

# 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

##### Street address

Shahid Mozaffar Azizi Street

##### City

Ardabil -Khalkhal

##### Province

Ardabil

##### Postal code

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##### Phone

+98 45 3242 6601

##### Email

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

##### Street address

Shahid Mozaffar Azizi Street

##### City

Khalkhal

##### Province

Ardabil

##### Postal code

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##### Phone

+98 45 3242 6601

##### Email

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

##### Street address

Shahid Mozaffar Azizi Street

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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**

Khalkhal university of medical sciences

**Full name of responsible person**

Mohammadi Heydari

**Position**

Faculty member-instructor

**Latest degree**

Master

**Other areas of specialty/work**

Health Technology Assessment

**Street address**

Shahid Mozaffar Azizi Street

**City**

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**Province**

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**Postal code**

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**Phone**

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**Email**

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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**