

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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

Name

Fatemeh Modaresifard

Name of organization / entity

Islamic Azad University of Marvdasht

Country

Iran (Islamic Republic of)

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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
Street address
 Floor.13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town, Tehran
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Postal code
 1467664962
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

Recruitment center

Name of recruitment center

Zand Institute of Higher Education

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

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Grant name

No specific grant was used to finance this study

Grant code / Reference number

درتامين مالی این مطالعه از گونت 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**

Persons

Person responsible for general inquiries**Contact****Name of organization / entity**

American Psychological Association

Full name of responsible person

Fatemeh Modaresifard

Position

Psychologist

Latest degree

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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

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