Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The Effectiveness of the Mindful Self-Compassion Therapy on Psychological Symptoms of Cardiovascular Diseases

Protocol summary

Study aim
The Effectiveness of the Mindful Self-Compassion Therapy on Psychological Symptoms of Cardiovascular Diseases

Design
Based on the inclusion criteria, a list of all patients who met the inclusion criteria is prepared. Then, random grouping with quadruple blocks is used to place individuals in groups (in this study, blinding is not done).

Settings and conduct
First, leaflets containing research information will be given to the participants and written and informed consent will be obtained from them before the implementation of the project. Participants will be assigned to one of the two experimental and control groups, which will initially be from both. The pre - test group is performed and the data is collected, then the experimental group (combining self-awareness compassion therapy with routine cardiovascular therapy) will receive one session per week for eight sessions. The control group will receive a CD and a relaxation book

Participants/Inclusion and exclusion criteria
1. Absence from more than two sessions of treatment sessions. 2. The unwillingness of the subject to continue the treatment process.

Intervention groups
It is a treatment plan that includes therapeutic components such as love, kindness, kind breathing, and informal exercises for daily living, as well as relaxing touching and writing a compassionate letter to oneself.

Main outcome variables
If the treatment of self-compassion is effective, it can be used to increase the quality index due to the effectiveness of the treatment in strengthening and promoting psychological well-being and reducing the psychological problems of these people. It also helps them better manage their illness by reducing the burden of mental health problems in these patients and ultimately affect the outcome of their cardiovascular disease treatment.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180205038630N5**
Registration date: **2020-11-18, 1399/08/28**
Registration timing: **prospective**

Last update: **2020-11-18, 1399/08/28**
Update count: **0**

Registration date
2020-11-18, 1399/08/28

Registrant information
Name
Ali Akbar Foroughi
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
2020-11-21, 1399/09/01
Expected recruitment end date
2021-01-20, 1399/11/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date

empty

Scientific title
The Effectiveness of the Mindful Self-Compassion Therapy on Psychological Symptoms of Cardiovascular Diseases

Public title
The Effectiveness of the Mindful Self-Compassion Therapy on Psychological Symptoms of Cardiovascular Diseases

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Based on the diagnosis of a cardiologist with cardiovascular disease Have a history of hospitalization due to cardiovascular complications Having a minimum education of 8 literacy classes No physical illnesses including: kidney failure and asthma according to the medical record No psychological disorders including substance abuse disorder, psychotic disorders, impulse control disorders, bipolar type 1, post-traumatic stress disorder according to structured clinical interview (SCID-I) Do not have first and second cluster personality disorders according to structured clinical interview (SCID-I) Achieve a score higher than the cut-off point in the Beck Anxiety and Depression Test Do not use supportive therapy sessions and other psychotherapy approaches six months before starting treatment The desire to participate in self-compassion group compassionate sessions

Exclusion criteria:
Absence from more than two sessions of treatment sessions The unwillingness of the subject to continue the treatment process

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Based on the inclusion criteria, a list of all patients who met the inclusion criteria is prepared. Then, to place people in groups, random blocking method with quadruple blocks is used

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
Ethics committee of kermanshah University of Medical Sciences

Street address
kermanshah University of Medical Sciences

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Province
Kermanshah

Postal code
6715847141

Approval date
2020-10-14, 1399/07/23

Ethics committee reference number
IR.KUMS.REC.1399.805

Health conditions studied

1

Description of health condition studied
Psychological symptoms

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Psychological symptoms of people with cardiovascular disease

Timepoint
Psychological symptoms of people with cardiovascular disease

Method of measurement
Beck Anxiety Scale. Ruminant Response Style Questionnaire. Structured Clinical Interview for Axis I, DSM-IV. Patient Health Questionnaire. Sleep Quality Questionnaire. Multidimensional Anger Scale. Self Compassion Scale (Short Form). Cognitive emotion regulation letter

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: People who receive mindful self

compassion treatment

Category

Behavior

2

Description

Control group: Those who do not receive special treatment but receive a CD and a relaxation book.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Kermanshah University of Medical Sciences

Full name of responsible person

Dr.aliakbar foroughi

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Sponsors / Funding sources

1

Sponsor

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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

Kermanshah University of Medical Sciences

Proportion provided by this source

50

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

Kermanshah University of Medical Sciences

Full name of responsible person

aliakbar foroughi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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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
Confidentiality of participants' information
Study Protocol
No - There is not 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
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable