Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The Effectiveness of Emotion-Focused Therapy (EFT) on Perceived Stress and alexithymia in Cardiovascular Patients

Protocol summary

Study aim
The aim of this study was to control stress and negative emotions in heart patients

Design
The clinical trial has an experimental group and a control group. People who meet the criteria for entering the research will be given a number, for example, if 50 people have the criteria to enter the research, they will be given a number from 1 to 50, respectively, then at least 15 of these numbers will be drawn by lot. It is considered for the experimental group and 15 people for the control group.

Settings and conduct
1. Collecting samples from Dr. Heshmat Rasht Specialized Heart Hospital 2. Interview of samples and check Inclusion criteria 3. Random allocation of samples in experimental and control groups EFT.4 Only the experimental group performs a 90-minute weekly session for 8 weeks 5. Blinding is not done

Participants/Inclusion and exclusion criteria
Inclusion criteria: cardiovascular disease, age range 20 to 55 years, relative stability of physical and mental health, high score on perceived stress and alexithymia ., Exclusion: other mental or physical illness, acute heart disease

Intervention groups
Emotion-focused therapy on the experimental group in the form of training on emotional awareness, symbolization and processing and conversion of emotion, in the form of therapeutic techniques. The control group does not receive training in this field, but like the experimental group, they participate in pre-test and post-test and answer the questionnaires.

Main outcome variables
alexithymia and perceived stress.

General information

Reason for update

Acronym
EFT

IRCT registration information
IRCT registration number: **IRCT20200808048335N1**
Registration date: **2020-10-01, 1399/07/10**
Registration timing: **prospective**

Last update: **2020-10-01, 1399/07/10**
Update count: **0**

Registration date
2020-10-01, 1399/07/10

Registrant information

Name
Maryam Aghelmasjedi
Name of organization / entity
Rahman Higher Education Institute
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-10-22, 1399/08/01

Expected recruitment end date
2020-11-21, 1399/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effectiveness of Emotion-Focused Therapy (EFT) on

Perceived Stress and alexithymia in Cardiovascular Patients

Public title
The effect of emotion in cardiac Patients
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
They have Cardiovascular disease They are relatively stable in terms of Physical and Mental health They have high Perceived Stress They have high Alexithymia
Exclusion criteria:
They have a Mental or other Physical Illness They have acute and severe symptoms of heart disease They are under 20 years old or over 55 years old People who are undergoing other psychological treatment at the same time
Age
From **20 years** old to **55 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
The method of simple randomization and its unit is individual. People who have the criteria to enter the research are assigned a number. For example, if 50 people have the criteria to enter the research, they are assigned a number from 1 to 50, respectively. The numbers, by lot, are at least 15 for the experimental group and 15 for the control group.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Rasht University of Medical Sciences
Street address
Namjoo Ave., Shahid Siadati St., Rasht., Technology & Research Vice-chancellor of University
City
Rasht
Province
Guilan
Postal code
41446-66949
Approval date
2020-07-01, 1399/04/11
Ethics committee reference number
IR.GUMS.REC.1399.157

Health conditions studied

1

Description of health condition studied
Topics covered include stress, alexithymia, and emotion-focused therapy
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
1. alexithymia Score in the Toronto alexithymia Questionnaire
Timepoint
Measurement of alexithymia at the beginning of the study (before the intervention) and 60 days after the start of treatment (EFT)
Method of measurement
Toronto alexithymia Questionnaire

2

Description
2. Perceived Stress Score in the Perceptual Stress Questionnaire Cohen et al.
Timepoint
Measurement of perceived stress at the beginning of the study (before the intervention) and 60 days after the start of treatment (EFT)
Method of measurement
Perceived Stress Questionnaire by Cohen et al

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Educating patients during 8 training sessions, 90 minutes and one session per week. The content of each session is stated separately.
1.Communication and Commitment in Treatment, Explaining Heart Disease, Causing and Maintaining Factors, Risk Factors, Describing Group Rules, Discussing

Confidentiality, Goals, Type of Emotion Focused Therapy Conceptualization, Assessment of Subjects Based on Ability to Focus On internal experiences 2. Identifying a faulty interactive cycle, identifying conflicting, dualistic, and critical feelings about yourself and important influential people in life 3. Identify basic emotions and express emotion, teach the naming of emotions in the present, discuss the four main emotions and their needs 4. Creating usually unpleasant emotional experiences in communication and family contexts and challenging them, placing the subjects in a two-chair dialogue position to identify the initial hidden emotion and debate between the empiricist and the self-critic 5. The use of relaxation techniques, speech, and self-criticism can be calmed down and the subject's experience of helplessness reduced. Put subjects in an empty chair to talk to influential people in their lives 6. Strengthening positive emotions through the process of forgiveness and self-criticism and its positive effects on patients' cardiac function and increasing awareness of the consequences of delaying the process of forgiveness. 7. Expressing your own values and how to live with them and pointing to emotional and emotional needs and ways to meet those needs in line with values (for example maintaining health as a value) 8.Review the skills offered and reinforce the changes made during treatment. Highlighting the differences between current and old interactions and summarizing points raised in previous sessions

Category

Behavior

2

Description

Control group: In this study, the control group will not receive any treatment training

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Heshmat Hospital

Full name of responsible person

Jalal Kheirkhah

Street address

Bayani St., Dr. Heshmat Heart Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Mohammad Reza Naghipour

Street address

Namjoo Ave., Shahid Siadati St., Rasht., Technology & Research Vice- chancellor of University

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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

Rasht 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

Rahman Institute of Higher Education

Full name of responsible person

Maryam Aghelmasjedi

Position

Invited faculty

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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