Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluating the effects of self-care mobile application on psychologic parameters of admitted patients with Covid-19: a randomized controlled trial

Protocol summary

Study aim
The effect of self-care mobile-based intervention on psychologic parameters of admitted patients with COVID-19

Design
A randomized, nonblinded, two-arm, parallel-group, phase 3 controlled trial on 112 patients. www.randomization.com website was used for randomization.

Settings and conduct
This study will be conducted on 112 patients admitted to Imam Reza hospital in Mashhad who diagnosed with COVID-19

Participants/Inclusion and exclusion criteria
Inclusion criteria: Hospitalized patients with COVID- 19; patients who own a smartphone; patients who have the ability to work with a smartphone; at least 18 years old. Exclusion criteria: Unwillingness to stay in the study; Transfer to wards where it is not possible to use a cellphone, such as the intensive care unit.

Intervention groups
This study consists of two groups. In addition to usual care, patients in the intervention group will receive a self-care smartphone application provided with the capability to educate patients, establish two-way interaction between patients and their attending physician, and psychological consultants. Patients in the control group will only receive usual care.

Main outcome variables
DASS-21 questionnaire score

General information

Reason for update
With the decrease in the number of patients with Covid-19 in Imam Reza hospital, the hospital was excluded from the coverage of corona-specific treatment. So, it was not possible to conduct the study. But with the increase in the number of patients in recent weeks, it was re-assigned to corona patients.

Acronym

IRCT registration information
IRCT registration number: **IRCT20170922036314N4**
Registration date: **2020-06-22, 1399/04/02**
Registration timing: **prospective**

Last update: **2020-08-08, 1399/05/18**
Update count: **1**

Registration date
2020-06-22, 1399/04/02

Registrant information

Name
Shokoufeh Aalaei

Name of organization / entity
Mashhad University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 51 3800 2429

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aalaeish931@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-07-10, 1399/04/20

Expected recruitment end date
2021-03-18, 1399/12/28

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Evaluating the effects of self-care mobile application on psychologic parameters of admitted patients with Covid-19: a randomized controlled trial

Public title
The effects of self-care cellphone application on stress, anxiety and depression among admitted patients with COVID-19

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
baseline literacy having a smartphone ability to work with smartphone at least 3 days hospitalization
Exclusion criteria:
Unwillingness to participate in the study Transfer to wards where it is not possible to use a mobile phone, such as the intensive care unit Deterioration of the patient's physical condition

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **112**

Randomization (investigator's opinion)
Randomized

Randomization description
Method of randomization: simple randomization; Unit of randomization: individual randomization; the tool used in randomization: sealed envelops; the random sequence will be built using www.randomization.com website

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; Mashhad University of Medical Sciences
Street address
Azadi square
City
Mashhad
Province
Razavi Khorasan
Postal code
9176644889

Approval date
2020-04-19, 1399/01/31

Ethics committee reference number
IR.MUMS.REC.1399.118

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
DASS-21 questionnaire score

Timepoint
Before intervention, at the time of discharge, 2 weeks after discharge

Method of measurement
DASS-21 questionnaire score (including depression, anxiety, stress scales)

Secondary outcomes

1

Description
respiratory rate

Timepoint
Before intervention, at the time of discharge

Method of measurement
physician assessment

2

Description
oxygen saturation

Timepoint
Before intervention, at the time of discharge

Method of measurement
pulse oxymetry

3

Description
lung involvement

Timepoint
Before intervention, at the time of discharge

Method of measurement

radiography

4

Description
Multi-organ failure
Timepoint
Before intervention, at the time of discharge
Method of measurement
kidney and liver function tests

5

Description
fever
Timepoint
Before intervention, at the time of discharge
Method of measurement
thermometer

6

Description
secondary infection
Timepoint
Before intervention, at the time of discharge
Method of measurement
physician assessment

Intervention groups

1

Description
Intervention group: The intervention group will use a mobile-based application from the time of admission to two weeks after discharge. Educational material in the application required for patients with COVID-19 is provided using valid educational resources and experts' consensus. Also, patients can ask their questions from care providers through application and receive appropriate answers. Also, the patients can record their symptoms and thus their physician will be able to monitor and control their illness remotely.
Category
Behavior

2

Description
Control group: The control group will not receive intervention
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza Hospital
Full name of responsible person
Dr. Mahnaz Amini
Street address
Emam Reza square, Ebne Sina avenue
City
Mashhad
Province
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9176644889
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Mohsen Tafaghodi
Street address
Azadi square
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+98 51 3882 7049
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TafaghodiM@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Aalaei Shokoufeh

Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Informatics
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Person responsible for scientific inquiries

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Person responsible for updating data

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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