Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

Comparison of the efficacy of compassion-focused therapy on depressive symptoms in individuals with severe and mild child maltreatment experience

Protocol summary

Study aim
Comparing the efficacy of compassion-focused therapy on depressive symptoms in individuals with severe and mild histories of childhood maltreatment

Design
Clinical trial, with control and experimental groups, parallel, one-sided blind, on 48 patients.

Settings and conduct
Initial sampling will be done by screening with Beck's Depression Inventory and Childhood Trauma Questionnaire In internal and external messengers in 2023. Then, according to the inclusion and non-inclusion criteria, 24 people are selected for the intervention group and 24 people for the control group. The intervention sessions will be held in groups and on the platform of virtual space.

Participants/Inclusion and exclusion criteria
Inclusion: moderate to high score in the Beck Depression Inventory, subclinical symptoms of depression based on the diagnostic interview, and the ability of read and write; Non-inclusion: A mild to moderate score in each of the subscales of the childhood trauma questionnaire, receiving psychotherapy and starting pharmacotherapy in the last 2 months, Psychotic symptoms, personality disorder, substance, and alcohol-related disorders, and severe suicidal ideation.

Intervention groups
In the experimental and control group, the compassion-focused therapy protocol developed by Gilbert will be used in 12 sessions. The two groups include people who have at least subclinical depression symptoms or who have scored medium to high scores in the Beck Depression Questionnaire. Still, their difference is that the experimental group members must have medium to high scores in at least one of the subscales of the childhood trauma questionnaire. In contrast, the control group includes people who did not get a mild high score in any of the subscales of the childhood trauma questionnaire. The questionnaires will be completed in a pre-test, post-test, and follow up after 2 months.

Main outcome variables
Depressive symptoms

General information

Reason for update

Acronym
CFT

IRCT registration information
IRCT registration number: **IRCT20230102057025N1**
Registration date: **2023-01-21, 1401/11/01**
Registration timing: **prospective**

Last update: **2023-01-21, 1401/11/01**
Update count: **0**

Registration date
2023-01-21, 1401/11/01

Registrant information

Name
Zahra Asl Soleimani

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
2023-04-04, 1402/01/15

Expected recruitment end date

2023-07-22, 1402/04/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the efficacy of compassion-focused therapy on depressive symptoms in individuals with severe and mild child maltreatment experience

Public title
The effect of compassion-focused therapy on depression in people with childhood maltreatment

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Obtain a score of at least 14 on the Beck Depression Inventory-second edition (BDI-II) Presence of minimal subclinical symptoms of depression based on the diagnostic interview (2-4 symptoms of major depression according to The Diagnostic and Statistical Manual of Mental Disorders-Fifth Edition(DSM-5) that include at least one of the core symptoms) The minimum ability to read and write

Exclusion criteria:
A mild to moderate score on any of the Childhood Trauma Questionnaire (CTQ) subscales Presence of psychotic symptoms based on diagnostic interview receiving psychotherapy in the last 2 months starting pharmacotherapy in the last 2 months The presence of diagnostic criteria for personality disorders based on diagnostic interviews Presence of severe suicidal ideation based on diagnostic interview Suffering from substance, alcohol and drug related disorders based on individual report and diagnostic interview

Age
From **18 years** old to **40 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **48**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
The statistical analyst is blind to research so data analysis can be done without bias

Placebo
Not used

Assignment
Parallel

Other design features
The study includes two groups with different characteristics that receive the same intervention

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of University of Social Welfare and Rehabilitation Sciences

Street address
Kodakyar Ave., Daneshjo Blvd.,Evin, Tehran

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1985713871

Approval date
2022-07-20, 1401/04/29

Ethics committee reference number
IR.USWR.REC.1401.068

Health conditions studied

1

Description of health condition studied
Major Depressive Disorder

ICD-10 code
F32

ICD-10 code description
Major depressive disorder, single episode

2

Description of health condition studied
Major Depressive Disorder

ICD-10 code
F33

ICD-10 code description
Major depressive disorder, recurrent

Primary outcomes

1

Description
Severity of signs and symptoms in patients with depression

Timepoint
Before the intervention, last session, 2 months after the intervention

Method of measurement
Beck Depression Inventory–II

Secondary outcomes

1

Description
Cognitive Emotion Regulation
Timepoint
Before the intervention, last session, 2 months after the intervention
Method of measurement
Cognitive Emotion Regulation Questionnaire- short form

2

Description
Behavioral Emotion Regulation
Timepoint
Before the intervention, last session, 2 months after the intervention
Method of measurement
Behavioral Emotion Regulation Questionnaire

3

Description
Interpersonal Emotion Regulation
Timepoint
Before the intervention, last session, 2 months after the intervention
Method of measurement
Interpersonal Emotion Regulation Questionnaire

4

Description
Self-Compassion
Timepoint
Before the intervention, last session, 2 months after the intervention
Method of measurement
Self-Compassion Scale (short form)

5

Description
Fears of Compassion
Timepoint
Before the intervention, last session, 2 months after the intervention
Method of measurement
Fears of Compassion Scales

Intervention groups

1

Description
Intervention group: The participants include people who have obtained a moderate or higher depression score (14 and above) based on the Beck Depression Inventory-II and diagnostic interview. The questionnaires are completed before the start of the intervention and at least in one of the subscales of the childhood trauma questionnaire, they have scored average or higher. The content of group sessions is held in 8 sessions of 90 minutes once a week. The sessions are conducted with themes such as emotion regulation systems, characteristics of compassion and a compassionate person, reasoning, attention, visualization, compassionate feelings and behavior, and self-compassion, optimism, empathy, relaxation exercises, and positive self-induction are used. . At the end of the intervention, the participants will complete the questionnaires as a post-test. In the follow-up phase, after 2 months, the participants will complete the research questionnaires again.
Category
Treatment - Other

2

Description
Control group: Compassion-focused therapy: The participants include people who have obtained a moderate or higher depression score (14 and above) based on the Beck Depression Inventory-II and diagnostic interview and have not scored higher than mild in any of the subscales of the childhood trauma questionnaire. The content of group sessions is held in 8 sessions of 90 minutes once a week. The sessions are conducted with themes such as emotion regulation systems, characteristics of compassion and a compassionate person, reasoning, attention, visualization, compassionate feelings and behavior, and self-compassion, optimism, empathy, relaxation exercises, and positive self-induction are used. . At the end of the intervention, the participants will complete the questionnaires as a post-test. In the follow-up phase, after 2 months, the participants will complete the research questionnaires again.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
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University of Social Welfare and Rehabilitation Sciences
Full name of responsible person
Zahra Asl Soleimani
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Sponsors / Funding sources

1

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Assistance of research and technology
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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
University of social welfare and rehabilitation 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
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Zahra Asl Soleimani
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Person responsible for updating data

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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
Not applicable

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

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
Start access after printing the results

To whom data/document is available
Researchers in academic institutions

Under which criteria data/document could be used
There are no other conditions

From where data/document is obtainable
Postal address: Zahra Asl Soleimani; Clinical psychology department, University of Social Welfare and Rehabilitation Sciences, Kodakyar Ave., Daneshjo Blvd., Evin, Tehran Email: Z.soleimani1991@gmail.com

What processes are involved for a request to access data/document
The requester can have the data after the request email be

Comments