

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Compare the effectiveness of logotherapy and mindfulness- based stress reduction therapy (MBSR) with routine treatments on Stress, Anxiety, Depression and Quality of life in patients with coronary heart disease

Protocol summary

Study aim

The purpose of study is to compare the efficacy of group logotherapy and mindfulness therapies on stress, anxiety and depression and quality of life in cardiac patients

Design

A clinical trial with a control group, with parallel groups, triple blind and randomized with a sample size of 60 patients. Sixty cardiac patients were randomly assigned to three groups of 20 patients, 2 intervention groups and 1 control group.

Settings and conduct

This study is performed at the heart disease prevention clinic of Afshar Hospital in Yazd and in order to stay blind, the groups refer to the clinic on different days.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Cardiac patients under 75 years of age; minimum literacy; informed consent; PCI treatment; EF> 40. non Inclusion criteria : Having heart valve disease; having arrhythmia; having chronic obstructive pulmonary disease (COPD); having diabetes complications; being on dialysis; seizure; stroke (CVA); being high risk for rehabilitation; having chronic underlying disease

Intervention groups

Intervention group one: Cardiac patients participating in mindfulness therapy group Intervention group two: Cardiac patients participating in the meaningful group therapy. Control group: Cardiac patients receiving routine psychological treatments at the heart rehabilitation center.

Main outcome variables

Depression; Anxiety; Stress; Quality of Life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170522034081N3**

Registration date: **2022-07-01, 1401/04/10**

Registration timing: **retrospective**

Last update: **2022-07-01, 1401/04/10**

Update count: **0**

Registration date

2022-07-01, 1401/04/10

Registrant information

Name

mahdieh ghanbari firoozabadi

Name of organization / entity

Yazd Cardiovascular Research Center, Shahid Sadoughi University of Medical Sciences, Yazd, Iran

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-23, 1397/06/01

Expected recruitment end date

2018-10-22, 1397/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compare the effectiveness of logotherapy and

mindfulness- based stress reduction therapy (MBSR) with routine treatments on Stress, Anxiety, Depression and Quality of life in patients with coronary heart disease

Public title

the effectiveness of logotherapy and mindfulness in patients with coronary heart disease

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age less than 75 years Have the least reading and writing skills Informed consent Type of treatment PCI EF above 40

Exclusion criteria:

Cardiac valve disease Cardiac arrhythmia Chronic obstructive pulmonary disease (COPD) Having diabetes complications Being dialysis convulsion Cerebrovascular accident (CVA) High risk In terms of cardiac rehabilitation Having chronic underlying illnesses Not having Heart failure disease (HF) Not having Implantable Cardioverter Defibrillator (ICD) Lack of pharmacotherapy and non-prescriptive therapies for psychiatric illnesses

Age

To **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization; Individual unit; A computer-generated random sequence number by SAS software; Build sequences based on numbers generated by SAS software and one of the people unrelated to the Research Project

Blinding (investigator's opinion)

Triple blinded

Blinding description

Until the end of the clinical trial; participants, researchers, outcome assessor, statistical analyst, therapists and monitoring committee will not be aware of the allocation.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee Of Shahid Sadoughi University of Medical Sciences

Street address

Shahid Sadoughi Blvd., Bahonar Square

City

Yazd

Province

Yazd

Postal code

8917945556

Approval date

2018-03-14, 1396/12/23

Ethics committee reference number

IR.SSU.REC.1396.213

Health conditions studied**1****Description of health condition studied**

Heart disease

ICD-10 code

I27

ICD-10 code description

Other pulmonary heart diseases

Primary outcomes**1****Description**

Quality of life

Timepoint

Before and after intervention

Method of measurement

Sf-36 Quality of Life Questionnaire

2**Description**

Stress score

Timepoint

Before and after intervention

Method of measurement

SSD Questionnaire

3**Description**

Depression score

Timepoint

Before and after intervention

Method of measurement

Beck Questionnaire depression

4

Description

Anxiety score

Timepoint

Before and after intervention

Method of measurement

Beck Questionnaire anxiety

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: undergoes mindfulness-based stress reduction therapy (MBSR) treatment protocol in 8 sessions of 90 minutes. The content of the sessions is as follows: Session 1: Introducing the participants, giving explanations about anxiety and depression and its effect on heart disease, raisin eating practice, breathing-focused meditation practice, body check exercise. Session 2: Body check exercise, inviting participants to discuss experiences of mindfulness exercises, examining barriers, examining the characteristics of mindfulness such as non-judgment or abandonment, practicing sitting meditation with a focus on breathing. Session 3: Practice seeing or hearing briefly, sitting meditation on concentration and body senses, three-minute breathing space, practicing conscious body movements. Session 4: practicing sitting meditation with a focus on breathing, discussing stress and the individual's usual reactions to difficult situations and alternative attitudes and reactions, conscious walking. Session 5: practicing sitting meditation with a focus on breathing, discussing the acceptance of the reality of the present situation as you are, practicing the second series of conscious body movements. Session 6: Three-minute breathing space, discussing thoughts that are often not real. Session 7: Practicing sitting meditation and open awareness, discussing the best way to take care of yourself, reviewing pleasant versus unpleasant daily activities, and learning to plan for pleasant activities, practicing love and kindness meditation. Session 8: Body checks exercise, review of trainings, evaluation of education, providing more resources.

Category

Behavior

2

Description

Second intervention group: under the group semantic therapy protocol of James C. Cronbach (1973) in 8 sessions of 90 minutes. These goals will be pursued in all sessions: 1. Helping participants to clarify values that are particularly meaningful to them. 2. Set reasonable goals. 3. Ensuring that participants' goals achieve meaningful personal values. 4. Practical planning to achieve goals. 5. Identify the strengths and weaknesses of the participants

that affect the achievement of their goals. 6. Consider strengths and weaknesses in planning to achieve goals that achieve participants' values.

Category

Behavior

3

Description

The control group receives the usual treatments of the Cardiac Rehabilitation Clinic, which is Cognitive-Behavioral Therapy (CBT). Cognitive-behavioral therapy will be in twelve sessions of 90 minutes. The structure of the sessions is such that in the first session, evaluation and diagnostic interview will be performed and the second to twelfth sessions will have the same structure as follows. The structure of the first session of treatment: setting the agenda and talking about its logic, examining the patient's mood, a brief overview of the patient's problems and, if necessary, their brief revision, identifying problems objectively and setting treatment goals, teaching the patient cognitive model, review patient expectations about treatment, patient education about their disorder, assigning homework, session summary, and feedback. The structure of the second session of treatment onwards includes a brief review of the previous week and the patient's mood, bridging the previous session, setting the agenda, reviewing the patient's homework, discussing the topics set in the agenda and assigning homework for next week, summarizing, and Feedback.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd Afshar Hospital

Full name of responsible person

Mozhgan Hemmati

Street address

Cardiac Rehabilitation Center, Afshar Hospital, Jomhuri Boulevard, Yazd, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Doctor Masoud Mirzayea

Street address

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Yazd University of Medical Sciences

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**

Yazd University of Medical Sciences

Full name of responsible person

Mozhgan Hemmati

Position

psychologist

Latest degree

Master

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

Dr.Mohamad Reza Vafaeenasab

Position

Physical medicine and rehabilitation

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

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

Yazd University of Medical Sciences

Full name of responsible person

Hakimeh Dadras

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

-

When the data will become available and for how long

-

To whom data/document is available

-

Under which criteria data/document could be used

-

From where data/document is obtainable

-

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

-

Comments

-