

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 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)

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+98 41 3386 2656

Email address

m.abbaszadeh90@gmail.com

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.

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Tabriz

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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

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5381637181

Phone

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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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No. 3, Shahid Yasini Alley, Fallahi Ave., Parvaz Town

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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