

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 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 patient Step 2: Counseling the patient about the health risks and benefits of behavior change The 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 up Then 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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bojnourd University of Medical Sciences

Full name of responsible person

Bahram Bibak

Street address

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North Khorasan

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+98 58 3151 0000

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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 scientific inquiries

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Person responsible for updating data

Contact

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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