

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

The Comparison of the effectiveness of emotional self-regulation strategies with coping strategies on emotional regulation and health development in the use of coronary heart disease

Protocol summary

Study aim

The aim of this study was to compare the effectiveness of emotional self-regulation strategies with pain coping strategies on emotional process regulation and health dimensions in coronary heart patients.

Design

A randomized clinical trial with parallel groups

Settings and conduct

The location of this study was Heshmatieh Hospital in Sabzevar. After coordination with hospital officials regarding the implementation of the study, the list of patients with coronary artery disease was received. Then, 67 patients were selected from the inclusion criteria and then 45 of them were randomly selected (lottery-type) and randomly assigned to three groups of emotional self-regulation strategies training, pain coping strategies training, and control group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Diagnosis of coronary heart disease
2. Ability to listen
3- Do not suffer from acute immunodeficiency and psychiatric disorders
4- Personal and conscious satisfaction
Exclusion Criteria: 1- Disrupting the order of the meeting
2. Two consecutive absences
3- Receiving any other psychotherapy intervention
4- Failure to do assignments

Intervention groups

For the first group, emotional self-regulation strategies training will be done for the second group to teach pain coping strategies. The third group will be the control group that will not receive any intervention.

Main outcome variables

Emotional process regulation and health dimensions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210529051425N1**

Registration date: **2021-07-10, 1400/04/19**

Registration timing: **registered_while_recruiting**

Last update: **2021-07-10, 1400/04/19**

Update count: **0**

Registration date

2021-07-10, 1400/04/19

Registrant information

Name

ehsan ebrahimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4465 1300

Email address

e.ebrahimi@iaukishint.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-01, 1400/03/11

Expected recruitment end date

2021-09-02, 1400/06/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparison of the effectiveness of emotional self-regulation strategies with coping strategies on emotional

regulation and health development in the use of coronary heart disease

Public title

Effectiveness of emotional self-regulation strategies and pain coping strategies in coronary heart patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of coronary heart disease Ability to listen No acute immune disease and psychiatric disorders Personal and informed consent

Exclusion criteria:

Receiving any other psychotherapy intervention Use of antidepressants and anti-stress medications

Age

From **25 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization unit: individual Randomization type: Block randomization, blocks with size of 6 Randomization tool: Random number table Random Chain Concealment Method: Use a matte envelope

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

Hormozgan University of Medical Sciences

Street address

No.51, Ibn Yamin, Ibn Yamin Street

City

Sabzvar

Province

Hormozgan

Postal code

96465223

Approval date

2020-05-17, 1399/02/28

Ethics committee reference number

IR.HUMS.REC.1399.082

Health conditions studied

1

Description of health condition studied

Coronary heart disease

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease of native coronary artery

Primary outcomes

1

Description

Emotional process regulation

Timepoint

Measurement will be done in the pre-test, post-test, and follow-up three months after post-test

Method of measurement

Emotion Regulation Questionnaire (ERS) Gross and John (2003)

2

Description

Mental health

Timepoint

Measurement will be done in the pre-test, post-test, and follow-up three months after post-test

Method of measurement

Goldberg General Health Questionnaire (GHQ-28) (1979)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group 1: Emotional self-regulation strategies training is a skill developed by Gross Educational Pack (2004) in a specialized and workshop (including emotional training, evaluation of emotional vulnerability and emotional skills of members, training attention change skills, changing behavioral and physiological consequences of emotion, and reassessment and planning for the application of training) in 8 sessions (two sessions per week and each session for 90 minutes) Training was given to the members of the group.

Category

Other

2

Description

Intervention group 2: Teaching pain coping strategies are skills developed by Smith et al. (2012) in a specialized and workshop training package (including providing attention-grabbing strategy for pain and its types, teaching positive self-talk, teaching ignoring pain strategy, Training in disaster strategy, and spirituality, and training to increase behavioral activity) were taught in 8 sessions (two sessions per week and each session for 90 minutes) for one month.

Category

Other

3

Description

Control group: The control group received no intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Sabzevar Heshmatieh Hospital

Full name of responsible person

Mohammad Hatami

Street address

No.51, Ibn Yamin, Ibn Yamin Street

City

Sabzevar

Province

Razavi Khorasan

Postal code

9645265

Phone

+98 51 4423 4756

Email

EHSAN.EBRAHIMI58@GMAIL.COM

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mohammad Hatami

Street address

No.51, Ibn Yamin, Ibn Yamin Street

City

Sabzevar

Province

Razavi Khorasan

Postal code

96542236

Phone

+98 51 4423 4756

Email

EHSAN.EBRAHIMI58@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

Ehsan Ebrahimi

Position

Ph.D. student

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

No.51, Ibn Yamin, Ibn Yamin Street

City

Sabzevar

Province

Razavi Khorasan

Postal code

96542263

Phone

+98 51 4423 4756

Email

EHSAN.EBRAHIMI58@GMAIL.COM

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Ehsan Ebrahimi

Position

Psychologist

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

Ibn Yamin St. - Ibn Yamin 51

City

Sabzevar

Province

Razavi Khorasan

Postal code

96542263

Phone

+98 51 4465 1300

Fax

Email

e.ebrahimi@iaukishint.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Ehsan Ebrahimi

Position

Psychologist

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

Ibn Yamin St. - Ibn Yamin 51

City

Sabzevar

Province

Razavi Khorasan

Postal code

96542263

Phone

+98 51 4465 1300

Fax

Email

e.ebrahimi@iaukishint.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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

Title and more details about the data/document

Only part of the data, such as information about the main outcome or the like, can be shared.

When the data will become available and for how long

Start of access period 6 months after printing results

To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

Any type of analysis on the data delivered is permitted

From where data/document is obtainable

Ehsan Ebrahimi

What processes are involved for a request to access data/document

The request will be sent by email to:

e.ebrahimi@iaukishint.ac.ir

Comments