

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 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)

Phone

+98 51 3800 2429

Email address

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 envelopes; 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

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aalaeish@mums.ac.ir

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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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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Phone

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Email

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Aalaei Shokoufeh

Position

Assistant Professor

Latest degree

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Person responsible for updating data**Contact****Name of organization / entity**

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Shokoufeh Aalaei

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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