

# 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**

##### **Street address**

Department of Clinical Psychology, School of Medicine, Kashan University of Medical Sciences and Health Services, Pezeshk Blvd, 5th of Qotbe Ravandi Blvd, Kashan

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##### **Phone**

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##### **Email**

javad.epost@gmail.com; javad.momeni@kaums.ac.ir

##### **Web page address**

### **Person responsible for scientific**

## **inquiries**

### **Contact**

#### **Name of organization / entity**

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## **Person responsible for updating data**

### **Contact**

#### **Name of organization / entity**

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## **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*