# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## Comparison of the Effectiveness of Integrative Behavioral Couple Therapy (IBCT), Narrative Couple Therapy (NCT) and Couple Schema Therapy (ST-C) on Quality of Life, Affective Capital, Depression, Stress, Hope and Marital Intimacy among Coronary Artery Patients & their Spouses

## Protocol summary

**Study aim**
Comparison of the Effectiveness of Integrative Behavioral Couple Therapy , Narrative Couple Therapy and Couple Schema Therapy on Quality of Life, Affective Capital, Depression, Stress, Hope and Marital Intimacy among Coronary Artery Patients & their Spouses

**Design**
The research design is quasi-experimental with pre-test, post-test and follow-up measurements compared to the control group. From patients referred to Isfahan Cardiovascular Rehabilitation Center, 80 people (including their spouses) are randomly selected and randomly assigned to 3 experimental groups and a control group.

**Settings and conduct**
This study compares integrated behavioral couple therapy, couple narrative therapy and couple schema therapy on the psychological variables of coronary artery disease patients and their spouses. The study is performed at the Cardiovascular Rehabilitation Center in Isfahan. Measurements are made in 3 stages: pre-test, post-test and follow-up. Interventions are in 8 90-minute sessions 8 weeks and the control group is without training. Participants are blind to the interventions.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: diagnosis of cardiovascular disease; Age between 25 and 65 years; diploma education at least; Non Inclusion criteria: use of psychiatric drugs; Acute or chronic mental disorders; Use of concomitant psychological therapies

**Intervention groups**
Three experimental groups and one control group The groups included 18 patients with their spouses. Group 1 received integrated behavioral therapy, group 2 received couple narrative therapy, group 3 received couple schema therapy (8 sessions of 90 minutes for 8 weeks), and the control group received no training.

**Main outcome variables**
Quality of Life, Affective Capital, Depression, stress, Hope, Marital Intimacy

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20180428039458N2**
Registration date: **2022-04-04, 1401/01/15**
Registration timing: **registered_while_recruiting**

Last update: **2022-04-04, 1401/01/15**
Update count: **0**

**Registration date**
2022-04-04, 1401/01/15

**Registrant information**

**Name**
Maryam Baghooli Kermani

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2022-03-11, 1400/12/20

**Expected recruitment end date**

2022-05-10, 1401/02/20

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the Effectiveness of Integrative Behavioral Couple Therapy (IBCT), Narrative Couple Therapy (NCT) and Couple Schema Therapy (ST-C) on Quality of Life, Affective Capital, Depression, Stress, Hope and Marital Intimacy among Coronary Artery Patients & their Spouses

**Public title**

Comparison of the Effectiveness of Integrative Behavioral Couple therapy, Narrative Couple therapy and Couple Schema Therapy in Coronary Artery Patients & their Spouses.

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Diagnosis of cardiovascular disease Being in the age range of 25 to 65 years old diploma education at least

**Exclusion criteria:**

Using psychiatric drugs Acute or chronic mental disorders (approved by a clinical psychologist) Using concomitant psychological therapies

**Age**

From **25 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**

Couples (about 80 couples) were purposefully selected based on the inclusion criteria and then selected by simple random method (lottery: according to the sampling framework among the community, a sample of the desired volume was selected from among the listed individuals (based on inclusion criteria) and then by lot (writing names on lottery cards and random selection of names) are divided into four groups (three intervention groups and one control group).

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Participants were blind to grouping and reporting.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Research Ethics Committees of Islamic Azad University - Isfahan (Khorasgan) Branch

**Street address**

Unit 1; Mahestan Building; Motahary Street; Felezi bridge; Isfahan

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Isfehan

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8184854783

**Approval date**

2022-02-22, 1400/12/03

**Ethics committee reference number**

IR.IAU.KHUISF.REC.1400.311

## Health conditions studied

### 1

**Description of health condition studied**

Coronary artery disease

**ICD-10 code**

I25.1

**ICD-10 code description**

Atherosclerotic heart disease of native coronary artery

## Primary outcomes

### 1

**Description**

Depression

**Timepoint**

Measurements will be performed in the pre-test (pre-intervention), post-test (8 weeks after the intervention) and follow-up (16 weeks after the intervention).

**Method of measurement**

Beck Depression Inventory

### 2

**Description**

Quality of life

**Timepoint**

Measurements will be performed in the pre-test (pre-intervention), post-test (8 weeks after the intervention) and follow-up (16 weeks after the intervention).

**Method of measurement**

Ware & Sherbourne Inventory

### 3

**Description**
Affective capital
**Timepoint**
Measurements will be performed in the pre-test (pre-intervention), post-test (8 weeks after the intervention) and follow-up (16 weeks after the intervention
**Method of measurement**
Golpavar Affective capital Inventory

### 4

**Description**
Hope
**Timepoint**
Measurements will be performed in the pre-test (pre-intervention), post-test (8 weeks after the intervention) and follow-up (16 weeks after the intervention
**Method of measurement**
Snyder hope Inventory

### 5

**Description**
Marital intimacy
**Timepoint**
Measurements will be performed in the pre-test (pre-intervention), post-test (8 weeks after the intervention) and follow-up (16 weeks after the intervention
**Method of measurement**
Thompson & Walker Inventory

### 6

**Description**
Stress
**Timepoint**
Measurements will be performed in the pre-test (pre-intervention), post-test (8 weeks after the intervention) and follow-up (16 weeks after the intervention
**Method of measurement**
Leung, Lam & Chan Inventory

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: Integrative behavioral couple therapy: Integrative behavioral couple therapy sessions are in the form of 8 90-minute tissue-based sessions and help couples to increase their satisfaction and adjustment. This approach includes three intervention strategies (empathetic unity, allied neutrality, and tolerance) designed to increase acceptance between couples. These sessions will be based on the integrated behavioral therapy protocol of Christensen and Jacobsen (1998).
**Category**
Behavior

### 2

**Description**
Intervention group: Couple narrative therapy: Couple narrative therapy sessions in the present study in the form of 8 90-minute sessions based on using a set of methods for understanding people's stories, deconstructing and rewriting these stories by the individual and with the help of the therapist . These sessions will be based Friedman and Combs treatment protocol(2008).
**Category**
Behavior

### 3

**Description**
Intervention group: Couple Schema Therapy: Couple schema therapy sessions in the present study in the form of 8 90-minute sessions based on the correction and modification of early maladaptive schemas that play a role in creating and perpetuating couples' communication problems. These sessions will be based on the guidelines of Young (2003) and Simeone-Difrancesco, Roeder, Stevens (2015).
**Category**
Behavior

### 4

**Description**
Control group: The control group (waiting list) does not receive any intervention.
**Category**
Behavior

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Isfahan Cardiovascular Research Center
**Full name of responsible person**
Masoumeh Sadeghi
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Shahid Rahmani Alley, next to Shahid Chamran Heart Center, after the Shahrestan bridge, the third Moshtaq Ave
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
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Payam Najafi
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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**
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
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Maryam Baghooli Kermani
**Position**
PhD-student
**Latest degree**
Master
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Psychology
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## Person responsible for scientific inquiries

**Contact**
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## Person responsible for updating data

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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 data can be potentially shared after making it "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**
It will be accessible for everyone

**Under which criteria data/document could be used**
There will be no specific condition

**From where data/document is obtainable**
Maryam Baghooli Kermani, Email: 6maryam@gmail.com

**What processes are involved for a request to access data/document**
There will not be any specific process, we will be responsive after receiving an email

**Comments**