

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

The effect of self-care education program on the Adherence to treatment of elderly with hypertension

Protocol summary

Study aim

The effect of self-care education on adherence for hypertensive elderly

Design

parallel clinical trial with two groups

Settings and conduct

Research Environment: The Heart Clinic Sayyad Shirazi Gorgan in Golestan University of Medical Sciences. The research sample included a sample of elderly patients with hypertension referring to the heart clinic of Sayyid Shirazi, Gorgan, during the research period, which will have criteria for entry into the study, by the available sampling method, initially entered into the study. Among those who are subjected to moderate, poor follow-up treatment (subtracting the score from the treatment sub scale of less than 49%), They will be randomly assigned to the intervention and control groups.. In the intervention group, the self-care educational program is provided in group and received routine care in the control group. Before, immediately and two months later, the adherence questionnaire will be completed. And at this time, the patient's blood pressure will also be recorded

Participants/Inclusion and exclusion criteria

Inclusion criteria: age over 60 years, the ability to read and write, consent, having no known disease and mental disorders, Having hypertension and specialist endorsement. Exit criteria: Absence of more than one session in the classroom, death, travel and relocation of the participant during the study, the patient's unwillingness to continue.

Intervention groups

intervention group: In addition to the usual care, the self-care training program (4 consecutive sessions per week for each group, 45 people are divided into five groups of nine, duration of each session is one And for half an hour, the time of the class will be presented at the morning, Immediately and 2 months after education each of the test groups will complete the questioner.

Main outcome variables

Adherence to treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180505039536N1**

Registration date: **2018-10-27, 1397/08/05**

Registration timing: **registered_while_recruiting**

Last update: **2018-10-27, 1397/08/05**

Update count: **0**

Registration date

2018-10-27, 1397/08/05

Registrant information

Name

Zahra Sabzi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3243 0310

Email address

dr.sabzi@goums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-01-21, 1397/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of self-care education program on the Adherence to treatment of elderly with hypertension

Public title

The effect of self-care education program on the Adherence to treatment of elderly with hypertension

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Compliance score of moderate and lesser treatment based on Mandealou's treatment compliance questionnaire

Exclusion criteria:

elderly with hypertension

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will randomly assigned to control and intervention groups based on the permutation blocks method. Six possible modes (AABB, ABAB,..) are listed and randomly determine the number of blocks required and the subjects will be placed on the test group (B) and control (A) respectively.

Blinding (investigator's opinion)

Single blinded

Blinding description

The outcome evaluator Data analysis is done by Anonymous to research

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Golestan University of Medical Sciences

Street address

Golestan University of Medical Sciences, Golestan, Gorgan, Iran

City

Gorgan

Province

Golestan

Postal code

49165-568

Approval date

2018-09-16, 1397/06/25

Ethics committee reference number

IR.GOUMS.REC.1397.109

Health conditions studied

1

Description of health condition studied

hypertension

ICD-10 code

I11

ICD-10 code description

Hypertensive heart disease

Primary outcomes

1

Description

adherence to treatment

Timepoint

Before, immediately and 2 months later

Method of measurement

Questionnaire scores of adherence to treatment

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Elderly people with hypertension have criteria to enter the study. In addition to routine care, an intervention will be performed on self-care program for hypertension for two weeks (two sessions per week and group) and "each group of 10" and each session will be given an hour. The training program will also be provided in writing to Pamphlet

Category

Behavior

2

Description

Control group: Elderly patients with hypertension who have been include criteria and receive routine care

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Sayad Shirazi Hospital, Golestan University of Medical Sciences, Gorgan, Iran

Full name of responsible person

Zahra Sabzi

Street address

Golestan University of Medical Sciences, Gorgan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Honarvar

Street address

Deputy of Research and Technology, Golestan University of Medical Sciences, Gorgan, Iran

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Web page address

http://goums.ac.ir/index.php?slc_lang=fa&sid=12

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Gorgan 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**

Gorgan University of Medical Sciences

Full name of responsible person

Zahra Sabzi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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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 more information.

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

All data will be shared after unidentifiable people.

When the data will become available and for how long

Data will be available for scholars working in academic and academic institutions.

To whom data/document is available

Meta-analysis is allowed on data

Under which criteria data/document could be used

Please contact the person responsible for the scientific data

From where data/document is obtainable

Access to data through email and after obtaining permission from researchers is possible

What processes are involved for a request to access data/document

For more information, please, check e-mail.

dr.sabzi@goums.ac.ir

Comments

Email the following email address zsgorgan@yahoo.com
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