

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

The effect of self-care education on the control of hypertension in patients with hypertension

Protocol summary

Self-efficacy; high blood pressure control

Study aim

The effect of self-care education on the control of hypertension in patients with hypertension

Design

Clinical trials with control group, with parallel and randomized groups

Settings and conduct

Patients with hypertension who referred to Isfahan health center who have hypertension records in the selected health care center were selected by random sampling method. 80 patients were selected. Then, the units were divided into two groups of 40 intervention and control groups, and the intervention group received a basic medical education at Isfahan Health Center No.1.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Satisfaction to participate in the study. Age 30 to 60 years Know about your blood pressure for at least 2 years. Have a case at the health center. Non-Inclusion criteria: Having severe mental illness requiring drug use. Having a debilitating physical disorder.

Intervention groups

After determining the control group and the intervention, self-efficacy education was conducted in 5 sessions of 90 minutes. Trainings were given to the experimental group by a trained health care provider supervised by the researcher. Educational interventions were used for group training, group discussion, and facial education. Training sessions focused on a set of self-efficacy strategies including success in performance, substitution experiences, verbal encouragement, physiological / emotional excitement. The control group did not have any training, but after the completion of the study, a briefing session was considered for the control group. Blood pressure was calibrated before and three months after training with mercuric pressure gauge and proper and standard principles for both groups were performed. Sherr and Cohen questionnaires were completed before and after the intervention by the patients.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171230038142N7**

Registration date: **2019-03-06, 1397/12/15**

Registration timing: **retrospective**

Last update: **2019-03-06, 1397/12/15**

Update count: **0**

Registration date

2019-03-06, 1397/12/15

Registrant information

Name

Khosro Tavakol

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 9134

Email address

tavakol@nm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-07, 1397/07/15

Expected recruitment end date

2018-12-21, 1397/09/30

Actual recruitment start date

2018-10-07, 1397/07/15

Actual recruitment end date

2018-12-30, 1397/10/09

Trial completion date

2019-03-02, 1397/12/11

Scientific title

The effect of self-care education on the control of hypertension in patients with hypertension

Public title

Investigating the effect of self-directed learning on blood pressure control

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Satisfaction to participate in the study Age 30 to 60 years Know about your blood pressure for at least 2 years. Have a case at the health center.

Exclusion criteria:

Having severe mental illness requiring drug use. Having a debilitating physical disorder.

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

2-3

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

Sampling method was multi-stage. So, in the first stage, a network was selected randomly from the health networks of the cities of Isfahan province by drawing lots. In the second step, a checklist was selected from the total number of health centers in the city. Again, completely randomized and 50% of the centers were selected using the lottery method. In the last stage, according to the sample size and case records, 80 patients in the center of the file were extracted and randomly divided into two groups of control and intervention. Individuals' selection and random allocation of subjects were divided into intervention and control groups using SPSS software.

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 Sciences

Street address

Hezar Jarib Ave., Isfahan University of Medical Sciences.

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Approval date

2018-10-03, 1397/07/11

Ethics committee reference number

IR.MUI.MED.REC.1397.056

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

self-efficacy

Timepoint

Before and three months after the last day of the intervention sessions

Method of measurement

The Sherer general self-efficacy questionnaire, which has 17 terms, is based on the 5-degree Likert scale (I completely disagree = 1, I totally agree = 5). The highest score of the questionnaire is 85 and the lowest score is 17.

2

Description

Perceived Stress

Timepoint

Before and three months after the last day of the intervention sessions

Method of measurement

Cohen's Perceived Stress Questionnaire, which has 14 questions in the 5-degree Likert scale (none = 5 to very much = 1), questions 4, 5, 6, 7, 8, 9, 10, 13 are scored in reverse order. .

3

Description

blood pressure

Timepoint

Before and three months after the last day of the intervention sessions

Method of measurement

The mercuric pressure gauge is calibrated and adhered to the correct principles and standard blood pressure measurement.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group had self-efficacy training in 5 sessions of 90 minutes. The training was given to the intervention group by a trained health care provider supervised by the researcher. Educational interventions were used for group training, group discussion, and facial education. Training sessions focused on a set of self-efficacy strategies including success in performance, substitution experiences, verbal encouragement, physiological / emotional excitement. Blood pressure was calibrated before the training and three months after training, and the mercury pressure gauge was calibrated and strict and standard principles were followed. Sherr and Cohen questionnaires were completed before and after the intervention by the patients.

Category

Treatment - Other

2

Description

Control group: No specific training. Just because of ethics and fairness, the researcher held a training session for the control group upon completion of the study. Blood pressure was calibrated before the training and three months after training, and the mercury pressure gauge was calibrated and strict and standard principles were followed. Sherr and Cohen questionnaires were completed with the intervention group before and after the intervention by the patients.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Province Health Centers.

Full name of responsible person

Reza Roozbehani

Street address

Hezar Jarib Ave. Isfahan University of Medical Sciences

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Ziba Farajzadegan

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Vice-Chancellor for Research of School of Medicine,. Isfahan University of Medical Sciences,. Hezar Jarib Ave.

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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

Reza Roozbehani
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Public Health/Community Medicine
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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

The whole information is unpublished after being unrecognizable and publishing the results.

When the data will become available and for how long

Information is available two years after the publication of the article.

To whom data/document is available

Assistants and specialists in social medicine, psychology and psychiatry

Under which criteria data/document could be used

To compare the information and the results with another similar study in another city or city of Isfahan.

From where data/document is obtainable

Deputy of Research and Student Deputy of Isfahan University of Medical Sciences

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

Send an e-mail to rerouzbah@gmail.com and get permission from the Research Vice-Dean and Student Deputy of Isfahan University of Medical Sciences.

Comments