

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 \geq 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

AgeFrom **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 sizeTarget 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

Phone

+98 71 3235 7282

Email

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