

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

The effect of pulmonary rehabilitation Mobile based application on quality of life, depression and Anxiety and activity daily living in patients Recovered of with Covid 19 undergoing pulmonary rehabilitation referred to the comprehensive respiratory clinic of Khorshid Hospital in 1400

Protocol summary

Study aim

Evaluation of the effect of mobile phone-based pulmonary rehabilitation software on quality of life, anxiety, depression and physical activity capacity in patients improved from Covid 19 under pulmonary rehabilitation

Design

A two-group clinical trial study with intervention and control groups with parallel groups that will be done by sampling the mini-mice program.

Settings and conduct

After confirming the research in the ethics committee and obtaining permission from the officials of Khorshid Hospital, patients will be divided into two groups of intervention and control with mini-miser software.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Declaration of willingness to participate in the study by completing the informed consent form; Age category 18-60 years; Internet access and smartphones, minimum literacy; No vision or hearing problems; Be literate at least 21 days after the onset of symptoms in a patient with severe Covid 19. Exclusion criteria: unwillingness to participate in the study; Participate in similar courses simultaneously; Conclusive evidence of venous and pulmonary embolism thrombosis; Acute symptoms of Covid 19 (temperature over 38 degrees); Systolic blood pressure less than 90, diastolic blood pressure less than 60; Systolic blood pressure above 140 and diastole above 90; History of ischemic or hemorrhagic stroke or neurodegenerative diseases; Major mental disorder according to psychiatrist; Any disorder in which the patient's mobility is active, patients with active cancer; Recipient of palliative care

Intervention groups

After explaining the goals and obtaining written informed

consent, the relevant questionnaires (Bartel, Nosocomial Depression Anxiety, Quality of Life Questionnaire sf12) will be provided to the samples.

Main outcome variables

Quality of Life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200411047029N2**

Registration date: **2022-03-07, 1400/12/16**

Registration timing: **registered_while_recruiting**

Last update: **2022-03-07, 1400/12/16**

Update count: **0**

Registration date

2022-03-07, 1400/12/16

Registrant information

Name

Ramin Sami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3222 2892

Email address

r.sami@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-19, 1400/11/30

Expected recruitment end date

2022-09-20, 1401/06/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of pulmonary rehabilitation Mobile based application on quality of life, depression and Anxiety and activity daily living in patients Recovered of with Covid 19 undergoing pulmonary rehabilitation referred to the comprehensive respiratory clinic of Khorshid Hospital in 1400

Public title

The effect of pulmonary rehabilitation Mobile base application

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Declare willingness to participate in the study by completing the informed consent form Age category 18-60 years Internet access and mobile phone to use mobile-based lung rehabilitation software Have a minimum literacy No vision or hearing problems Have the literacy to use a mobile phone to work with mobile-based lung rehabilitation software At least 21 days have elapsed since the onset of symptoms in patients with severe coronary artery disease.

Exclusion criteria:

Reluctance to participate in the study Participate in similar courses simultaneously Definitive evidence of venous and pulmonary thromboembolism Acute symptoms of Covid 19 (temperature over 38 degrees) Systolic blood pressure less than 90 mm Hg, diastolic blood pressure less than 60 mm Hg Systolic blood pressure above 140 mm Hg and diastole above 90 mm Hg History of heart disease class 4-2 Ischemic or hemorrhagic stroke or neurodegenerative diseases Major mental disorder according to psychiatrist (schizophrenia, paranoid disorders and major depression) Any disorder that restricts the patient's ability to move during pulmonary rehabilitation Patients with active cancer Patients receiving palliative care Absence of more than 2 sessions in pulmonary rehabilitation training programs or failure to answer the researcher's call more than 2 times a week

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **38**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to divide patients into two groups, they will be given mini-mapping software. Mini-magnification (or mini-magnifier) is the name of a software that is used to divide samples into groups in clinical trials. There are always variables in research projects that may affect the accuracy of the study (confounding variables); By entering these variables in this software, the variables are distributed among the research groups in such a way that there is the least difference between the groups, and therefore this method is preferable to the randomization method. Sampling process until the number Research units will continue to reach the desired number.

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 isfahan University of Medical Sciences

Street address

hezarjarib

City

isfahan

Province

Isfahan

Postal code

81746-73461

Approval date

2022-02-22, 1400/12/03

Ethics committee reference number

IR.ARI.MUI.REC.1400.105

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

covid 19

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes

1

Description

Quality of Life

Timepoint

6 months

Method of measurement

SF-12 Quality of Life Questionnaire, HADS Hospital Anxiety and Depression Scale, Bartel Scale

Secondary outcomes

1

Description

Stress and depression

Timepoint

6 months

Method of measurement

Anxiety and Depression Clinical Scale
Questionnaire(HADS)

2

Description

Fasting days of life

Timepoint

6 months

Method of measurement

Bartel Questionnaire

Intervention groups

1

Description

In the intervention group (mobile-based pulmonary rehabilitation software) after completing the questionnaires as a pre-test, a briefing session will be held by a specialist nurse on how to work with the software for them and then the educational content of how Patient care will be installed in the same content as the face-to-face training group in the form of software that can be installed on the Android operating system on patients' mobile phones or tablets. This software consists of different parts, the first part includes the management of software users, where it is possible to insert and edit patient information from the management and the possibility of entering personal information through the software. The second part includes educational content. The educational content in the software is similar to the face-to-face training group. The third part includes sending notifications to all users and the last part is the possibility of talking to the patient and caregiver with an online counselor. An online counselor in this plan is someone who is available to patients around the clock, who in the software discussion section, any questions and ambiguities about working with the program or educational content, any emergency or non-emergency counseling related to The condition of patients and ...

responds.

Category

Rehabilitation

2

Description

Control group: The control group in the face-to-face training session of patients, educational content according to the needs of patients in groups of 5 people in 12 sessions that will last twice a week and each session will last 1 to 3 hours.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

khoshid medical educational research complex

Full name of responsible person

Mohsen Forghani

Street address

Ostandari

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3224 5681

Fax

Email

nour@mui.ac.ir

Web page address

<http://nour.mui.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Kamal Heidari

Street address

Hezajarib

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3668 0048

Email

khabarnameh@mui.ac.ir

Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source
Esfahan University of Medical Sciences
Proportion provided by this source

1

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
Esfahan University of Medical Sciences

Full name of responsible person
Ramin Sami

Position
Faculty

Latest degree
Specialist

Other areas of specialty/work
Internal Medicine

Street address
Hezarjarib

City
Isfahan

Province
Isfahan

Postal code
81746-73461

Phone
+98 31 3668 0048

Email
r.sami@med.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Ramin Sami

Position
faculty

Latest degree
Subspecialist

Other areas of specialty/work

Internal Medicine

Street address
Hezarjarib

City
Isfahan

Province
Isfahan

Postal code
81746-73461

Phone
+98 913 322 1022

Email
r.sami@med.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Ramin Sami

Position
faculty

Latest degree
Subspecialist

Other areas of specialty/work
Internal Medicine

Street address
Ostandari

City
Isfahan

Province
Isfahan

Postal code
81746-73461

Phone
+98 913 322 1022

Email
r.sami@med.mui.ac.ir

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

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable