

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Evaluation of the effectiveness of integrated and population-based psycho-spiritual care package on self-efficacy and health-related quality of life in adults with cardiovascular disease

Protocol summary

Study aim

Determining the effect of psycho-spiritual approach in improving self-efficacy and quality of life in people with cardiovascular diseases

Design

Clinical trial, with parallel groups, single-blind, randomized, on 80 patients, will be used for randomization from <https://www.sealedenvelope.com>.

Settings and conduct

This research will be carried out in the clinics of Imam Hossein Hospital in Tehran. Before the implementation of the intervention, self-efficacy and health-related quality of life of the participants will be filled by relevant questionnaires. Then, the intervention will be carried out in the intervention group, and immediately after the end of the intervention, and 2 months after the intervention, the questionnaires will be completed again in both groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Men and women aged 18 to 65 with heart diseases, diagnosed with one or more types of cardiovascular disease by a doctor and at least one year passed since the diagnosis, being interested in participating in the study, not having mental incompetence including any type of mental disorder or cognition that hinders participation in the process of mutual interaction, adherence to the program, or giving informed consent to participate in this study, being able to speak Persian. Exclusion Criteria: Participation in other similar interventions, suffering from other chronic disorders such as diabetes.

Intervention groups

In the control group, routine care will be done. In the intervention group, interventions will be conducted for 6 weeks and 1 session of 90 minutes per week with a psycho-spiritual approach by a psychologist and a psycho-nurse with experience in the field of psycho-

spiritual approach and in a group.

Main outcome variables

Self-efficacy and quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220704055366N1**

Registration date: **2023-03-15, 1401/12/24**

Registration timing: **prospective**

Last update: **2023-03-15, 1401/12/24**

Update count: **0**

Registration date

2023-03-15, 1401/12/24

Registrant information

Name

Mohammadamin Jandaghian Bidgoli

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-21, 1402/02/01

Expected recruitment end date

2023-11-22, 1402/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of integrated and population-based psycho-spiritual care package on self-efficacy and health-related quality of life in adults with cardiovascular disease

Public title

Integrated and population-based psycho-spiritual care package

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Suffering from one of the types of cardiovascular diseases Being able to speak Persian Interest in the participation

Exclusion criteria:

Suffering from psychiatric disorders Participation in other similar interventions

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to select the sample, after preparing a list of cardiovascular patients referring to Imam Hossein hospital clinics, they will be contacted. Then, 80 people who wish to participate in the research will be selected using available sampling and will be included in the study based on the criteria for entering the research. And they will be randomly assigned to two groups of psycho-spiritual approach and control, each of which will have 40 participants. In order to randomize the samples, the block randomization method, which is a limited randomization method related to studies with groups with the same sample size, will be used. Also, in this study, according to the sample size, two blocks of 40 will be considered. In order to implement this method, <https://www.sealedenvelope.com> will be used. And on the mentioned site, the title of the two groups (psycho-spiritual intervention and control), the number of blocks and the volume of each block will be mentioned, which includes two blocks of 40. Then, according to the randomization obtained from the site and the last three numbers of the patients' files, randomization will be done. In this way, in the face of the obtained randomizations, we will write down the last three numbers of the patients' files in order from the least to

the most, and according to that, the patients in each of the control groups and the psycho-spiritual approach will be accepted.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study is a blinded clinical trial. Therefore, blinding will be implemented in the evaluators who will analyze the study data. For this purpose, the questionnaires that will be completed by the researchers in all three groups, in the form of a contract between the researchers. Also, it will be specified with one of the English letters above it, which questionnaire was completed by the participants of which of the study groups; However, the evaluators of the data analysis will not be aware of the English letter of agreement between the researchers assigned to each group.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committees of School of Pharmacy and Nursing & Midwifery- Shahid Beheshti University

Street address

In front of Rajaei Hospital, Valiasr-Niayesh Junction, Vali Asr St. Tehran

City

Tehran

Province

Tehran

Postal code

8741668551

Approval date

2022-08-09, 1401/05/18

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1401.100

Health conditions studied**1****Description of health condition studied**

Cardiovascular diseases

ICD-10 code

R94.3

ICD-10 code description

Abnormal results of cardiovascular function studies

Primary outcomes

1

Description

Quality of life score

Timepoint

Measuring the quality of life score at the beginning of the study, 10 weeks later, 22 weeks later

Method of measurement

The 36-Item Short Form Health Survey (SF-36)

2

Description

Self-efficacy

Timepoint

Measuring the quality of life score at the beginning of the study, 10 weeks later, 22 weeks later

Method of measurement

Sullivan's cardiac self-efficacy scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: the intervention group will be formed in order to create group coordination in a group approved by all members. Group meetings will be held in groups of 40 people. In order to implement the psycho-spiritual approach in the intervention group, 10 sessions of 45-90 minutes will be held every week by a psychologist and a psycho-nurse with experience in the field of psycho-spiritual approach and with the coordination of the patients in a group. Considering that the conditions of cardiovascular patients are special, it is difficult for them to participate in face-to-face classes. Therefore, they may not be able to participate in the class in person. In addition, if they gather in one place for training, some diseases may be transmitted and become a problem. Therefore, according to the mentioned cases, it was preferred that the training be virtual, but nevertheless, a decision will be made according to the conditions of the patients in this field. The spiritual approach is written using the content of the chapter on spiritual methods to relieve the pain of patients from the book of spiritual care. Dr. Mino Asadzandi, a member of the academic faculty of Baqiyatullah University of Medical Sciences and the Medicine and Religion Research Center, will be implemented. Also, the psychological approach will be implemented using the contents of the group psychotherapy book (theoretical and practical basics) by Yalom and Lashech translated by Mahshid Yasai. The first session will be designed for familiarization and introduction, sessions 2 to 4 will be designed for a spiritual approach, and sessions 5 to 10 will be designed for a psychological approach.

Category

Treatment - Other

2

Description

Control group: The control group will receive usual care such as pharmacotherapy.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital

Full name of responsible person

Mohammadamin Jandaghian-Bidgoli

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Shahid Madani St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Hossein Vahidi

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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

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mohammadamin Jandaghian-Bidgoli

Position

Student

Latest degree

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Only part of the data, such as information related to the main outcome and general demographic information, can be shared.

When the data will become available and for how long

The access period starts 3 months after the results are published

To whom data/document is available

Doctors, nurses, midwives, researchers working in universities as well as medical centers and hospitals and clinical psychologists

Under which criteria data/document could be used

In order to use it for scientific purposes and by mentioning the source used and requesting the journal in which the article will be published.

From where data/document is obtainable

Communication via e-mail (if it is possible to share information from a legal and ethical point of view, such as sharing the primary result of the study) to receive information, contact the following e-mail address: Responsible author's e-mail: zare2121@gmail.com. If you need to write a letter, the following postal address of the responsible author is available: College of Nursing and

Midwifery, Nyayesh-Vali Asr junction, Tehran,

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

Finding the email of the responsible author, stating the reason, complying with ethical and legal issues; In this case, a quick response will be given to the requester.

Comments