

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jun 2026

Study of the feasibility and effectiveness of well-being therapy on psychological well-Being, optimism, positive and negative affects and depression in coronary patients

Protocol summary

Study aim

Feasibility trial and study of the effectiveness of well-being therapy on psychological wellbeing, optimism, positive and negative affects and depression in coronary patients

Design

Study design was experimental with pre-test, post-test and follow-up measurements compare with attention control group. From patients referring to Saheb al-Zaman Hospital in Shahreza 40 participants were randomly selected and assigned to the psychological well-being intervention or attention control condition randomly using concealed cards.

Settings and conduct

Psychological well-being is a protective factor for cardiovascular health. This study examined the effectiveness of well-being therapy on psychological variables of cardiac patients. This study was performed on cardiac patients referred to Saheb Al-Zaman Hospital of Shahreza. Measurements were performed at pre-test, post-test and follow-up. The intervention was created based on Ryff psychological well-being (1989). Experimental group received well-being therapy during 8 sessions (90 minutes, for 8 weeks) and attention control group received usual medical education. Participants were blind to grouping and also the study staff were blind until the end of the pre-test measurements. Statistical analysts were also blind to grouping.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Documented diagnosis of coronary artery disease 2- Agreement for participation in study
Exclusion criteria: 1- Receive any other psychological intervention or treatment

Intervention groups

Intervention groups included the experimental group and attention control group. Each group included 20 coronary patients. Experimental group received well-being therapy

during 8 sessions (90 minutes, for 8 weeks) and attention control group received usual medical education.

Main outcome variables

1- Feasibility 2- Psychological well-being

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171010036693N2**

Registration date: **2018-10-07, 1397/07/15**

Registration timing: **retrospective**

Last update: **2018-10-07, 1397/07/15**

Update count: **0**

Registration date

2018-10-07, 1397/07/15

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 913 820 7022

Email address

eshaghi1453@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-08-06, 1396/05/15

Expected recruitment end date

2017-09-06, 1396/06/15

Actual recruitment start date

2017-08-06, 1396/05/15
Actual recruitment end date
2017-09-09, 1396/06/18
Trial completion date
2018-01-08, 1396/10/18

Scientific title
Study of the feasibility and effectiveness of well-being therapy on psychological well-Being, optimism, positive and negative affects and depression in coronary patients

Public title
Study of the effectiveness of well-being therapy on coronary patients

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Documented diagnosis of coronary artery disease
Minimal reading and writing skills Agree to participate in study
Exclusion criteria:
Physical problems or psychological disorders that prevent participation in intervention sessions Receive any other psychological intervention or treatment

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **40**
Actual sample size reached: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Present study was a randomized pilot trial to examine psychological wellbeing intervention among patients with heart disease who were randomly selected from patients referring to Saheb al-Zaman Hospital in Shahreza. Participants were then randomized to the psychological wellbeing intervention or the control condition using concealed cards with group assignment listed that were only accessed by study staff following completion of baseline assessments.

Blinding (investigator's opinion)
Single blinded

Blinding description
Participants were blind about the grouping and assignments. Also group assignment listed were only accessed by study staff following completion of baseline assessments. Statistical analysts were also blind to the groups.

Placebo
Used

Assignment
Factorial

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
islamic azad university khorasgan branch
Street address
University Blvd, Arghavanieh, The East Jey St., Isfahan
City
Isfahan
Province
Isfahan
Postal code
۸۶۱۷۷۴۳۱۱۱

Approval date
2017-12-13, 1396/09/22

Ethics committee reference number
IR.IAU.KHUISF.REC.1397.077

Health conditions studied

1

Description of health condition studied
Cardiac patients with definite diagnosis of coronary artery disease

ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The primary outcome is the psychological well-being and feasibility of the intervention

Timepoint
Measurements were performed at pre-test (Before the intervention), post-test (9 weeks after the intervention) and follow-up (15 weeks after the intervention).

Method of measurement
Instrument included Ryff psychological well-being questionnaire (1993).

Secondary outcomes

1

Description
Depression, Optimism (Life Orientation), and positive and negative affects

Timepoint

Measurements were performed at pre-test (Before the intervention), post-test (9 weeks after the intervention) and follow-up (15 weeks after the intervention).

Method of measurement

Instruments included Beck Depression Inventory (1996), Life Orientation Test (LOT, 1985), and positive and negative affects questionnaire (PANAS 1989).

Intervention groups

1

Description

Intervention group: Intervention group received well-being therapy based on Ryff psychological well-being (2014) during 8 sessions (weekly, 90 minutes, for 8 weeks).

Category

Behavior

2

Description

Control group: Attention control group received usual medical education during 8 sessions (weekly, 90 minutes, for 8 weeks).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Sahib al-Zaman Hospital

Full name of responsible person

Leila Eshaghi

Street address

Sahib Al Zaman Hospital - Sahib Al Zaman St. -
Shahreza city

City

Shahreza

Province

Isfahan

Postal code

۸۶۱۷۷۴۳۱۱۱

Phone

+98 31 5322 3000

Email

eshaghi1453@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mohammad Nurbakhsh

Street address

2nd Kilometer of Mobarakeh Road-Boroujen -

City

Boroujen

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8871898555

Phone

+98 38 3422 3812

Email

info@iauboroujen.ac.ir

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

1

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

Leila Eshaghi

Position

M.A. Student

Latest degree

Master

Other areas of specialty/work

Psychology

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2nd Kilometer of Mobarakeh Road- Boroujen

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Gholam Reza Nikrahan

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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

Yes - There is 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

Yes - There is 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

The total potential data can be shared after being "unidentifiable"

When the data will become available and for how long

Start the access period 6 months after publishing of the results

To whom data/document is available

برای همه قابل دسترس خواهد بود

Under which criteria data/document could be used

شرط خاصی وجود نخواهد داشت

From where data/document is obtainable

لیلا اسحاقی eshaghi1453@gmail.com

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

فرایند خاصی وجود نخواهد داشت صرفاً از طریق ارسال ایمیل پاسخگو خواهیم بود

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Leila Eshaghi

Position

M.A. Student

Latest degree

Master

Other areas of specialty/work

Psychology

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