

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Design, Implementation and Evaluation of a mobile-based education and self-care application for COVID-19 disease

Protocol summary

Study aim

Design, Implementation and Evaluation of a mobile-based education and self-care application for COVID-19 disease

Design

The study will be in two groups, with a sample size of 70 based on similar studies. Simple randomization was performed in this study. And this is a one-way blind study. The random number table method is also used for randomization.

Settings and conduct

Khalkhal University of medical sciences

Participants/Inclusion and exclusion criteria

Patients with COVID-19 who do not need to be hospitalized. Having the skills to work with smartphones

Intervention groups

The intervention group receives a mobile-based self-care educational application. The control group will not have technology-based intervention and receive the routine training of health centers.

Main outcome variables

Improving patients' knowledge in the field of self-care and better disease management. Reduce the duration of disease recovery by monitoring and controlling the treatment process. Involve the patient in the care and treatment of the disease.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210509051231N1**

Registration date: **2021-06-23, 1400/04/02**

Registration timing: **registered_while_recruiting**

Last update: **2021-06-23, 1400/04/02**

Update count: **0**

Registration date

2021-06-23, 1400/04/02

Registrant information

Name

Mohammad Heydari

Name of organization / entity

Khalkhal University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 45 3242 6606

Email address

heydari.mohammad12@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-05, 1400/03/15

Expected recruitment end date

2021-07-05, 1400/04/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Design, Implementation and Evaluation of a mobile-based education and self-care application for COVID-19 disease

Public title

Evaluation of the effect of using COVID-19 mobile-based self-care application on patients with COVID-19 who do not need to be hospitalized

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with COVID-19 who do not need to be hospitalized Having the skills to work with smart phones age range of 20 to 70 years

Exclusion criteria:

unwilling to participate those that require hospitalization for worsening of their condition

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

With simple randomization and using a random number table and individual randomization unit. To randomize, we use a table consisting of random digits 0 to 9. Each digit of this table is repeated the same on average. There is no pattern of recognizable numbers. In this method, each number is assigned to a treatment group. We start from the first line of the table and move down line by line. For the two treatments, we put the numbers 0 to 4 for treatment A and the numbers 5 to 9 for treatment B. The numbers in the first line of the table are as follows: 0,5,2,7,8,4,3,7,4,1,6,8,3,8,5,1,5,6,9,6, ... Now for people based on the above numbers, we have the following allocation: A, B, A, B, B,... We will continue the above process until the two groups are completed.

Blinding (investigator's opinion)

Single blinded

Blinding description

Data analyzers will be blind in our study.

Placebo

Not used

Assignment

Parallel

Other design features

In this study, we evaluate a self-care mobile-based application in two groups of intervention and control. The content produced in this application is based on a review of texts and based on global guidelines in the field of Covid 19 disease. People in the study population are divided into two groups. In the intervention group, a self-care educational application is used for two to three weeks. In the control group, the treatment process continues routinely according to the training of comprehensive health centers.

Secondary Ids

empty

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

Medical Ethics Committee of Khalkhal University of Medical Sciences

Street address

Shahid Mozaffar Azizi Street

City

Khalkhal

Province

Ardabil

Postal code

۵۶۸۱۷۶۱۳۵۱

Approval date

2020-11-18, 1399/08/28

Ethics committee reference number

IR.KHALUMS.REC.1399.010

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

Covid19- Disease

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes**1****Description**

Duration of clinical symptoms and disease

Timepoint

at the baseline and 28 days after intervention

Method of measurement

Patient status checklist

2**Description**

Duration of recovery

Timepoint

at the baseline and 28 days after intervention

Method of measurement

Patient status checklist

Secondary outcomes

empty

Intervention groups**1****Description**

The fourth stage will be the clinical intervention and evaluation stage of software, in which the patients with Covid-19 who are required to self-quarantine at home

and follow self-care protocols are divided into intervention and control groups. For the intervention group, the software will be installed on the smartphone and participants will be asked to use the software as a guide for compliance with health protocols, drug compliance, diet, exercise, and daily habits (smoking, sleep, and rest) for 4 weeks. After 4 weeks, the participants in both groups will be asked to complete a study checklist. The checklist has 3 parts. The first part includes demographic information of the participants in the study. The second part includes questions related to clinical symptoms of the disease (fever, body aches, cough, sore throat, gastrointestinal symptoms, and lack of smell and taste) as yes and no, duration of each symptom (as an open question) as well as total duration of the disease, with two yes and no questions on transmission to other family members and the number of people to whom the disease has spread. The third part includes phrases related to quarantine care protocols (health protocols, drug compliance, diet, exercise and daily habits (smoking, sleep and rest) in 3 options of I followed (score 3), I did not follow (score 2) and no case (score 1) that the participants will answer the questions according to their performance and finally the score of this part will be obtained. Since the present tool is a checklist, so investigating its validity and reliability is not necessary.

Category

Treatment - Devices

2

Description

Control group: For the control group, routine care is provided by the University of Medical Sciences and software will be not provided to them.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Medical centers of Khalkhal city

Full name of responsible person

Mohammad Heydari

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Shahid Mozaffar Azizi Street

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Ardabil -Khalkhal

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Phone

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heydari.mohammad12@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khalkhal university of medical sciences

Full name of responsible person

Esmaeel Mehraeen

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Khalkhal

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Ardabil

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es.mehraeen@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Khalkhal 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

Khalkhal university of medical sciences

Full name of responsible person

Mohammad Heydari

Position

Faculty member- instructor

Latest degree

Master

Other areas of specialty/work

Health Technology Assessment

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Khalkhal university of medical sciences

Full name of responsible person

Mohammad heydari

Position

Faulty member-instructor

Latest degree

Master

Other areas of specialty/work

Health Technology Assessment

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Faculty member-instructor

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

Yes - There is 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

I haven't decided yet - the release schedule is still unknown

When the data will become available and for how long

I haven't decided yet - the release schedule is still unknown

To whom data/document is available

I haven't decided yet - the release schedule is still unknown

Under which criteria data/document could be used

I haven't decided yet - the release schedule is still unknown

From where data/document is obtainable

I haven't decided yet - the release schedule is still unknown

What processes are involved for a request to access data/document

I haven't decided yet - the release schedule is still unknown

Comments