsible for updating data

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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