Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

Evaluation of the effectiveness of online mindful self-compassion training on the psychological symptoms associated with the Covid-19 pandemic in individuals with a history of Covid-19 infection themselves or family members

Protocol summary

Study aim
Determining the effectiveness of self-conscious self-compassion online therapy on the psychological symptoms associated with Covid-19 pandemic in individuals with a history of Covid-19 infection or family members

Design
This study included two groups of control and treatment group, each of which consisted of 20 samples of people.

Settings and conduct
in this study; After the publishing communiques in Kermanshah, questionnaires (GAD-7,Coronavirus Anxiety Scale ,OCS ,COVID-19-PTSD and sleep quality) will be provided online; The people who are eligible to participate in the test will be selected and after a complete explanation about the study and completion of the informed consent will be randomly assigned to the experimental and control groups by a table of random numbers. Two weeks later in the middle of treatment, immediately after the end of treatment and two months after the end of treatment, the questionnaires are completed by both experimental and control groups and the results are collected and evaluated in pre-test, mid-test, post-test and follow-up Will be placed.

Participants/Inclusion and exclusion criteria
People who became infected with the virus themselves or a family member during the Covid-19 pandemic; People should not have Covid-19 while studying.

Intervention groups
The intervention group receives mindful self-compassion treatment consciously. The control group uses progressive muscle relaxation therapy as a baseline treatment. The results of the intervention group in compare with the baseline treatment are measured.

Main outcome variables
Reduction of coronary anxiety, coronary obsession, symptoms of post-traumatic stress due to coronary artery, better sleep quality in people with a history of Covid-19 infection or family members

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180312039056N4**
Registration date: **2021-07-17, 1400/04/26**
Registration timing: **prospective**

Last update: **2021-07-17, 1400/04/26**
Update count: **0**

Registration date
2021-07-17, 1400/04/26

Registrant information

Name
Seyed Mojtaba Ahmadi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-07-23, 1400/05/01

Expected recruitment end date
2021-08-23, 1400/06/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effectiveness of online mindful self-compassion training on the psychological symptoms associated with the Covid-19 pandemic in individuals with a history of Covid-19 infection themselves or family members

Public title
Evaluation of the effectiveness of online mindful self-compassion training on the psychological symptoms associated with the Covid-19 pandemic in individuals with a history of Covid-19 infection themselves or family members
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
A standard deviation greater than the mean in the Corona Anxiety Inventory (principal outcome variable) The higher score than average in other questionnaires (secondary outcome variable) Do not take psychiatric medications. No suicidal thoughts Not having a severe mental illness No cognitive problems or cognitive diseases such as Alzheimer's Familiarity with the Internet Ability to read and write
Exclusion criteria:
Absence from two or more meetings Failure to complete treatment assignments Failure to complete the questionnaires in the post-test and follow-up stages Getting sick to coronavirus, during the intervention
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **75**
Randomization (investigator's opinion)
Randomized
Randomization description
All study participants were 40 people who were randomly divided into control and experimental groups. At the same time, a pretest was performed for both groups.
Blinding (investigator's opinion)
Single blinded
Blinding description
he assessment will be carried out by two evaluators without knowing the nature of the evaluation.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee in Kermanshah University of Medical Sciences
Street address
Central office of Kermanshah University of Medical Sciences, Kermanshah, Shahid Beheshti Blvd
City
Kermanshah
Province
Kermanshah
Postal code
715847141 6
Approval date
2021-04-27, 1400/02/07
Ethics committee reference number
IR.KUMS.REC.1400.093

Health conditions studied

1

Description of health condition studied
COVID-19
ICD-10 code
U07.2
ICD-10 code description
COVID-19, virus not identified

Primary outcomes

1

Description
Corona anxiety
Timepoint
At the beginning of the intervention, 2 weeks after the intervention, 8 weeks after the intervention, 2 months after the end of the intervention
Method of measurement
Coronavirus Anxiety Scale

Secondary outcomes

1

Description
Corona anxiety
Timepoint

At the beginning of the intervention, 2 weeks after the intervention, 8 weeks after the intervention, 2 months after the end of the intervention

Method of measurement

Coronavirus Anxiety Scale

2

Description

Post-traumatic stress disorder Related to Covid-19

Timepoint

At the beginning of the intervention, 2 weeks after the intervention, 8 weeks after the intervention, 2 months after the end of the intervention

Method of measurement

Post-traumatic stress disorder Related to Covid-19 Questionnaire

3

Description

Obsession with COVID-19

Timepoint

At the beginning of the intervention, 2 weeks after the intervention, 8 weeks after the intervention, 2 months after the end of the intervention

Method of measurement

Obsession with COVID-19 Scale

4

Description

Sleep quality

Timepoint

At the beginning of the intervention, 2 weeks after the intervention, 8 weeks after the intervention, 2 months after the end of the intervention

Method of measurement

The Pittsburgh Sleep Quality Index

5

Description

Self-Compassion

Timepoint

At the beginning of the intervention, 2 weeks after the intervention, 8 weeks after the intervention, 2 months after the end of the intervention

Method of measurement

Self-compassion Scale (Short form)

6

Description

Mindfulness

Timepoint

At the beginning of the intervention, 2 weeks after the intervention, 8 weeks after the intervention, 2 months after the end of the intervention

Method of measurement

Five Factor Mindfulness Questionnaire

Intervention groups

1

Description

Intervention group: online mindful self-compassion training

Category

Treatment - Other

2

Description

Control group: Progressive muscle relaxation

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Medicine

Full name of responsible person

Dr. seyed mojtaba ahmadi

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School of Medicine, Daneshgah St. Shahid Shirudi Blvd, Kermanshah

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kermanshah 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
Kermanshah University of Medical Sciences
Full name of responsible person
Khatereh Heshmati
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
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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
Study data, therapeutic protocol
When the data will become available and for how long
After publishing articles

To whom data/document is available

All those interested in research in this area

Under which criteria data/document could be used

-

From where data/document is obtainable

Khatereh Heshmati Email: Khaterehheshmati@gmail.com

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

Sending email to Khatereh Heshmati and after confirmation by members of the research team, the data will be sent

Comments