Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 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

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Iran (Islamic Republic of)

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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.
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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
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

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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