

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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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

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Kermanshah

Postal code

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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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

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

Psychology

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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: Khatereheshmati@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