Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

Isfehan

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
Mohammad Nurbakhsh

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2nd Kilometer of Mobarakeh Road-Boroujen -

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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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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 صرفا از طریق ارسال ایمیل پاسخگو خواهیم بود
Comments