

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 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)

Phone

+98 31 5554 0021

Email address

javad.momeni@kaums.ac.ir

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

Other areas of specialty/work

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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