# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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
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**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 Organizetion 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**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*