

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison the effectiveness of group mindfulness-based stress reduction and group cognitive-behavioral stress management on biological markers and psychological symptoms in patients with essential hypertension

#### Protocol summary

##### Summary

The purpose of this study is comparison the effectiveness of group mindfulness-based stress reduction and group cognitive-behavioral stress management on biological markers and psychological symptoms in patients with essential hypertension. This research is a randomized, pretest, post-test, with a control group design, in the form of randomized clinical trial. 60 patients with essential blood pressure who are not controlled their blood pressure by medication will allocate randomly to one of the 3 groups: group of mindfulness-based stress reduction (MBSR), group of cognitive-behavioral stress management and control group. 8 weekly sessions (each session 1/5 hours) group intervention based on MBSR for MBSR group and 8 weekly sessions (each session 1/5 hours) group intervention based on cognitive-behavioral stress management for another group will run. Before and after treatment, research variables such as blood pressure, interleukin 6, oxidative stress, quality of life, anxiety and perceived stress will be assessed and evaluated.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017103137145N1**  
Registration date: **2017-11-14, 1396/08/23**  
Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2017-11-14, 1396/08/23

#### Registrant information

##### Name

Farshad Sheybani

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3711 2721

##### Email address

farshad.sheybani@gmail.com

#### Recruitment status

##### Recruitment complete

#### Funding source

This research is related to the PhD dissertation and its funding will be provided by the Iran University of Medical sciences

#### Expected recruitment start date

2017-11-16, 1396/08/25

#### Expected recruitment end date

2017-12-11, 1396/09/20

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparison the effectiveness of group mindfulness-based stress reduction and group cognitive-behavioral stress management on biological markers and psychological symptoms in patients with essential hypertension

#### Public title

Effect of stress reduction on blood pressure

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: Diagnosis of essential hypertension with uncontrolled hypertension despite the treatment according to a cardiologist evaluation; Age between 30 and 60 years; Consent to participate in the research based on the written informed consent form. Exclusion criteria: Secondary blood pressure; Having major depressive disorder; Generalized anxiety disorder; Panic disorder and Post traumatic stress disorder during 1 year ago; Receiving Mindfulness or cognitive-behavioral therapy by a psychologist or psychiatrist in the past.

## Age

From **30 years** old to **60 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Iran University of Medical Sciences

##### Street address

Shahid Hemmat Highway, Tehran.

##### City

Tehran

##### Postal code

1333813444

#### Approval date

2017-06-21, 1396/03/31

#### Ethics committee reference number

IR.IUMS.FMD.REC 1396.9211521215

## Health conditions studied

### 1

#### Description of health condition studied

Essential hypertension

#### ICD-10 code

I10

#### ICD-10 code description

Essential (primary) hypertension

## Primary outcomes

### 1

#### Description

blood pressure

#### Timepoint

before and after of intervention

#### Method of measurement

Home Blood Pressure Monitoring (HBPM)

### 2

#### Description

stress oxidative

#### Timepoint

before and after of intervention

#### Method of measurement

proxidane and antioxidants balance (PAB)

### 3

#### Description

interleukin 6

#### Timepoint

before and after of intervention

#### Method of measurement

ELISA method using the Biovendor Germany IL-6 kit

### 4

#### Description

anxiety

#### Timepoint

before and after of intervention

#### Method of measurement

Beck Anxiety Inventory

### 5

#### Description

quality of life

#### Timepoint

before and after of intervention

#### Method of measurement

The World Health Organization Quality of Life Instrument  
- short form (WHOQOL-BREF)

### 6

#### Description

perceived stress

#### Timepoint

before and after of intervention

**Method of measurement**

perceived stress scale (PSS) cohen

**Secondary outcomes**

empty

**Intervention groups****1****Description**

The MBSR-based group intervention is based on the 8th session of Jon Kabat Zinn's approach, which lasts 1.5 hours each session.

**Category**

Lifestyle

**2****Description**

Cognitive-behavioral stress management group sessions are based on the Cognitive-Behavioral Stress Management Book (Anthony, Ironson, and Schneiderman, 2010). The duration of each session is 1.5 hours.

**Category**

Behavior

**3****Description**

The control group receives standard blood pressure treatment.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Rasoul Akram Hospital

**Full name of responsible person**

Farshad Sheybani

**Street address****City**

Tehran

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Dr Behrooz Birashk

**Street address**

School of Behavioral Sciences and Mental Health,  
Mansouri St, Niyayesh St, Sattarkhan St, Tehran, Iran.

**City**

Tehran

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

Yes

**Title of funding source**

Iran University of Medical Sciences

**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**

Iran University of Medical Sciences

**Full name of responsible person**

Farshad Sheybani

**Position**

Ph.D student in clinical psychology

**Other areas of specialty/work****Street address**

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

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## Person responsible for updating data

### Contact

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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*