Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effectiveness of Self-Compassion-Focused Therapy on Cognitive Vulnerability to Depression in Students of Bu-Ali Sina University

Protocol summary

Study aim

The objective of the present study was to determine the effectiveness of self-compassion-focused therapy on cognitive vulnerability to depression as one of the causes of the onset or recurrence of depressive episodes in people who were not depressed at the time of the research but were cognitively susceptible to depression.

Design

Clinical trial with control group, Sampling was done in two stages; First, 311 series of questionnaires by available sampling method were provided to students for screening., then according to the research criteria, 52 people were screened at this stage, and finally, by random assignment, 20 people were placed in the experimental group and 20 people in the control group.

Settings and conduct

. A self-compassion-focused therapy package was administered to the experimental group for eight 90 minutes sessions. However, the control group did not receive any treatment. The intervention was performed online (with Skype), by a specialist psychologist who had been trained in self-compassion-focused therapy courses.

Participants/Inclusion and exclusion criteria

The inclusion criteria included depression z scores of less than 1, dysfunctional attitude scores of higher than 128, attribution style and cognitive triad z scores of higher than 1, and self-esteem z scores of below 1; these individuals should have a cognitive vulnerability to depression. The inclusion criteria included the lack of depression symptoms and psychotherapy in the past two months.

Intervention groups

The experimental group underwent compassion-focused therapy for 8 sessions of 90 minutes. The control group: the control group did not receive any treatment

Main outcome variables

increasing self-esteem; reducing internal, stable, and general attribution styles in negative situations; reducing dysfunctional attitudes; reducing cognitive vulnerability to depression.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220907055911N1**
Registration date: **2022-09-29, 1401/07/07**
Registration timing: **retrospective**

Last update: **2022-09-29, 1401/07/07**
Update count: **0**

Registration date

2022-09-29, 1401/07/07

Registrant information

Name

Mehran Farhadi

Name of organization / entity

Bu-Ali Sina University

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-20, 1398/12/01

Expected recruitment end date

2020-03-05, 1398/12/15

Actual recruitment start date

2020-05-04, 1399/02/15

Actual recruitment end date

2020-05-20, 1399/02/31

Trial completion date

2020-10-21, 1399/07/30

Scientific title

The Effectiveness of Self-Compassion-Focused Therapy on Cognitive Vulnerability to Depression in Students of Bu-Ali Sina University

Public title

The effect of self-compassion on cognitive vulnerability to depression

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

All students of Bu-Ali Sina University (Before screening) The lack of depression symptoms (After screening) Not receiving psychotherapy services in the past two months (After screening) These individuals should have a cognitive vulnerability to depression (After screening)

Exclusion criteria:

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **311**

Actual sample size reached: **311**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling was done in two stages; First, for the purpose of screening, 311 series of questionnaires were provided to the students by available sampling method, then according to the criteria of the research, 52 people were screened at this stage. First, 40 people were randomly selected (40 questionnaire codes were selected by lottery from among the 52 available codes), and finally, these 40 people were randomly assigned (again, by lottery from among the 40 available codes, one of the selected codes was assigned to experimental and control groups were assigned), 20 people were in the experimental group and 20 people were in the control group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

It has an experimental group and a control group, the experimental group all underwent the same type of intervention, but the control group did not receive any intervention. Pre-test and post-test were performed on both groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee Hamedan of University of Bu-Ali Sina

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Approval date

2020-05-02, 1399/02/13

Ethics committee reference number

IR.BASU.REC.1399.008

Health conditions studied

1

Description of health condition studied

Cognitive Vulnerability to Depression

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Cognitive vulnerability score to depression

Timepoint

Before the start of the intervention and four days after the end of the intervention

Method of measurement

(According to the score of the Beck Depression Inventory, these people should not be depressed at the time of the intervention (z-scores less than 1) and also according to the scores of the dysfunctional attitude scale (scores of higher than 128), attribution style questionnaire and Cognitive Triad Inventory (z-scores of higher than 1) and self-esteem scale (z-scores lower than 1), these individuals should have cognitive vulnerability to depression.

2

Description

Dysfunctional attitudes score

Timepoint

Before the start of the intervention and four days after the end of the intervention

Method of measurement

Dysfunctional Attitude Scale and Cognitive Triad Inventory

3

Description
reducing internal, stable, and general attribution styles in negative situations score
Timepoint
Before the start of the intervention and four days after the end of the intervention
Method of measurement
Attributional Style Questionnaire

4

Description
Self-esteem score
Timepoint
Before the start of the intervention and four days after the end of the intervention
Method of measurement
Rosenberg Self-Esteem Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The experimental group underwent compassion-focused therapy for 8 sessions of 90 minutes. Neff, defined self-compassion as a three-component construct, which includes kindness to oneself versus self-judgment, human sharing versus isolation, and vigilance versus extreme assimilation. Therefore, Gilbert used this structure in the treatment sessions, and finally proposed self-compassion-focused therapy. In fact, self-compassion-focused therapy focuses on the four areas of past and historical experiences, underlying fears, strategies for being safe, and unintended consequences. self-compassion-focused therapy package was developed and designed based on the theoretical guidelines of Gilbert's compassionate mind. Session one, purpose: introduction and general explanations. content: familiarity with members, workshop rules, members' goals for attending the meetings, the logic of intervention sessions, the definition of compassion, the importance and the effects of compassion. Session two, purpose: introducing emotional regulation systems. content: introducing three emotional regulation systems and the way they affect the individual; explaining the difference between a threat-focused mind and a compassionate mind. Session three, purpose: introducing mindfulness technique. content: teaching relaxing breath and the way to perform it; introducing mindfulness skills, physical examination techniques, moment-to-moment attention, and conscious eating (e.g., raisin eating practice). Session four, purpose: introducing the characteristics of compassion and a compassionate person. content: explaining the six characteristics of compassion (i.e., sensitivity, well-being care, empathy, sympathy, non-judgment, and tolerance of turmoil); defining a compassionate person and his characteristics (i.e., wisdom, power, kindness, non-judgment, and responsibility); explaining the fact that the client must learn skills in order to become a compassionate person. Session five, purpose: introducing compassionate reasoning and compassionate attention. content: teaching how to visualize self-compassion; imagining your best state; performing the technique of compassionate chair. Session six, purpose: introducing techniques to cultivate a compassionate mind. content: reconstructing hard emotional memories through focusing on compassionate identity; further cultivating the relief system; building a compassionate inner relationship. Session seven, purpose: introducing compassionate feeling (showing compassion to others and receiving compassion from them). content: practicing self-compassion; creating an ideal and complete compassionate model; having a brief reference to the concept of fear of compassion. Session eight, purpose: introducing compassionate behaviors. content: explaining the true meaning of compassionate behaviors; generating ideas for compassionate behaviors; teaching compassionate letter writing and summarizing.
Category
Other

2

Description
Control group: The control group did not receive any treatment.
Category
Other

Recruitment centers

1

Recruitment center
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1

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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
Bu-Ali Sina University
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

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable