

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the Effectiveness of Cognitive Behavioral Therapy and Dialectical Behavior Therapy on Perceived Stress and Coping Skills in Patients after Myocardial Infarction

Protocol summary

Study aim

Determination of the effectiveness of dialectical behavior therapy on perceived stress and coping skills in patients after myocardial infarction

Design

Clinical trials with control group, with parallel groups, without blindness, randomized

Settings and conduct

In this study, 45 patients were selected by simple random sampling method in Noor Speciality Heart Clinic in Rasht. First, by random number table, individuals were randomly divided into three groups, and in each group, 15 patients were randomly assigned.

Participants/Inclusion and exclusion criteria

Entry requirements: Patients with myocardial infarction, Having at least a third level of secondary education, Age range 30 to 60 years (due to the greater prevalence of the disease in this age range), receiving scores of one standard deviation higher than mean in the mental health test. Non-compliance: Patients with fictitious disorders, patients with acute pain, patients suffering from mood disorders and anxiety undergoing psychiatric or other psychological treatment, absence in training sessions

Intervention groups

In this study, 45 patients were selected by simple random sampling method in Noor Speciality Heart Clinic in Rasht and were assigned to one control group and two intervention groups (15 people in each group). Two intervention groups included the intervention group1: cognitive-behavioral therapy group, the intervention group2: dialectical behavioral therapy, each received eight 90-minute weekly training sessions for 2 months and the control group did not receive any intervention. Subjects in each group were evaluated by the Perceived Stress questionnaire and Coping Skills questionnaire at before, after and 3 months after the intervention.

Main outcome variables

Perceived Stress and Coping Skills

General information

Reason for update

Acronym

CBT (Cognitive Behavioral Therapy); DBT (Dialectical Behavior Therapy); MI (Myocardial Infarction)

IRCT registration information

IRCT registration number: **IRCT20180205038626N5**

Registration date: **2020-05-14, 1399/02/25**

Registration timing: **registered_while_recruiting**

Last update: **2020-05-14, 1399/02/25**

Update count: **0**

Registration date

2020-05-14, 1399/02/25

Registrant information

Name

Zahra Ahmadnia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3361 8177

Email address

zahmadnia@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-07, 1399/02/18

Expected recruitment end date

2020-08-08, 1399/05/18

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the Effectiveness of Cognitive Behavioral Therapy and Dialectical Behavior Therapy on Perceived Stress and Coping Skills in Patients after Myocardial Infarction

Public title
Comparison of the Effectiveness of Cognitive Behavioral Therapy and Dialectical Behavior Therapy on Stress in Patients after Myocardial Infarction

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients with myocardial infarction, Having at least a third level of secondary education, Age range 30 to 60 years (due to the greater prevalence of the disease in this age range), receiving scores of one standard deviation higher than mean in the mental health test
Exclusion criteria:
 Patients with fictitious disorders, Patients with acute pain, Patients who were under psychiatric treatment or other psychological treatment due to mood disorders and anxiety, Absence from training sessions

Age
From **30 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **48**

Randomization (investigator's opinion)
Randomized

Randomization description
Based on random blocks method and considering 6 blocks, 8 blocks will be produced for 48 patients. After providing the list, a special code is assigned to each person, and for the application of concealment, sealed envelopes that are numbered orderly will be 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 Rasht Islamic Azad University

Street address

Darvazeh Lakan, Islamic Azad University, Rasht

City

Rasht

Province

Guilan

Postal code

41476-54919

Approval date

2020-05-06, 1399/02/17

Ethics committee reference number

IR.IAU.RASHT.REC.1399.006

Health conditions studied

1

Description of health condition studied

Myocardial Infarction

ICD-10 code

I21

ICD-10 code description

Ischaemic heart diseases

Primary outcomes

1

Description

Perceived Stress and Coping Skills

Timepoint

before intervention, end of each psychotherapy session and three months after intervention

Method of measurement

Perceived Stress Questionnaire and Coping Skills Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

In this study, 45 patients were selected by simple random sampling method in Noor Speciality Heart Clinic in Rasht and were assigned to one control group and two intervention groups (15 people in each group). Two intervention groups included the intervention group1: cognitive-behavioral therapy group, the intervention group2: dialectical behavioral therapy, each received eight 90-minute weekly training sessions for 2 months. Subjects in each group were evaluated by the Perceived

Stress questionnaire and Coping Skills questionnaire at before, after and 3 months after the intervention.

Category
Treatment - Other

2

Description
Control group: The control group did not receive any intervention.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Noor specialist heart clinic

Full name of responsible person
Azam Nouri Saeed

Street address
Moalem Ave., Noor specialist heart clinic, Rasht

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-

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+98 13 3353 4441

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
Seyed Mozaffar Mir Bargkar

Street address
Darvazeh Lakan Ave., Islamic Azad University, Rasht,

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icrc.info2019@gmail.com

Grant name

Grant code / Reference number

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

Title of funding source

Islamic Azad 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

Person responsible for general inquiries

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Azam Nouri Saeed

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

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Dr. Heshmat Rasht Hospital, Masala Square, Baniyan St

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Person responsible for scientific inquiries

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Person responsible for updating data

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Postal code

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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