Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effectiveness of cognitive-behavioral stress management using the remote care system (application) of Covid 19 patients on the severity and duration of symptoms of this disease, psychological symptoms, psychosocial adaptation, cognitive status and changes in the level of ferritin and CRP and Spo2 in the blood of Covid 19 patients.

Protocol summary

Study aim

Determining effectiveness of cognitive-behavioral stress management using the remote care system (application) of covid 19 patients on the severity and duration of symptoms of this disease, psychological symptoms, psychosocial adaptation, cognitive status and changes in the level of ferritin and CRP and Spo2 in the blood of covid 19 patients.

Design

Quasi-experimental study, with simple individual randomization using random number table tool in two groups of control and experimental, in parallel, one-way blind, with pretest and posttest, on 70 patients with covid 19

Settings and conduct

This research on covid 19 patients who have not been spend more than 5 days after the onset of their first symptoms and have been discharged from the Dr. gharazi isfahan hospital to continue quarantine at home and the mentioned psychological intervention is done online through the system (application) of remote care of covid 19 patients.

Participants/Inclusion and exclusion criteria

Covid 19 patients who have not been spend more than 5 days after the onset of their first symptoms and have been discharged from the hospital to continue quarantine at home and having a smartphone and being literate ; People who are too old or illiterate that to find information from them is difficult

Intervention groups

Cognitive-behavioral stress management using the remote care system (application) of covid 19 patients

Main outcome variables

severity and duration of symptoms of covid 19 disease; psychological symptoms; psychosocial adaptation; cognitive status; changes in the level of ferritin and CRP and Spo2 in the blood of covid 19 patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201205049610N1**
Registration date: **2022-11-19, 1401/08/28**
Registration timing: **retrospective**

Last update: **2022-11-19, 1401/08/28**
Update count: **0**

Registration date

2022-11-19, 1401/08/28

Registrant information

Name

Hossein Hosseini naveh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3432 2616

Email address

mn.h.h.naveh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-04, 1399/10/15

Expected recruitment end date

2021-01-19, 1399/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of cognitive-behavioral stress management using the remote care system (application) of Covid 19 patients on the severity and duration of symptoms of this disease, psychological symptoms, psychosocial adaptation, cognitive status and changes in the level of ferritin and CRP and Spo2 in the blood of Covid 19 patients.

Public title

Effect of cognitive-behavioral stress management on Covid 19 patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Covid 19 patients who have not been spend more than 5 days after the onset of their first symptoms and have been discharged from the hospital to continue quarantine at home. Having a smartphone Being literate

Exclusion criteria:

People who are too old or illiterate that to find information from them is difficult

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

The sample people are selected by simple individual randomization by roll of a dice (numbers 1, 2 and 3 in the experimental group and numbers 4, 5 and 6 in the control group).

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

Research Ethics Committees of Islamic Azad University- Najafaba Branch

Street address

Islamic Azad University Blvd, Najafabad

City

Najafabad

Province

Isfehan

Postal code

۸۵۱۴۱۴۳۱۳۱

Approval date

2021-04-29, 1400/02/09

Ethics committee reference number

IR.IAU.NAJAFABAD.REC.1400.059

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

Severity and duration of Covid 19 disease symptoms

Timepoint

Daily monitoring of symptoms of covid 19 disease, from the first day of entry into the study to 21 days

Method of measurement

Evaluation of symptom severity by daily fever measurement and body pain scoring with McGill Pain Questionnaire and weakness scoring with Energy / Fatigue subscale from Quality of Life Questionnaire. duration of covid 19 disease symptoms by daily symptom monitoring and number of days recorded that each of the subjects experiences symptoms

2

Description

Score of psychological symptoms (depression, anxiety and stress) in the 21-question questionnaire of depression, anxiety and stress Laweibond and Laweibond 1995

Timepoint

Perform pre-test before the intervention and post-test after the intervention

Method of measurement

Measurement of this variable using 21-question

questionnaire of depression, anxiety and stress Laweibond and Laweibond 1995

3

Description
Psychosocial adaptation
Timepoint
Perform pre-test before the intervention and post-test after the intervention
Method of measurement
Measurement of this variable using the 160-question Bell Psychosocial Adjustment Questionnaire 1961

4

Description
cognitive status
Timepoint
Perform pre-test before the intervention and post-test after the intervention
Method of measurement
Measurement of this variable using the standard questionnaire of Mini-Mental State Examination of Folstein et al. 1975

5

Description
Changes in ferritin and C-reactive protein blood levels and saturation of peripheral oxygen of covid 19 patients
Timepoint
Perform pre-test before the intervention and post-test after the intervention
Method of measurement
Perform a blood test to check the serum level of ferritin and C-reactive protein in the blood and check the percentage of saturation of peripheral oxygen in the blood using a pulse oximeter in two stages, before and after the intervention.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: training cognitive and behavioral techniques for stress management using the covid 19 Remote Care System (application) that is given to these patients online
Category
Lifestyle

2

Description
Control group: for the control group, only routine medical and nursing care and recommendations and nutrition training is taught
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr. Gharazi Hospital of Isfahan
Full name of responsible person
Hossein Hosseini Naveh
Street address
Dr. Gharazi Hospital; Gharazi Avenue; Kaveh Boulevard
City
Isfahan
Province
Isfehan
Postal code
8196773365
Phone
+98 31 3491 2000
Email
gharazi.hos@tamin.ir
Web page address
https://www.tamin.ir/news/service/134

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Mehdi Rafiei
Street address
Daneshgah Boulevard; Islamic Azad University Najafabad
City
Najaf Abad
Province
Isfehan
Postal code
8514143131
Phone
+98 31 4229 2929
Email
info@iaun.ac.ir
Web page address
https://iaun.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Islamic Azad University
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

Islamic Azad University

Full name of responsible person

Hossein Hosseini naveh

Position

Ph.D. student

Latest degree

Master

Other areas of specialty/work

Psychology

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No.46; Unit 3; Mohammad Complex; Alley 5 (Salman); Stadium St; East Baharestan St; Kaveh St; Isfahan

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All individual data of study participants will be shared after Unidentifiable Persons

When the data will become available and for how long

Access permission, three months after printing the results

To whom data/document is available

Researchers working in academic and scientific institutions, health care workers

Under which criteria data/document could be used

Use to conduct similar research or to discover relationships and correlations or to conduct structural equation research and path analysis

From where data/document is obtainable

Communicate with Mr. Hossein Hosseini Naveh at E.mail: mn.h.h.naveh@gmail.com

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

Documents will be sent to their email by providing evidence of their Necessity need for data.

Comments