Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Sep 2026

Comparison of interactive psycho-educational interventions via social networks with placebo on anxiety and self-efficacy of patients infected with COVID-19 and lived in home quarantine

Protocol summary

Study aim
Comparison of interactive psycho-educational interventions via social networks with placebo on anxiety and self-efficacy of patients infected with COVID-19 and lived in home quarantine

Design
A clinical trial with control group, parallel group randomized trial and single blinded

Settings and conduct
The setting is Shiraz city. In this study, a person who collects the outcomes of the study, as well as a statistician and health care provider, will be blind until the end of the study and completion of the data analysis and reporting.

Participants/Inclusion and exclusion criteria
The inclusion criteria of this study are aging ≥ 18 years, having diagnosis of COVID-19, being able to use cell phone and having access to Internet, being at home quarantine at least 48 hours, having need to be in home quarantine at least one week. Patients who are admitted in hospital, are died, have severe symptoms that not being able to speak, perform exercise or complete the questionnaires, have previous experience of home quarantine and have psychological diseases such as psychosis and dementia are excluded.

Intervention groups
The patients in the intervention group are enrolled in a WhatsApp group. They would receive numerous videos, audio files, and educational texts regarding mental health, coping strategies, positive thinking, hope, spiritual well-being, and some enjoyable activities such as relaxation music. Other psychological interventions are included encouraging the patients to apply trained psychological techniques, and sharing good memories of their lives, gratitude and thanking God, and expressing their positive abilities in a variety of areas in the group. Every day, a researcher is contacted to the subjects and approved they would continued and followed as order.

Main outcome variables
self-efficacy and anxiety

General information

Reason for update
Since the approval of this clinical trial in IRCT on 2020-05-01, the recruitment start date changed to 2020-05-02.

Acronym

IRCT registration information
IRCT registration number: **IRCT20130616013690N7**
Registration date: **2020-05-01, 1399/02/12**
Registration timing: **prospective**

Last update: **2020-05-08, 1399/02/19**
Update count: **1**

Registration date
2020-05-01, 1399/02/12

Registrant information

Name
Masoume Rambod

Name of organization / entity
Shiraz University of Medical Science

Country
Iran (Islamic Republic of)

Phone
+98 71 1647 4258

Email address
rambodm@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-05-02, 1399/02/13

Expected recruitment end date
2020-06-19, 1399/03/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of interactive psycho-educational interventions via social networks with placebo on anxiety and self-efficacy of patients infected with COVID-19 and lived in home quarantine

Public title
Effect of interactive psycho-educational interventions on patients infected with COVID-19
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
aging ≥ 18 years having diagnosis of COVID-19 being able to use cell phone and having access to Internet being at home quarantine at least 48 hours having need to be in home quarantine at least one week
Exclusion criteria:
who is admitted in hospital is died have severe symptoms that not being able to speak, perform exercise or complete the questionnaires has previous experience of home quarantine has psychological diseases such as psychosis and dementia
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
At first the cellphone numbers of the patients who has inclusion criteria are obtained. Then, 50 participants randomly are selected using randomization software. Then, in order to allocation the subjects in to the intervention or control group, a randomization software is used.
Blinding (investigator's opinion)
Single blinded
Blinding description
The person who is collected the outcomes by a Link and the statistician are blind in to the intervention and control groups.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic Committee of Shiraz University of Medical Sciences
Street address
Vice chancellor for research affairs, seven floor, Shiraz University of Medical Science, beside Helal Ahmar, Zand Ave, Shiraz, Iran
City
Shiraz
Province
Fars
Postal code
۱۴۳۳۶ - ۷۱۳۴۸
Approval date
2020-03-17, 1398/12/27
Ethics committee reference number
IR.SUMS.REC.1399.012

Health conditions studied

1

Description of health condition studied
Coronavirus disease (COVID-19)
ICD-10 code
B34.2
ICD-10 code description
Coronavirus infection, unspecified

Primary outcomes

1

Description
self-efficacy
Timepoint
Before, one week and two weeks after the intervention
Method of measurement
People to Promote Health (SUPPH) questionnaire

2

Description
Anxiety
Timepoint
Before, one week and two weeks after the intervention
Method of measurement
State-Trait Anxiety Inventory

Secondary outcomes

empty

Intervention groups

1

Description
"Intervention group:" The patients in the intervention group are enrolled in a WhatsApp group. They will receive numerous videos, audio files, and educational texts regarding mental health, coping strategies, positive thinking, hope, spiritual well-being, and some enjoyable activities such as relaxation music. Other psychological interventions are included encouraging the patients to apply trained psychological techniques, sharing good memories of their lives, gratitude and thanking God, and expressing their positive abilities in a variety of areas in the group.The intervention is performed for eleven days from morning to 9 pm, and the files are entered in the WhatsApp group every two hours during the day.

Category
Lifestyle

2

Description
Control group: This group would receive the routine care and would not receive any of the interventions of the intervention group.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Shiraz city

Full name of responsible person
Maryam Shaygan

Street address
Nursing and Midwifery University, Namazee Sq, Zand Ave, Shiraz

City
Shiraz

Province
Fars

Postal code
7193613119

Phone
+98 71 3647 4258

Email
shayganm@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Younes Ghasemi

Street address
Vice chancellor for research affairs of Shiraz University of Medical Sciences, Zand Street, Shiraz, Iran

City
Shiraz

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Fars

Postal code
71348-14336

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vcrdep@sums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
Maryam Shaygan

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Nursing and Midwifery University, Namazee Sq, Zand Ave, Shiraz

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Maryam Shaygan

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

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Person responsible for updating data

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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
primary outcome measure

When the data will become available and for how long
starting 6 months after publication

To whom data/document is available
This will be available for people working in academic institutions

Under which criteria data/document could be used
The results of this study will be used for others.

From where data/document is obtainable
Contact to Maryam Shaygan email address, (shayganm@sums.ac.ir).

What processes are involved for a request to access data/document
Contact to Maryam Shaygan email address, (shayganm@sums.ac.ir).

Comments