Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

The Efficiency of Cognitive-Behavioral Couple Therapy on Quality of Life, Depression, Anxiety and Stress in Patients with Coronary Artery Bypass

Protocol summary

Study aim

The main purpose of this study is to evaluate the effectiveness of cognitive-behavioral couple therapy on quality of life, depression, anxiety and stress in patients with coronary artery bypass grafting and includes the following sub-objectives: 1. The evaluation of demographic characteristics of patients 2. The Evaluation of patients' psychological characteristics 3. Holding cognitive-behavioral couple therapy sessions for the experimental group 4. Follow up the effect of the interventions on improving the quality of life and reducing depression, anxiety and stress of patients during the study period.

Design

randomized; Controlled clinical trial with a random allocation of 30 patients to the intervention and control groups

Settings and conduct

Training sessions for the experimental group will be held at Shahid Madani Hospital in Tabriz for 10 sessions.

Participants/Inclusion and exclusion criteria

Patients who have undergone coronary artery bypass grafting (CABG) in the past year; more than a year has passed since their marriage. Patients over the age of 65, patients with Infarction, Those who are addicted to alcohol and drugs and those whose heart rate is less than 40% will not be included in the study.

Intervention groups

In this study, there will be two groups: the experimental group and the control group. The experimental group will receive 10 sessions of cognitive-behavioral couple therapy training. The control group will not receive any intervention.

Main outcome variables

This study will help improve the quality of life of patients with coronary artery bypass grafting and reduce their depression, anxiety and stress.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200725048202N1**
Registration date: **2020-10-18, 1399/07/27**
Registration timing: **registered_while_recruiting**

Last update: **2020-10-18, 1399/07/27**
Update count: **0**

Registration date

2020-10-18, 1399/07/27

Registrant information

Name

Maryam Abbaszadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3386 2656

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-18, 1399/07/27

Expected recruitment end date

2020-11-05, 1399/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Efficiency of Cognitive-Behavioral Couple Therapy on Quality of Life, Depression, Anxiety and Stress in Patients with Coronary Artery Bypass

Public title
The Effect of Cognitive-Behavioral Couple Therapy on Patients with Coronary Artery Bypass
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with coronary artery bypass grafting surgery Being married More than a year has passed since their marriage Patients have undergone coronary artery bypass graft surgery in the past year
Exclusion criteria:
Patients over 65 years Depression, anxiety, stress and poor quality of life are caused by illness Patients who do not want to participate in sessions in pairs Patients with myocardial infarction Be addicted to alcohol and drugs Participate in other psychological training sessions in parallel EF (Ejection Fraction) is under 40%
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
From the patients who obtained the desired scores in DASS-21 and SF36 questionnaires, 30 patients were selected by convenience sampling method and randomly assigned to experimental and control groups.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Other
Other design features
In this study, there will be two groups: the experimental group and the control group. The experimental group will receive 10 sessions of cognitive-behavioral couple therapy training. The control group will not receive any intervention.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Azad University, Tabriz branch
Street address
Faculty of Medical Sciences, Islamic Azad University, Tabriz Branch, Next to Kosar Sports Complex, Manzarieh Square, Soleiman Khater Ave.
City
Tabriz
Province
East Azarbaijan
Postal code
5157944533
Approval date
2020-08-18, 1399/05/28
Ethics committee reference number
IR.IAU.TABRIZ.REC.1399.048

Health conditions studied

1

Description of health condition studied
Coronary artery bypass
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Quality of life score in Varosherbon Questionnaire
Timepoint
Measurement of quality of life at the beginning of the study (pre-test), 30 days, 62 days after the intervention (post-test)
Method of measurement
Varosherbon Quality of Life Questionnaire

2

Description
Depression score in Lovibond and Lovibond Scale
Timepoint
Measurement of depression at the beginning of the study (pre-test), 30 days, 62 days after the intervention (post-test)
Method of measurement
Lovibond and Lovibond Depression, Anxiety and Stress Scale

3

Description
Anxiety score in Lovibond and Lovibond Scale
Timepoint
Measurement of anxiety at the beginning of the study (pre-test), 30 days, 62 days after the intervention (post-test)
Method of measurement
Lovibond and Lovibond Depression, Anxiety and Stress Scale

4

Description
Stress score in Lovibond and Lovibond Scale
Timepoint
Measurement of stress at the beginning of the study (pre-test), 30 days, 62 days after the intervention (post-test)
Method of measurement
Lovibond and Lovibond Depression, Anxiety and Stress Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The group will receive 10 sessions of cognitive-behavioral couple therapy training.
Category
Behavior

2

Description
Control group: Members of this group will not receive any training and will only answer the questionnaires at specified intervals (at the beginning of the training sessions for the intervention group, 30 days and 62 days after the start of the training).
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Madani Hospital
Full name of responsible person
Dr. Naser Safaei
Street address
University Ave.
City
Tabriz
Province
East Azarbaijan
Postal code
5165665933
Phone
+98 41 3337 3900
Email
Madanihearthosp@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Dr. Farahvash
Street address
Next to Azadegan Park, Islamic Azad University, Shabestar Branch
City
Shabestar
Province
East Azarbaijan
Postal code
5381637181
Phone
+98 41 4242 5311
Email
info@iaushab.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
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
Maryam Abbaszadeh
Position
Student
Latest degree
Master
Other areas of specialty/work
Psychology
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Person responsible for scientific inquiries

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Person responsible for updating data

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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 more information.
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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The study protocol, statistical analysis, informed consent form and clinical study report will be provided to those who are interested in research in this field. The data should be used with reference to the source and for research purposes.
When the data will become available and for how long
6 months after the publication of the study results, the data will be available.
To whom data/document is available
All researchers interested in working on this study, will have access to this data.
Under which criteria data/document could be used
The data should be used for research purposes only. The study protocol is used unchanged.
From where data/document is obtainable
Requests should be sent to the following email: m.abbaszadeh90@gmail.com
What processes are involved for a request to access data/document
After the requests are submitted and reviewed by the researcher, if the request is approved, the data file will be sent to the applicant about one week to ten days after confirmation.
Comments