

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### The effect of cognitive behavioral intervention on selfcare behaviors and blood pressure control in patients with primary high blood pressure

#### Protocol summary

Improving self-care behaviors and controlling blood pressure in patients

#### Study aim

Overall objective: To determine the effect of a behavioral cognitive intervention on self-care behaviors and blood pressure control in patients with primary hypertension  
Partial Objectives: 1- Determining and comparing the average score of awareness, self-efficacy, outcome expectations, evaluation of outcome expectations and self-regulation of high blood pressure self-care behaviors in the control and intervention group before and one month after the educational intervention 2- Determining and comparing the average scores of recommended self-care behaviors and its areas (adherence to treatment, nutritional behaviors and blood pressure control) before and one month after the educational intervention between the two groups. 3- Determining and comparing the mean systolic and diastolic blood pressure measured before and one month after the educational intervention between the two groups.

#### Design

A clinical trial with a control group (factorial), one-way blind, randomized (Lottery), on 100 patients.

#### Settings and conduct

The clinical trial study will be conducted with a randomized controlled group on patients over 30 years of age with primary hypertension in Darcheh 1 Health Center in Isfahan with cognitive-behavioral intervention on the test group. The study will be conducted without informing the two groups of assignment to the test or control group and as a blind side

#### Participants/Inclusion and exclusion criteria

1- A person with primary hypertension 2- Age over 30 years old 3- Tendency to participate in research and complete the consent form

#### Intervention groups

The Cognitive Behavioral Educational Intervention Program based on Cognitive Behavioral Theory and Self-Regulation will be held during 6 training sessions for 1 month for test group participants.

#### Main outcome variables

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200621047870N1**

Registration date: **2020-07-04, 1399/04/14**

Registration timing: **retrospective**

Last update: **2020-07-04, 1399/04/14**

Update count: **0**

##### Registration date

2020-07-04, 1399/04/14

##### Registrant information

##### Name

Elham Ebrahimi dorcheh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3375 5127

##### Email address

elhamebrahimi1344@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-09-19, 1398/06/28

##### Expected recruitment end date

2019-10-12, 1398/07/20

##### Actual recruitment start date

2019-10-17, 1398/07/25

##### Actual recruitment end date

2019-12-22, 1398/10/01

**Trial completion date**

2019-12-22, 1398/10/01

**Scientific title**

The effect of cognitive behavioral intervention on self-care behaviors and blood pressure control in patients with primary high blood pressure

**Public title**

Investigating the effect of educational intervention on self-care behaviors and blood pressure control

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

A person with primary hypertension Age over 30 years old

**Exclusion criteria:**

Not wanting to participate in the study and not completing the consent form

**Age**

From **30 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **100**

Actual sample size reached: **84**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Simple random sampling is a lottery. (Writing the names of the patients on the card and placing them in a box and combining and mixing the cards in the box and then randomly selecting them from inside the box.)

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Participants in the study included patients with primary hypertension who will randomly assign to the experimental and control groups by lottery. During the course of research and communication with patients (obtaining consent, completing questionnaires and collecting data before and after the intervention, performing the intervention) no information will be given to the patient about his or her assignment to the test and control group. Also, any connection between the test and control group will be prevented. It is worth mentioning that in order to observe the scientific and moral standards after the intervention, self-care training classes will be held for the control group.

**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 Sciences

**Street address**

Isfahan, Hezar Jarib St., Isfahan University of Medical Sciences

**City**

Esfahan

**Province**

Isfahan

**Postal code**

81746-73461

**Approval date**

2019-09-16, 1398/06/25

**Ethics committee reference number**

IR.MUI.RESEARCH.REC.1398.360

**Health conditions studied****1****Description of health condition studied**

High blood pressure

**ICD-10 code**

I10

**ICD-10 code description**

Essential (primary) hypertension

**Primary outcomes****1****Description**

Blood pressure level

**Timepoint**

Before the educational intervention and one month after the educational intervention

**Method of measurement**

Mercury sphygmomanometer

**Secondary outcomes**

empty

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

Intervention group: In this study, in addition to receiving conventional care for patients with hypertension, the intervention group will participate in cognitive-behavioral training classes based on behavioral cognitive theory

and self-regulation related to blood pressure self-care behaviors. The training program will include 6 sessions, each lasting 2 hours during a month by the researcher. The educational content was determined and adjusted based on the reliable source of the Ministry of Health. The objectives of each session include: the first session : goals setting and planning for action in promoting self-care behaviors. second session : awareness of the disease. fifth session : self-regulation and the promotion of self-care behaviors, and the sixth session will focus on self-assessment and response to self-behavior. The trainings will be held in groups using a combination of teaching methods of lecturing, question and answer, brainstorming, group discussion and role-playing. During training classes, media such as pamphlets, books, posters, videos and educational photos are used to increase learning. Also, the checklist designed by the researcher related to recording self-care behaviors will be completed by the intervention group.

#### Category

Other

## 2

#### Description

Control group: The control group will not receive any training intervention.

#### Category

N/A

## Recruitment centers

## 1

#### Recruitment center

##### Name of recruitment center

Dorcheh Comprehensive Health Center 1

##### Full name of responsible person

Elham ebrahimi dorcheh

##### Street address

Isfahan, Dorcheh, Basij Street

##### City

Esfahan

##### Province

Isfahan

##### Postal code

84316-36631

##### Phone

+98 31 3376 8797

##### Email

elhamebrahimi1344@gmail.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

Isfahan, Shiraz Gate, Hezar Jarib St., Isfahan  
University of Medical Sciences

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174673461

##### Phone

+98 31 3668 0048

##### Fax

+98 31 3668 2006

##### Email

jazb@mui.ac.ir

##### Web page address

http://www.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

Elham ebrahimi dorcheh

##### Position

MSC student

##### Latest degree

Bachelor

##### Other areas of specialty/work

Health Promotion

##### Street address

Isfahan University of Medical Sciences, Hezar Jarib St.

##### City

Esfahan

##### Province

Isfahan

##### Postal code

81746-73461

##### Phone

+98 31 3668 0048

##### Email

elhamebrahimi1344@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Elham Ebrahimi dorcheh

**Position**

MSC student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Health Promotion

**Street address**

Isfahan University of Medical Sciences, Hezar Jarib St.

**City**

Esfahan

**Province**

Isfahan

**Postal code**

81746-73461

**Phone**

+98 31 3668 0048

**Fax****Email**

elhamebrahimi1344@Gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Elham ebrahimi dorcheh

**Position**

MSC student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Health Promotion

**Street address**

Isfahan University of Medical Sciences, Hezar Jarib St.

**City**

Esfahan

**Province**

Isfahan

**Postal code**

81746-73461

**Phone**

+98 31 3668 0048

**Email**

elhamebrahimi1344@gmail.com

## 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**

All potential data can be shared after people have not been identified

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

Start access after printing results

**To whom data/document is available**

All people working in the academic, scientific and industrial sectors are able to receive data

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

1- Using information to conduct scientific and research studies 2- Not changing the information and observing the moral standards

**From where data/document is obtainable**

1- Researchers and authors of research projects 2- Vice Chancellor for Research of the University (Isfahan University of Medical Sciences) \* Communication routes for executives and authors of research projects: 1- Ms. Elham Ebrahimi Dorcheh: Address: No. 26, Safa Alley, Imam St., Dorcheh, Isfahan Contact Number: 09133764592 Email Address: elhamebrahimi1344@gmail.com 2- Dr. Ahmad Ali Eslami Address: Isfahan, Hezar Jarib St., Isfahan University of Medical Sciences, School of Health, Department of Health Education Contact Number: 09124214268 Email Address: eslamiaa@gmail.com

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

After contacting the project executors and reviewing the applicant's scientific and ethical competence, the information will be provided to her as soon as possible.

**Comments**