

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Effectiveness of an educational intervention (the Encourage Autonomous Self-Enrichment Program) on self- management in Patients with high blood pressure referred to Farshchian cardiac outpatient in Hamadan 2018.

Protocol summary

Study aim

The effect of Encourage Autonomous Self-Enrichment on self- management in Patients with high blood pressure referred to Farshchian cardiac outpatient in Hamadan

Design

simple randomized, controlled clinical trial with a parallel group design of 75 patients

Settings and conduct

This study is a six-stage educational process that is performed for hypertensive patients in both male and female gender in Farshchian heart clinic.

Participants/Inclusion and exclusion criteria

Patients have the ability to read and write At least 6 months have been diagnosed with early onset and ongoing treatment They are being treated for high blood pressure Failure to participate in a co-effective study on study variables Having the right physical conditions to attend training sessions Ability to answer the phone Suffering Primary blood pressure Being Healthy Psychological Did not have history of CVA and MI Not having chronic diseases affecting quality of life All patients are under the supervision of a doctor

Intervention groups

This is an experimental clinical trial on 70 patients were recruited from Farshchian health center affiliated to Hamadan University of Medical Sciences which have been sampled simply and randomized divided in to experimental and control groups. The control group received only routine visits, while experimental group receive EASE program. then encouraged to accomplish self management program and followed up by telephone and meeting during 12 weeks. At the end of twelfth week, blood pressure measured in experimental and control groups. questionnaire related to self management at experimental and control group are completed and be compared.

Main outcome variables

The patient independently manage their illness and needs and improve their quality of life.

General information

Reason for update

Acronym

EASE

IRCT registration information

IRCT registration number: **IRCT20170123032129N6**

Registration date: **2018-10-20, 1397/07/28**

Registration timing: **prospective**

Last update: **2018-10-20, 1397/07/28**

Update count: **0**

Registration date

2018-10-20, 1397/07/28

Registrant information

Name

Azim Azizi

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 0150

Email address

a.azizi@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-23, 1397/08/01

Expected recruitment end date

2019-01-31, 1397/11/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of an educational intervention (the Encourage Autonomous Self-Enrichment Program) on self- management in Patients with high blood pressure referred to Farshchian cardiac outpatient in Hamadan 2018.

Public title

Effectiveness of an educational intervention (the Encourage Autonomous Self-Enrichment Program) on self- management in Patients with high blood pressure

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients have the ability to read and write At least 6 months have been diagnosed with early onset and ongoing treatment They are being treated for high blood pressure Failure to participate in a co-effective study on study variables Having the right physical conditions to attend training sessions Ability to answer the phone Suffering Primary blood pressure Being Healthy Psychological Did not have history of CVA and MI Not having chronic diseases affecting quality of life All patients are under the supervision of a doctor

Exclusion criteria:

Get extensive information about managing blood pressure from other sources or changing the treatment protocol Significant acute abnormalities and severe blood pressure or crisis Patient death

Age

From **40 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

After referring to the outpatient heart clinic for patients with hypertension and introducing them to the authorities, the samples will be selected first. having criteria for entering the study will be reviewed. then 35 cards with A letters and 35 cards with B letter will be placed inside sealed envelopes and each patient will select one of these cards randomly without placement, and if you select the letter A, will be In the test group and if the card is selected B, they will be in the control group.

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 Hamadan University of Medical Sciences

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Av, Hamadan, Iran.

City

Hamedan

Province

Hamadan

Postal code

65178

Approval date

2018-09-26, 1397/07/04

Ethics committee reference number

IR.UMSHA.REC.1397.405

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

Primary blood pressure

ICD-10 code

I10

ICD-10 code description

Essential (primary) hypertension

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

Blood pressure

Timepoint

All variables at baseline and at the end of 3 months are evaluated

Method of measurement

Manometer

2**Description**

BMI

Timepoint

All variables at baseline and at the end of 3 months are evaluated

Method of measurement

Calibrated scale and meter

3**Description**

Nutritional status

Timepoint

All variables at baseline and at the end of 3 months are evaluated

Method of measurement

Questionnaire

4**Description**

Physical activity

Timepoint

All variables at baseline and then at the end of 3 months are evaluated

Method of measurement

Questionnaire

5**Description**

paraclinic (Blood)tests: TG, cholestrol, Na of urine(24 hours)

Timepoint

At baseline and at the end of 3 months are evaluated

Method of measurement

Labratory kits

Secondary outcomes**1****Description**

Self-management behaviors

Timepoint

At the beginning of the study and 3 months after the study

Method of measurement

Likert questionnaire

2**Description**

Self-care behaviors

Timepoint

At the beginning of the study and 3 months after the study

Method of measurement

Likert questionnaire

3**Description**

Self-regulation behaviors

Timepoint

At the beginning of the study and 3 months after the study

Method of measurement

Likert questionnaire

4**Description**

Self-monitoring behaviors

Timepoint

At the beginning of the study and 3 months after the study

Method of measurement

Likert questionnaire

5**Description**

Response to the disease

Timepoint

At the beginning of the study and 3 months after the study

Method of measurement

Likert questionnaire

6**Description**

Training EASE program

Timepoint

During the 3 months of intervention

Method of measurement

Not

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

Intervention group: After registration of patients who want to participate in research projects. The goals and the process of research will be explained to them. Patient's informed consent will be filled out. If they have inclusion criteria, they participate in the study. demographic information will be taken. This study was designed as a simple randomized controlled etrial with one-to-one allocation into two groups. The intervention group participated in the EASE program will be 35 and control group too.The EASE program in six steps is as follows for the intervention group: During step 1 of this program, information about the participant's demographic characteristics, treatment plan, and examination data was gathered. The appropriateness of each patient's medical care was confirmed, and participants were evaluated to ensure their psychological and physical preparedness. Client-professional relationship a major influence on healthcare behaviors (Interaction model) (First session). In Step 2, nurses encouraged participants to independently clarify issues related to their lifestyle and determine the self-management techniques needed for a healthier lifestyle (Express the positive and negative issues of lifestyle in relation to blood pressure), and Self-management

approaches to improve healthy lifestyles (The factors and behaviors that reduce the blood pressure and its complications will be named and appropriate answers will be encouraged) (Promotion model, Self efficacy) (second session). In Step 3, participants were involved in the setting of specific goals to foster self-efficacy and received support for their autonomous achievement of these goals, as enhanced self-efficacy is thought to lead to behavioral changes (Self efficacy, Promotion model) (second session). In step 4, techniques for achieving these goals were selected. In this study, self-monitoring was used to monitor the participants' actions and emotions toward their goals. The participants used self-monitoring techniques that involved monitoring of their actions and related benefits, which were logged using monitoring notes. Other techniques were added according to the participant's condition; these included behavioral reinforcement and incremental goal achievement (action goals were set using small steps that initiated from achievable goals). Encouraging achievements, planning minor goals for achieving success and gaining positive experiences, encouraging verbal and nonverbal ways to increase repetition of behavior, creating optimism and hope for breakthroughs that will all enhance patient self-efficacy (Promotion model, Self efficacy) (The third and fourth sessions). For Step 5, the nurses supported the participants' achievements of their action goals through interviews (fifth meeting) and phone or e-mail communication that patients will be contacted for 3-5 weeks every three days every 10 to 10 minutes, and guidance and encouragement will be used to strengthen positive behaviors and will support the achievements of the participants in achieving the desired goals (Promotion model, Self efficacy). For step 6: Achieving the desired goals will be evaluated. After eight weeks from the completion of the study, the variables will be re-evaluated as self-report at the clinic's meeting for re-examination (sixth session).

Category

Behavior

2

Description

35 patients will be in control group. The control group won't participate in education sessions. The control group will receive routine education based on health centers program according to national protocols. At the first, control group will receive self-management, and self-monitoring of blood pressure questionnaires. Blood tests, Body Mass Index, blood pressure, will be measured too. After 3 months, the questionnaires, Clinical blood tests and BMI, blood pressure will be done again.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Farshchian Heart Hospital

Full name of responsible person

Laleh Almasi

Street address

Farshchian Cardiology and Cardiology Center, Shahid Fahmida Blvd, Hamedan

City

Hamadan

Province

Hamadan

Postal code

65178

Phone

+98 81 3838 1740

Fax

+98 81 3838 1686

Email

hcvc@umsha.ac.ir

Web page address

http://hcvc.umsha.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Saeed Bashirian

Street address

Hamadan University of Medical Science, Shahid Fahmide boulevard

City

Hamadan

Province

Hamadan

Postal code

65178

Phone

+98 81 3838 0150

Email

l.almasi@umsha.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

عظیم عزیزی

Position

PhD in Nursing

Latest degree

Ph.D.

Other areas of specialty/work

Medical Education

Street address

Hamadan University of Medical Science, Shahid
Fahmide boulevard

City

Hamadan

Province

Hamadan

Postal code

00988138380150

Phone

+98 81 3838 0150

Email

a.azizi@umsh.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Azim Azizi

Position

موقعیت شغلی PhD in nursing

Latest degree

Ph.D.

Other areas of specialty/work

Medical Education

Street address

Hamadan University of Medical Science,
Shahid Fahmide boulevard

City

Hamadan

Province

Hamadan

Postal code

00988138380150

Phone

+98 81 3838 0150

Email

a.azizi@umsh.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Azim Azizi

Position

PhD in nursing

Latest degree

Ph.D.

Other areas of specialty/work

Medical Education

Street address

Hamadan University of Medical Science, Shahid
Fahmide boulevard

City

Hamadan

Province

Hamadan

Postal code

00988138380150

Phone

+98 81 3838 0150

Fax**Email**

a.azizi@umsh.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available