

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

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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

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W Toosi St, Isfahan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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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

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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