Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The Comparison of the Effectiveness of Pharmacotherapy and online Compassion-Based Therapy in Reducing the Severity of Post Traumatic Symptoms, Increasing Post-Traumatic Growth, Improving Quality of life, and Studying Changes in Hippocampal and Amygdala Volume in Improved Patients with Coronavirus

Protocol summary

Study aim
Comparing the effectiveness of medical treatment and online compassion-focused treatment in reducing the severity of post-traumatic stress symptoms, increasing post-traumatic growth, improving quality of life, and studying the volume of the hippocampus and amygdala in recovered patients with coronavirus

Design
Clinical trial with intervention, control and follow-up group, phase 2 on 60 patients. The research design was semi-experimental with pre-test-post-test and follow-up with one control group and two experimental groups

Settings and conduct
The location of the experiment was in Shiraz city and the field of experimental research and how to conduct psychotherapy intervention online, drug therapy under the supervision of a psychiatrist and brain imaging were performed in person. Blinding was not used in this study

Participants/Inclusion and exclusion criteria
60 patients with delta variant of covid-19 diagnosed with symptoms of post-traumatic stress disorder in Shiraz city. Inclusion criteria: not having specific mental disorders, being literate in reading and writing, suffering from corona disease Exclusion criteria: not fully attending classes, having a mental disorder

Intervention groups
The first experimental group was subjected to compassion-focused therapy online (depending on the conditions and tools available to the patient) during eight sessions, and the second experimental group was under the supervision of a psychiatrist and treated with fluoxetine at a dose of 20 mg in a period of 6 It was used up to 8 weeks to treat post-traumatic stress disorder patients. The control group did not receive any treatment during this period.

Main outcome variables
Post-traumatic stress symptoms; growth after injury; The quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230408057849N1**
Registration date: **2023-05-04, 1402/02/14**
Registration timing: **retrospective**

Last update: **2023-05-04, 1402/02/14**
Update count: **0**

Registration date
2023-05-04, 1402/02/14

Registrant information

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2021-08-22, 1400/05/31

Expected recruitment end date

2021-09-06, 1400/06/15

Actual recruitment start date

2021-08-22, 1400/05/31

Actual recruitment end date

2021-09-06, 1400/06/15

Trial completion date

2022-09-15, 1401/06/24

Scientific title

The Comparison of the Effectiveness of Pharmacotherapy and online Compassion-Based Therapy in Reducing the Severity of Post Traumatic Symptoms, Increasing Post-Traumatic Growth, Improving Quality of life, and Studying Changes in Hippocampal and Amygdala Volume in Improved Patients with Coronavirus

Public title

Investigating the effect of fluoxetine and online compassion-focused therapy in the treatment of post-chronic patients with post-traumatic stress disorder

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:

1- Being a resident of Shiraz city 2- having a positive PCR in Delta variant Corona virus 3- having a history of hospitalization and discharge.

Exclusion criteria:

Older participant Not living in Shiraz city Not having a history of hospitalization in the corona ward

Age

No age limit

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **70**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

سامانه ملی اخلاق در پژوهش های زیست پزشکی

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Approval date

2022-08-20, 1401/05/29

Ethics committee reference number

IR.IAU.M.REC.1401.015

Health conditions studied

1

Description of health condition studied

Post Traumatic Stress Disorder

ICD-10 code

F43.1

ICD-10 code description

Post-traumatic stress disorder (PTSD)

Primary outcomes

1

Description

The percentage of people whose questionnaire score was reported to be low

Timepoint

Measuring the severity of post-traumatic stress symptoms, one week before the start of the intervention (pre-test) and 2 weeks after the intervention (post-test) and for the follow-up stage 3 months after the intervention

Method of measurement

Post-traumatic growth and development questionnaire, post-traumatic stress disorder questionnaire (PCL-5), World Health Organization quality of life questionnaire - short form, brain imaging to measure the Hippocampus and Amygdala

2

Description

The percentage of people whose questionnaire scores are high

Timepoint

Measurement of growth and development after the accident, one week before the start of the intervention (pre-test) and 2 weeks after the intervention (post-test) and for the follow-up stage 3 months after the intervention

Method of measurement
Post-traumatic growth and development questionnaire

3

Description
The percentage of people whose questionnaire scores are reported to be high
Timepoint
Measuring the quality of life, one week before the start of the intervention (pre-test) and 2 weeks after the intervention (post-test) and for the follow-up stage 3 months after the intervention
Method of measurement
World Health Organization quality of life questionnaire - short form

4

Description
Changes in the size of the Hippocampus and Amygdala
Timepoint
At the beginning of the study (before the interventions) and one year after the interventions
Method of measurement
Brain imaging to measure the hippocampus and amygdala

Secondary outcomes

empty

Intervention groups

1

Description
The first intervention group: Pharmacotherapy: Prozac brand name، fluoxetine drug from the serotonin reuptake inhibitors (SSRIs) category at a dose of 20 mg, 2 times a day, morning and evening, in a period of 6 to 8 weeks, Exir pharmaceutical factory
Category
Treatment - Drugs

2

Description
The intervention group: Compassion-focused therapy, online, in eight ninety-minute sessions, once a week and in a group setting. description of meetings; The first session: getting to know the group members with each other, explaining the group rules, explaining the symptoms of post-traumatic stress, talking about their problems, explaining how the mind works and how and why it malfunctions. The second session: explanation and description of compassion: what compassion is and how to overcome problems through it. The third session: thinking about compassion towards others, paying attention and focusing on compassion, thinking about compassionate compassion, compassionate behavior, portraying compassion The fourth session: increasing warmth and energy, mindfulness, acceptance, wisdom and strength, warmth and non-judgment. Sixth session: practice the color of compassion, sound and image of compassion, and letter writing based on compassion .Seventh session: writing letters of compassion, practicing anger and compassion, practicing fear of compassion, preparing for the end of the group. Eighth session: reviewing, summarizing, ending the group's work, and doing the post-test
Category
Lifestyle

3

Description
Control group: They did not receive any intervention
Category
Other

Recruitment centers

1

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1

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Grant name
No specific grant was used to finance this study
Grant code / Reference number
درتامین مالی این مطالعه از گرنت مشخصی استفاده نشده است
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
The financial sponsor of this thesis is the PhD student, Mrs. Fateme Modaresi Fard
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
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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
All data is potentially shareable after de-identifying individuals
When the data will become available and for how long
The access period starts one year after the results are

published

To whom data/document is available

The data of this study will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

The data of this study will be used in other similar researches for resources

From where data/document is obtainable

Future researchers should contact the responsible author via email to use the data of this study.
fatemehmodaresifard@gmail.com

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

After sending the request email, the responsible author will send the data within a period of 7 days

Comments