

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

The Effectiveness of a Psycho-education package based on Bioenergy economy with Emphasis on forgiveness on improvement of Quality of Life, and vegetative function of Patients with coronary Heart Disease

Protocol summary

Study aim

Determining the effectiveness of an Audio Psycho-education Package based on Bioenergy economy with Emphasis on forgiveness on improving life quality and vegetative indicators of coronary heart patients

Design

Clinical trial with control group, without blinding, randomized

Settings and conduct

Coronary patients referring Allameh Behlool Hospital in Gonabad were assigned to two control and experimental groups. The experimental group was trained in 8 sessions with audio podcasts. Patients were asked to do the exercises of each session available to them in the Telegram group twice a week and report on it in the next session.

Participants/Inclusion and exclusion criteria

- Having coronary heart disease based on diagnosis of a cardiologist in the hospital file - Having history of hospitalization - Severity of coronary heart disease should be considered according to moderate risk stratification. - All patients take medication. - Be one of the MI patients groups. - Do not be stable - Person's desire to enter research - Lack of chronic diseases and debilitating complications (such as thyroid, kidney, and liver diseases) - Physical ability of individuals to attend and follow the implementation process of the plan - Iranian nationality - Age 20 to 65 - Homogeneity in terms of socio-economics

Intervention groups

The Audio Psycho-education Package performed based on Bioenergy economy with Emphasis on forgiveness and the topics of Tensegrity relaxation, Body Awareness, Attention Work, Narrative Work, Relation Work, Intra-Intermediate Forgiveness, and Transpersonal Forgiveness. (Dr. Goli's protocol, 1398). Each podcast includes lessons, exercises, lesson summaries, and

weekly assignments. There was no specific intervention for the control group, although both groups received routine cardiovascular drugs and routine care.

Main outcome variables

Life Quality, Vegetative function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200401046913N1**

Registration date: **2020-04-09, 1399/01/21**

Registration timing: **retrospective**

Last update: **2020-04-09, 1399/01/21**

Update count: **0**

Registration date

2020-04-09, 1399/01/21

Registrant information

Name

Jahanshir Tavakolizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3884 8529

Email address

drtavakolizadehj@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2019-10-23, 1398/08/01

Actual recruitment start date

2019-10-07, 1398/07/15

Actual recruitment end date

2019-11-06, 1398/08/15

Trial completion date

2020-03-17, 1398/12/27

Scientific title

The Effectiveness of a Psycho-education package based on Bioenergy economy with Emphasis on forgiveness on improvement of Quality of Life, and vegetative function of Patients with coronary Heart Disease

Public title

The Effectiveness of a Psycho-education package based on Bioenergy economy with Emphasis on forgiveness on improvement of Quality of Life, and vegetative function of Patients with coronary Heart Disease

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

- Having coronary heart disease based on the diagnosis of a cardiologist in the hospital file - Having a history of hospitalization - The severity of coronary heart disease should be considered according to moderate risk stratification. - All patients take medication - Be one of the MI patients. - Do not be stable - The person's desire to enter the research - Lack of chronic diseases and debilitating complications (such as thyroid, kidney, and liver diseases) - Physical ability of the person to attend and follow the process of project implementation (age is not too old) - Iranian nationality - Age 20- 65 year - Homogeneity in terms of socio-religious economics

Exclusion criteria:

- Absence of more than 3 sessions in training classes - Migration of the patient or death of the patient during the study - Withdrawal of the person to continue participating in the research

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Actual sample size reached: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

by simple random sampling

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 Isfahan University of Medical Sciences

Street address

School of Medicine,. Gonabad University of Medical Sciences., Dr Mahdizadeh Ave., Asian Road

City

Gonabad

Province

Razavi Khorasan

Postal code

9691793718

Approval date

2019-12-11, 1398/09/20

Ethics committee reference number

IR.MUI.RESEARCH.REC.1398.467

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**

Life quality

Timepoint

Before intervention (pre-test), after intervention (post-test) and follow-up (after one month from the end of the intervention)

Method of measurement

THE WORLD HEALTH ORGANIZATION QUALITY OF LIFE (WHOQOL) -BREF

2**Description**

Vegetative Indicators

Timepoint

Before intervention (pre-test), after intervention (post-test) and follow-up (after one month from the end of the intervention)

Method of measurement

Standard monitoring device

Secondary outcomes

1

Description

Forgiveness

Timepoint

Before intervention (pre-test), after intervention (post-test) and follow-up (after one month from the end of the intervention)

Method of measurement

Forgiveness Questionnaire (Ray and et al)

Intervention groups

1

Description

Intervention group: A group that is under group training with an audio podcast for 8 sessions and routine cardiovascular care and medications.

Category

Treatment - Other

2

Description

Control group: that is only under routine cardiovascular care and medications

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Bohloul Hospital

Full name of responsible person

Shahrzad Mohseni

Street address

Bohloul Hospital., Vahdat Blvd ., Sadi Ave

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dr.tavakolizadeh@gmu.ac.ir

Web page address

<http://bohloul.gmu.ac.ir/Index.aspx?lang=1&sub=0>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Shahla Khosravan

Street address

Vice chancellor for research and technology.,
Gonabad University of Medical Sciences., dr
Mahdizadeh Ave.,Asian road

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sdhprc@gmu.ac.ir

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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

Gonabad 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

Gonabad University of Medical Sciences

Full name of responsible person

Jahanshir Tavakolizadeh

Position

Full Professor

Latest degree

Subspecialist

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

Ph.D.

Other areas of specialty/work

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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

There is no need to publish personal data at the article

Study Protocol

No - There is not 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

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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available