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

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
Self-efficacy; high blood pressure control

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
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Iran (Islamic Republic of)
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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
Isfehan

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
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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