Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of education based on empowerment model on adherence to hypertension treatment in the elderly

Protocol summary

Study aim
Determining the effect of education based on empowerment model on adherence to hypertension treatment in the elderly with hypertension in comprehensive health centers in Gorgan

Design
A clinical trial with the control group, randomized, second phase on 56 elderly people with hypertension. The rand function of Excel software will be used for randomization.

Settings and conduct
From among the comprehensive health centers of Gorgan city, 4 attached urban bases are selected as sample selection centers for the intervention and 4 attached urban bases are selected as sample selection centers for the control group by simple random sampling (with placement). Having the contact numbers of elderly with hypertension in the Nab system, they will be contacted and invited to visit the health centers submitted by the service. In the training class of the health center, we will provide them with a treatment compliance questionnaire. We will include 56 people who scored 0-49% of the questionnaire in a simple random manner.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Literacy for reading and writing, Having hypertension, Obtaining (0 to 49%) of the MATQ Chronic Disease Compliance Questionnaire, Being over 60 years old, Not having mental disorders such as dementia based on self-report Exclusion criteria: Unavailability or lack of follow-up, Death or migration

Intervention groups
The people of the intervention group are divided in to 4 groups of 7 people. They will participate in training classes during one month in 5 sessions based on the use of the empowerment model which includes 4 Pattern : perceived threat, self-efficacy, educational participation and evaluation. Then, 3 months after the intervention, the questionnaire will be provided to them.

Main outcome variables
Educational intervention, Score from the questionnaire, Age

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220531055040N1**
Registration date: **2022-07-10, 1401/04/19**
Registration timing: **prospective**

Last update: **2022-07-10, 1401/04/19**
Update count: **0**

Registration date
2022-07-10, 1401/04/19

Registrant information

Name
najme imanzadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 17 3324 9837

Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-07-31, 1401/05/09

Expected recruitment end date
2022-08-31, 1401/06/09

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of education based on empowerment model on adherence to hypertension treatment in the elderly

Public title

The effect of education based on empowerment model on adherence to hypertension treatment in the elderly

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Literacy for reading and writing Ability to communicate visually and verbally Having a systolic blood pressure greater than or equal to 140 or a diastolic blood pressure greater than or equal to 90 Obtaining low and medium scores (0 to 49%) of the MATQ Chronic Disease Compliance Questionnaire Being over 60 years old Not having mental disorders such as dementia based on self-report

Exclusion criteria:

Age less than 60 years Inability to communicate verbally in Persian language

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

First, out of 19 urban bases, 8 bases are selected randomly, then again by simple random sampling (by placement), 4 centers are selected as sample selection centers for intervention and 4 centers are selected as sample selection centers for the control group. Using the pure system and from the list of patients with high blood pressure in the second six months of the year randomly available based on the number of people on the list who met the inclusion criteria, we will give a questionnaire of compliance with treatment and people who score percentage They got 0 to 49 percent. For example, in the intervention and control group, we will enter the study, so that 7 people from each center will enter the study and 56 people will be studied.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Factorial

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,The beginning of Shast Kola Road, Gorgan

City

Gorgan

Province

Golestan

Postal code

4994174515

Approval date

2022-05-29, 1401/03/08

Ethics committee reference number

IR.GOUMS.REC.1401.067

Health conditions studied

1

Description of health condition studied

Hypertensive heart disease

ICD-10 code

I11

ICD-10 code description

Hypertensive heart disease

Primary outcomes

1

Description

Score of treatment adherence questionnaire

Timepoint

Before intervention, three months after intervention

Method of measurement

Questionnaire of adherence to the treatment of chronic diseases

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The empowerment program for patients with hypertension will be based on the model constructs as follows: At this stage, empowerment strategies such as peer support will be used to promote

patients' self-care behaviors. Training in the peer group will be done in groups of 7 people. For this reason, according to the number of samples in the intervention group (28 people) and the need to group them, patients are divided into 4 groups of 7 people. The duration of each session was about 40-60 minutes. For each subgroup, up to 5 empowerment sessions according to weekly and regular needs, with training by the researcher in health center training classes based on the empowerment model and sitting in a circle around the class. Will be held. If any of the elderly can not attend one day of the week assigned to them, they can participate with another group on another day of the week. Control group: They will continue the current training of the center according to the previous procedure and will complete the questionnaires separately without contacting the intervention group. It is necessary to explain that the common examination in the health center covered by the elderly will include nutritional matters and regular visits to the doctor in terms of progress and blood pressure control.

Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Integrated health centers in Gorgan

Full name of responsible person
Safura Ghaneh

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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
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
Ghanbar Rohi

Position
Associate Professor

Latest degree
Ph.D.

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)
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