

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

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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

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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

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