

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Comparing the effect of interpersonal psychotherapy and compassion focused therapy on the grief experience and quality of life in first-degree relatives of the deceased caused by Covid 19

Protocol summary

Study aim

Determining and comparing the effect of interpersonal psychotherapy and compassion focused therapy on the grief experience and quality of life in first-degree relatives of the deceased caused by Covid 19

Design

Single-blind, randomized clinical trial without a control group, with parallel groups, on 40 patients

Settings and conduct

Forty people whose first-degree relatives have died due to COVID-19 in the last 6 months and are eligible to be included and have a file in one of the Khorshid and Al-Zahra hospitals, will be selected and will enter the study if satisfied. These people are randomly divided into two groups. One group will receive interpersonal psychotherapy and the other group will receive compassion focused therapy.

Participants/Inclusion and exclusion criteria

The individuals who have experienced the death of a first-degree relative due to COVID 19 during the last six months, grief experience questionnaire (GEQ) score of >34, willing to participate in the study, aged over 18 yrs. , no major psychiatric illness (schizophrenia, bipolar), Obsession, personality disorders) and drug use disorders (based on an interview with a psychiatric assistant). Exclusion criteria include not attending treatment sessions for more than two consecutive sessions and exacerbation of symptoms and the need for psychiatric hospitalization.

Intervention groups

First intervention group: Individuals in this group will be treated as interpersonal psychotherapy in 6 sessions of 45 minutes to one hour individually with the presence of a trained clinical psychologist and an assistant psychiatrist. Second intervention group: Individuals in this group will be treated with compassion focused therapy in 6 sessions of 45 minutes to one hour

individually in the presence of a trained clinical psychologist and an assistant psychiatrist.

Main outcome variables

Grief experience score; Quality of life score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201119049445N1**

Registration date: **2021-02-13, 1399/11/25**

Registration timing: **registered_while_recruiting**

Last update: **2021-02-13, 1399/11/25**

Update count: **0**

Registration date

2021-02-13, 1399/11/25

Registrant information

Name

Hajar Salimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3222 2127

Email address

salimi85ha@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-20, 1399/11/01

Expected recruitment end date

2021-05-21, 1400/02/31

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the effect of interpersonal psychotherapy and compassion focused therapy on the grief experience and quality of life in first-degree relatives of the deceased caused by Covid 19

Public title
Comparing the effect of psychotherapy on the grief experience and quality of life in first-degree relatives of the deceased caused by COVID 19

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Death of a first-degree relative due to COVID19 in the last six months Grief Experience Questionnaire (GEQ) score of >34 Being consent to participate in the study The age of >18 yrs. No major psychiatric illness (schizophrenia, bipolar, obsessive-compulsive disorder, personality disorders) Drug use disorder based on an interview with a psychiatric assistant
Exclusion criteria:
Failure to attend treatment sessions for more than two consecutive sessions Exacerbation of symptoms and the need for psychiatric hospitalization

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Forty eligible students will be randomly selected using convenience sampling. These people are then coded with the aid of Random Allocation software and are automatically divided into two groups. The relevant codes will be entered in the raw checklists and each of these checklists will be randomly assigned to one person and that person will be randomly studied in one of the two groups.

Blinding (investigator's opinion)
Single blinded

Blinding description
Due to the different content of individual psychotherapy and compassion focused therapy sessions, the intervener is aware of the two groups, but the participant will not be aware of the difference in the type of treatment due to lack of awareness of the other group. In addition, the

person collecting the information and the statistician will not be aware of the two groups before the end of the treatment period.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezar Jarib street, Azadi square.

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2020-09-20, 1399/06/30

Ethics committee reference number

IR.MUI.MED.REC.1399.519

Health conditions studied

1

Description of health condition studied

Early signs of grief based on obtaining a score of more than 34 from the grief experience questionnaire

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Grief score

Timepoint

Before and 4 weeks after the intervention

Method of measurement

Grief Experience Questionnaire

2

Description

Quality of Life

Timepoint

Before and 4 weeks after the intervention

Method of measurement

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: Individuals in this group will be treated as interpersonal psychotherapy in 6 sessions of 45 minutes to one hour individually with the presence of a trained clinical psychologist and an assistant psychiatrist. In these sessions, the person will be trained to recognize the symptoms of depression, correct relationships (including reviewing the history of the relationship with the deceased; high intimacy or guilt due to inaction and anger of the deceased); Expanding relationships with the deceased (such as examining positive relationships with the deceased during life, the ability of clients to care for the deceased) and expanding relationships with other relatives and family (including examining the quality and quantity of previous relationships with others and role play for Verbal communication, expression of feelings and self-disclosure.

Category

Treatment - Other

2

Description

Second intervention group: Individuals in this group will undergo compassion-focused therapy in 6 sessions of 45 minutes to one hour individually with the presence of a trained clinical psychologist and a psychiatrist assistant. In these sessions, the person will be trained to get familiar with the general concept of self-compassion and empathy and the practice of rhythmic calming breathing; self-critical education and its types, expressing the causes of self-criticism and its consequences, preparing a diary of daily mistakes and accepting them and the skills to solve them, the exercise of self-esteem and self-worth by mentioning their positive characteristics.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Khorshid hospital

Full name of responsible person

Hajar Salimi

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Ostandari street.

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2

Recruitment center

Name of recruitment center

Al-Zahra Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjooy Javanmard

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Isfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Hajar Salimi
Position
Assistant Professor
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available