Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Compare the effectiveness of logotherapy and mindfulness- based stress reduction therapy (MBSR) with routtine 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
Iran (Islamic Republic of)

Phone
+98 35 3525 8354

Email address
m.ghanbari@ssu.ac.ir

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 routtine 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 rehabailitation 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 Rhabilitation Center, Afshar Hospital, Jomhouri Boulevard, Yazd, Iran
City
Yazd
Province
Yazd
Postal code
8917945556
Phone
+98 21 3525 8354
Email
Mozhganhemmaty@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Doctor Masoud Mirzayea
Street address
Shahid Sadoughi boulevard, Bahonar square
City
Yazd
Province
Yazd
Postal code
8917945556
Phone
+98 35 3724 0172
Email
Mmirzaei@ssu.ac.ir

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
Street address
Cardiac Rehabilitation Center; Afshar hospital; Jomhouri blvd
City
Yazd
Province
Yazd
Postal code
8917945556
Phone
+98 35 3525 8354
Email
mozhganhemmaty@gmail.com

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
Street address
Cardiac Rehabilitation Center; Afshar hospital; Jomhouri blvd
City
Yazd
Province
Yazd
Postal code
8917945556
Phone
+98 35 3525 8354
Email
rzvafaee@yahoo.com

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
Street address
Cardiac Rehabilitation Center; Afshar hospital; Jomhouri blvd
City
Yazd
Province
Yazd
Postal code
8917945556
Phone
+98 35 3525 8354
Email
Dadras.hakimeh@gmail.com

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

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