

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Comparison of the Effectiveness of Online Multimedia Psycho-educational Interventions with routine Psychological Care on the Perceived Stress and Resilience of hospitalized Patients with COVID-19

Protocol summary

Study aim

The purpose of this study was to investigate the effect of online multimedia psycho-educational interventions on the perceived stress and resilience of hospitalized patients with COVID-19.

Design

Cluster randomized controlled trial with a parallel control group, double-blinded, on 50 patients. Random assignment of wards was performed by an independent observer not involved in this study, using a coin toss.

Settings and conduct

Participants in this fully online trial were consecutive patients who were hospitalized in 2 hospitals in Shiraz, after being diagnosed with COVID-19. Patients were requested to complete the baseline questionnaires within 48 h of admission to the ward. Patients allocated to the intervention group every day received videos, podcasts, texts and pictures during 2 weeks. Immediately at the end of the second week, the online instruments of the perceived stress and resilience were reapplied and the posttreatment scores were obtained.

Participants/Inclusion and exclusion criteria

Age over 18 years
Willingness to take part in the study
Diagnosis of COVID-19 by clinical manifestations and laboratory results
Having access and ability to work with the media
Hospitalization of patient due to infection with COVID-19

Intervention groups

All eligible participants in wards allocated to the intervention condition received online multimedia psychoeducational interventions during 2 weeks, whilst patients in wards allocated to the control condition received face-to-face or telephone-based psychological counseling in case of need. Psychoeducational interventions mainly included cognitive-behavioural techniques, mindfulness-based stress reduction and positive psychotherapy. We used WhatsApp as a tool to

deliver multimedia psychoeducational contents (videos, podcasts, texts and pictures) to patients.

Main outcome variables

Perceived Stress; Resilience

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201001048893N1**

Registration date: **2020-10-03, 1399/07/12**

Registration timing: **retrospective**

Last update: **2020-10-03, 1399/07/12**

Update count: **0**

Registration date

2020-10-03, 1399/07/12

Registrant information

Name

Maryam Shaygan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3626 7345

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m2620.shaygan@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-10, 1398/12/20

Expected recruitment end date

2020-04-19, 1399/01/31

Actual recruitment start date

2020-04-02, 1399/01/14
Actual recruitment end date
 2020-04-30, 1399/02/11
Trial completion date
 2020-05-14, 1399/02/25

Scientific title
 Comparison of the Effectiveness of Online Multimedia
 Psycho-educational Interventions with routine
 Psychological Care on the Perceived Stress and
 Resilience of hospitalized Patients with COVID-19

Public title
 Effect of Online Psycho-educational Interventions on
 Psychological Health of Patients with COVID-19

Purpose
 Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
 Age over 18 years Willingness to take part in the study
 Diagnosis of COVID-19 by Clinical Manifestation and
 Laboratory Results Having internet access and ability to
 work with the media Hospitalization of Patient due to
 Infection with COVID-19
Exclusion criteria:
 Previous Experience of Quarantine Unwillingness or
 Inability to Continue Contributing to the Study Having a
 History of Psychiatric Disorders or taking Psychiatric
 Medications Death or Transfer to the ICU

Age
 From **18 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
 Target sample size: **50**
 Actual sample size reached: **48**

Randomization (investigator's opinion)
 Randomized

Randomization description
 We chose to use a cluster randomized controlled trial
 with hospital wards as the units of randomization (rather
 than individual patients). The primary reason for
 identifying the cluster randomized design was to protect
 against the 'contamination' that could occur in
 individually randomized trials. The risk of contamination
 was minimized by the fact that the hospitalized patients
 in the intervention and control hospital wards were not in
 contact with each other. In order to minimize imbalance
 across the intervention and control groups, we used a
 pair-matched randomization of clusters, before the start
 of intervention. Accordingly, to ensure comparability of
 the intervention and control groups, we randomly
 allocated one ward in each hospital to the intervention
 group and the other to the control group. Random
 assignment of wards was performed by an independent

observer not involved in this study, using a coin toss.

Blinding (investigator's opinion)
 Double blinded

Blinding description
 Patients were blinded to patient group assignment. In
 other words, because the patients in the experimental
 and control groups were hospitalized in two different
 wards of the hospital, they did not know how to educate
 the patients in the other wards of the hospital. Moreover,
 evaluator and analyzer of data were not informed of
 patient's treatment assignment. This goal was achieved
 by the fact that all online questionnaires had a code and
 the person assessing the questionnaires and analyzing
 the data were unaware of the grouping type of the owner
 of each questionnaire.

Placebo
 Not used

Assignment
 Parallel

Other design features
 One of the strengths of this study was the design of a
 new psycho-educational package based on cognitive-
 behavioral approaches, positive psychology and
 mindfulness targeting patients with Covid-19.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical
 Sciences

Street address

School of Nursing and Midwifery, Nemazee Square,
 Zand St., Shiraz, Iran

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Fars

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71936-13119

Approval date

2020-03-18, 1398/12/28

Ethics committee reference number

IR.SUMS.REC.1399.011

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19 confirmed by laboratory testing

Primary outcomes

1

Description

Primary outcome is Resilience score on the Connor-Davidson Resilience Scale.

Timepoint

Immediately before intervention and 2 weeks later

Method of measurement

Connor-Davidson Resilience Scale

2

Description

Primary outcome is Perceived Stress score on the Perceived Stress Scale (PSS).

Timepoint

Immediately before intervention and 2 weeks later

Method of measurement

Perceived Stress Scale (PSS)

Secondary outcomes

empty

Intervention groups

1

Description

Psychoeducational interventions mainly included cognitive-behavioural techniques, mindfulness-based stress reduction and positive psychotherapy. We used WhatsApp as a tool to deliver daily multimedia psychoeducational contents (videos, podcasts, texts and pictures) to patients. Cognitive-behavioural techniques were used to teach patients how to recognize and mitigate their cognitive biases, especially in relation to disease and the likelihood of adverse events due to disease. Mindfulness techniques were incorporated to help patients recognize their negative thoughts and emotions about the disease and reduce the intensity and impact of those thoughts and emotions on their level of stress. In order to increase positive emotions and optimism in patients, positive psychotherapy exercises such as "Positive Reminiscence" and "Finding Meaning", were taught to the patients. On average, 2 educational videos (7-8 minutes), 15 educational texts and podcasts were sent to patients for 2 weeks. Patients were daily encouraged to perform daily exercises. They shared the effectiveness or questions about how to perform the exercises with the therapy team.

Category

Treatment - Other

2

Description

Control group: Patients in wards allocated to the control condition received face-to-face or telephone-based psychological counseling in case of need.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Chamran hospital

Full name of responsible person

Zahra Yazdani

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2

Recruitment center

Name of recruitment center

Ali Asghar hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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Grant name
Vice Chancellor for Research, Shiraz University of Medical Sciences

Grant code / Reference number
22029

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
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

Anonymous study data will be shared in correspondence with the project manager.

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

A closer look at the data of patients with Covid 19

From where data/document is obtainable

Contact via email

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

After obtaining permission from the security unit and the university's vice chancellor for research, the data will be made available to the individual.

Comments