

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jul 2026

### The Effect of Mindfulness Meditation, when Compared to routine education on Mental Health in Patients with Hypertension

#### Protocol summary

##### Study aim

Determining the Effect of 8-Week Psychological Therapy as Mindfulness on Mental Health in Patients with Hypertension

##### Design

Clinical trials with control group, with parallel groups, randomized

##### Settings and conduct

The study was conducted in 1398 in Isfahan. The target population of Hypertension referred to the Imam Ali hospital's comprehensive health center (Isfahan).

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Hypertension with the approval of a specialist, The history of regular visits for at list past 6 months, Absence of alcohol and substance abuse, Ability to attend medical sessions, Lack of pregnancy and lactation. Exclusion criteria: Participate in training sessions outside of research project protocol, Acute psychological illness.

##### Intervention groups

A total of 80 people are randomly selected for each group and then the participants are allocated to intervention and control groups. For the intervention group, 8 sessions of 2 hours a week, once a Mindfulness education is conducted by a psychologist with a skill in this field and then they will do homework for 4 weeks, which is reported weekly in the form of a self report.

##### Main outcome variables

The amount of anxiety, depression and stress levels,

treatment such as mindfulness can significantly reduce this problem and its subsequent damage. On the other hand, both hypertension and mental health disorders affect the quality of life of individuals and control of these factors can have an effective role in improving the quality of life. We therefore sought to test the effect of mindfulness on blood pressure and quality of life in patients with hypertension.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190410043230N1**

Registration date: **2019-06-10, 1398/03/20**

Registration timing: **retrospective**

Last update: **2020-01-18, 1398/10/28**

Update count: **1**

##### Registration date

2019-06-10, 1398/03/20

##### Registrant information

###### Name

Shabnam Pournemati

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 3670 1368

###### Email address

sh.pournemati@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-07-23, 1397/05/01

##### Expected recruitment end date

2018-09-23, 1397/07/01

##### Actual recruitment start date

2018-07-23, 1397/05/01

##### Actual recruitment end date

#### General information

##### Reason for update

Hypertension is an important cardiovascular risk factor. Recent meta-analyzes have emphasized the positive effect of mindfulness interventions on hypertension, but further studies are recommended. On the other hand, given the devastating effects of stress and depression on blood pressure, an affordable, reasonable and repeatable

2018-09-23, 1397/07/01  
**Trial completion date**  
 2018-12-22, 1397/10/01

**Scientific title**  
 The Effect of Mindfulness Meditation, when Compared to routine education on Mental Health in Patients with Hypertension

**Public title**  
 The Effect of Mindfulness Meditation, when Compared to routine education on Mental Health in Patients with Hypertension

**Purpose**  
 Supportive

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
 Hypertension with the approval of a specialist The history of regular visits to the center for at list the past 6 months  
 Absence of alcohol and substance abuse Failure to receive psychological treatment in the past year Ability to attend medical sessions Earn a minimum score of 7 from the DASS21 questionnaire before starting the study  
 Lack of pregnancy and lactation  
**Exclusion criteria:**  
 Acute psychological illness Having chronic illnesses, such as cancer or any other serious medical conditions  
 Participate in psychotherapy sessions outside the research project protocol

**Age**  
 From **30 years** old to **59 years** old

**Gender**  
 Both

**Phase**  
 N/A

**Groups that have been masked**  
*No information*

**Sample size**  
 Target sample size: **80**  
 Actual sample size reached: **80**

**Randomization (investigator's opinion)**  
 Randomized

**Randomization description**  
 Randomization method: Randomization block  
 Randomization unit: Individual Randomization layer: Not done Randomization tool: Random sequence generation software (excel) How to creat random sequence: Using random blocks, each block contains 4 people and assign a number from 1 to 6 to each block.

**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

Ethics Committee of Isfahan University of Medical Science

##### Street address

Isfahan University of Medical Science, Hezar Jarib Street, Isfahan, Iran

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174675731

#### Approval date

2018-09-03, 1397/06/12

#### Ethics committee reference number

IR.MUI.MED.REC.1397.015

## Health conditions studied

### 1

#### Description of health condition studied

Hypertension

#### ICD-10 code

I10

#### ICD-10 code description

Essential (primary) hypertension

## Primary outcomes

### 1

#### Description

Anxiety, Depression and Stress

#### Timepoint

Beginning of the study and 13 weeks after the intervention

#### Method of measurement

DASS21 questionnaire

## Secondary outcomes

### 1

#### Description

blood pressure

#### Timepoint

Beginning of the study and 13 weeks after the intervention

#### Method of measurement

In a sitting position from right arm after 15 minutes rest with a standard Mercury barometer. The mean of 2 measures (5 minutes interval) will be considered as blood pressure

## 2

### **Description**

quality of life

### **Timepoint**

Beginning of the study and 13 weeks after the intervention

### **Method of measurement**

short form (SF)-36 QUESTIONNAIRE

## **Intervention groups**

### 1

#### **Description**

Intervention group: 8 weekly 2 hours sessions of Mindfulness training is conducted by a PhD in psychology, And then they will do homework for 4 weeks which is reported weekly in the form of a self report.

#### **Category**

Rehabilitation

### 2

#### **Description**

Control group: There is no treatment on this group.

#### **Category**

Other

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Imam Ali City Comprehensive Health Center

##### **Full name of responsible person**

Dr Anahita Babak

##### **Street address**

W Toosi St, Isfahan, Iran

##### **City**

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##### **Province**

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##### **Postal code**

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##### **Phone**

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babakanahita@yahoo.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

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

Esfahan University of Medical Sciences

##### **Full name of responsible person**

Dr Shaghayegh Haghjoo Javanmard

##### **Street address**

Medical School of Isfahan, Deputy of Research

#### **City**

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#### **Province**

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#### **Email**

sh.haghjoo@med.mui.ac.ir

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

Yes

#### **Title of funding source**

Esfahan University of Medical Sciences

#### **Proportion provided by this source**

100

#### **Public or private sector**

Public

#### **Domestic or foreign origin**

Domestic

#### **Category of foreign source of funding**

*empty*

#### **Country of origin**

#### **Type of organization providing the funding**

Academic

## **Person responsible for general inquiries**

#### **Contact**

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

Esfahan University of Medical Sciences

##### **Full name of responsible person**

Dr Anahita Babak

##### **Position**

Associated Professor

##### **Latest degree**

Ph.D.

##### **Other areas of specialty/work**

Medical Biology

##### **Street address**

Medical University, Hezar Jerib Ave, Isfahan, Iran

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## **Person responsible for scientific inquiries**

#### **Contact**

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

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Associated Professor  
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Specialist  
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## Person responsible for updating data

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

### Title and more details about the data/document

Whole data will be available

### When the data will become available and for how long

Immediately after publishing manuscript

### To whom data/document is available

To whom is in need to this data

### Under which criteria data/document could be used

Email to Dr Anahita Babak, Email:  
babakanahita@yahoo.com

### From where data/document is obtainable

Dr Anahita Babak Email: babakanahita@yahoo.com

### What processes are involved for a request to access data/document

Send an Email to Dr Anahita Babak

### Comments