

# 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  $\geq 18$  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. 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

**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

#### Province

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

##### Street address

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

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##### Province

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##### Phone

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##### Email

shayganm@sums.ac.ir

## 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

### Contact

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Maryam Shaygan

**Position**

Associate professor

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**Email**

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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**