Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 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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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

City

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Province

Fars

Postal code

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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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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