Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effect of self-care behavior training based on the 5A model on health self-care behaviors to control blood pressure in the elderly

Protocol summary

Study aim

Determining the effect of teaching self-care behaviors based on the behavior change model (5A) on health self-care behaviors to control blood pressure in the elderly

Design

Clinical trial, with simple randomization, without blinding, on 90 patients

Settings and conduct

This clinical trial study will be conducted on 90 elderly people over 60 years of age with high blood pressure who referred to the Babol University of Medical Sciences hospital clinic in 1402. The elderly will be randomly divided into two test groups (45 people) and control (45 people). Model 5A self-management program includes group training and individual guidance. The elderly will be followed up by phone calls within 12 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Over 60 years old, Suffering from high blood pressure diagnosed by a doctor, With the possibility of access and follow-up by phone Exclusion criteria: Absence of malignant diseases, insufficiency and neurological diseases based on the medical history entered in the medical record.

Intervention groups

Referees are divided into two groups of 45 people, test and control. The control group will receive common treatments or the use of common drugs. In addition to common treatments, the test group will also receive training on self-care behaviors based on the 5A model. The self-management program will be implemented for each patient in the test group in 5 stages during 12 weeks.

Main outcome variables

Behavioral change leading to blood pressure control

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230812059127N1**
Registration date: **2023-11-01, 1402/08/10**
Registration timing: **retrospective**

Last update: **2023-11-01, 1402/08/10**
Update count: **0**

Registration date

2023-11-01, 1402/08/10

Registrant information

Name

Seyedeh Sadaf Bozorgnia Hosseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3536 4129

Email address

s.bozorgnia.h@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-07, 1402/07/15

Expected recruitment end date

2023-10-12, 1402/07/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Investigating the effect of self-care behavior training based on the 5A model on health self-care behaviors to control blood pressure in the elderly

Public title
Investigating the effect of self-care training on behavior change in blood pressure control
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Age over 60 years Diagnosis of hypertension for at least one year based on medical records Having hypertension diagnosed by a doctor Speak in persian With the possibility of access and follow-up by phone
Exclusion criteria:
Suffering from malignant diseases based on the medical history entered in the medical record Suffering from heart failure based on the medical history entered in the medical record Suffering from kidney failure based on the medical history recorded in the medical record Suffering from hyperthyroidism based on the medical history recorded in the medical record Suffering from depression and neurological diseases based on the medical history entered in the medical record
Age
From **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
90 people who have been diagnosed with high blood pressure by a doctor and who meet the criteria for entering the study are selected easily from among those who refer to the hospital clinic of Babol University of Medical Sciences. After that, they will be randomly divided into 2 intervention and control groups. For this purpose, the cards with the test and control written on them are put in a box and each of the samples is asked to choose a card randomly, after that people with test cards in the test group and people who have a control card, are placed in the control group.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of North Khorasan University of Medical Sciences
Street address
Dolat Blvd., Central Building of North Khorasan University of Medical Sciences, Bojnourd
City
Bojnourd
Province
North Khorasan
Postal code
9414974877
Approval date
2023-08-12, 1402/05/21
Ethics committee reference number
IR.NKUMS.REC.1402.065

Health conditions studied

1

Description of health condition studied
hypertension
ICD-10 code
I10
ICD-10 code description
Essential (primary) hypertension

Primary outcomes

1

Description
Behavior change
Timepoint
The Hypertension-Self-care Activity Level Effects questionnaire will be completed once at the beginning of the research and again after 12 weeks for both groups (test and control).
Method of measurement
Hypertension-Self-care Activity Level Effects questionnaire

Secondary outcomes

1

Description
Hypertension
Timepoint
The systolic and diastolic blood pressure of the client is measured and recorded by the research assistant in two stages, the first week and the twelfth week respectively.
Method of measurement
Mercury sphygmomanometer

Intervention groups

1

Description
Control group: Referees are divided into two groups of 45 people, test and control. The first group will receive common treatments or the use of common drugs.
Category
Behavior

2

Description
Intervention group: In addition to common treatments, the second group will also receive training on self-care behaviors based on the A5 model.The self-management program will be implemented for each patient in the test group in 5 stages during 12 weeks. In the first week of the research, the first, second and third stages will be implemented in the following order:First step: Examining the awareness, behaviors and beliefs of the patientStep 2: Counseling the patient about the health risks and benefits of behavior changeThe third step: agreement with the patient in the field of setting realistic goals(The first three stages will be done during a 2-hour session in one day)Step 4: Helping to develop a practical plan (with a family member)A 2-hour group training session will be held one week after individual guidance to increase the patient's awareness of their disease.Fifth step: follow upThen the performance of the patients will be followed for 12 weeks. In order to ensure the implementation of the practical plans by the patients in the first 2 weeks, phone calls will be made three times a week and after that weekly phone calls will be made with the patients to remind them to complete the practical plans. In addition, the progress of the patient will be followed up once every 4 weeks during a face-to-face meeting. In this meeting, the agreed program and the patient's self-report book will be reviewed so that essential changes can be made if needed.After the end of 12 weeks, the aforementioned questionnaires will be provided to the patients of both groups and they will be examined in terms of the studied variables.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Hospital Clinic of Babol University of Medical Sciences
Full name of responsible person
Seyedeh Sadaf Bozorgnia Hosseini
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Sharifi Blvd. 13 Sharifi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bojnourd University of Medical Sciences
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Bahram Bibak
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INFO@NKUMS.AC.IR
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Bojnourd 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
Bojnourd University of Medical Sciences
Full name of responsible person
Seyedeh Sadaf Bozorgnia Hosseini
Position
Masters student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available