Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 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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Iran (Islamic Republic of)
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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
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Farshad Sheybani
Position
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Person responsible for scientific inquiries

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Other areas of specialty/work

Street address

City

Postal code

Phone

00

Fax

Email

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