Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 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)

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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
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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
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Bagheiat-allah University of Medical Sciences

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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
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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