Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Randomized controlled trial comparing the effectiveness of Mindfulness based stress reduction and Cognitive behavioral therapy on anger, perceived stress, quality of life and blood pressure in cardiac patients

Protocol summary

Summary

Objectives: This study aimed to compare the effectiveness of Mindfulness based stress reduction (MBSR) and Cognitive behavioral therapy (CBT) on anger, perceived stress, quality of life and blood pressure in cardiovascular patients at Kashan. (2) Design: General plan of this study is consisted of experimental pre-test and post-test with follow-up period. (3) Setting and conduct: Sixty subjects who met the criteria for cardiovascular disease and were able to complete the program were selected by convenient sampling and were randomly assigned in two groups (MBSR and CBT). Participants in two groups filled out Cohen's perceived stress scale, Spielberger's State and Trait Anger Expression Inventory (STAXI-2), and McNew Quality of life questionnaire as pre-test and post- test and two month after intervention. The data were analyzed by SPSS-15 using the Multivariate Analysis of Covariance (MANCOVA). (4) Participants including major eligibility criteria: Inclusion criteria: Cardiac patients with controlled symptoms; Age 35-60 years. Exclusion criteria: A history of substance abuse; Get a history of psychological interventions during the past month. (5) Interventions: The first intervention is consisted of 8 sessions (each session is 120 minutes) of Mindfulness based stress reduction for the first experimental group. The second intervention is consisted of 8 sessions (each session is 120 minutes) of Cognitive behavior therapy for the second experimental group. (6) Main outcome measures: Main outcome measures variables in this research are anger, perceived Stress, quality of life and blood pressure

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015012520794N1**
Registration date: **2015-03-23, 1394/01/03**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-03-23, 1394/01/03

Registrant information

Name

Javad Momeni

Name of organization / entity

Kashan University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Kashan University of Medical Sciences and Health Services

Expected recruitment start date

2015-02-24, 1393/12/05

Expected recruitment end date

2015-03-01, 1393/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Randomized controlled trial comparing the effectiveness of Mindfulness based stress reduction and Cognitive behavioral therapy on anger, perceived stress, quality of life and blood pressure in cardiac patients

Public title
Comparing the effectiveness of Mindfulness based stress reduction and Cognitive behavioral therapy on anger, perceived stress and quality of life and blood pressure in cardiac patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Cardiac patients with controlled symptoms; age 35-60 years; Willing and able to participate in the mindfulness based stress reduction programme and cognitive behavior therapy; Minimum education level diploma. Exclusion criteria: Renal diseases; Active malignant disease such as cancer; History of epilepsy or seizures during the 6 months prior to the first meeting; Pregnancy or lactation period; A history of substance abuse; Get a history of psychological interventions during the past month

Age
From **35 years** old to **60 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kashan University of Medical Sciences and Health Services

Street address
Vice chancellor for research of Kashan University of Medical Sciences and Health Services, Pezeshk Blvd, 5th of Qotbe Ravandi Blvd, Kashan, Iran

City
Kashan

Postal code
8715988141

Approval date
2015-01-07, 1393/10/17

Ethics committee reference number
4912

Health conditions studied

1

Description of health condition studied
Heart Disease

ICD-10 code
I20,I21,I2

ICD-10 code description
For morbidity, duration as used in categories I21, I22,I24 and I25 refer to the interval elapsing between onset of the ischaemic episode and admission to care. For mortality, duration refers to the interval elapsing between onset and death.

2

Description of health condition studied
Anger

ICD-10 code

ICD-10 code description

3

Description of health condition studied
Perceived Stress

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Perceived Stress

Timepoint
before intervention, After intervention, 2 month after intervention

Method of measurement
Perceived Stress Scale by Cohen

2

Description
Anger

Timepoint
Before intervention, After intervention, 2 month after intervention

Method of measurement
Spielberger's State and Trait Anger Expression Inventory (STAXI-2)

3

Description
Quality of Life
Timepoint
Before intervention, After intervention, 2 month after intervention
Method of measurement
McNew Quality of Life Questionnaire

4

Description
Added at 2015-12-25: blood pressure
Timepoint
Added at 2015-12-25: Before intervention, After intervention, 2 month after intervention
Method of measurement
Added at 2015-12-25: measure by blood pressure monitor

Secondary outcomes

empty

Intervention groups

1

Description
Mindfulness Based Stress Reduction; 8 sessions; 2 hours, First intervention group
Category
Behavior

2

Description
Cognitive Behavioral Therapy; 8 sessions; 2 hours; Second intervention group
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr Rayegan Cardiology and Angiology Center
Full name of responsible person
Dr Fariba Rayegan
Street address
Dr Rayegan Cardiology and Angiology Center, Shahid Beheshti St, Kashan, Iran
City
Kashan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research of Kashan University of Medical Sciences and Health Services
Full name of responsible person
Dr Qolam Ali Hamidi
Street address
Vice chancellor for research of Kashan University of Medical Sciences and Health Services, Pezeshk Blvd, 5th of Qotbe Ravandi Blvd, Kashan
City
Kashan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research of Kashan University of Medical Sciences and Health Services
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Kashan University of Medical Sciences and Health Services
Full name of responsible person
Javad Momeni
Position
M.Sc Candidate in Clinical Psychology
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Person responsible for scientific

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty