

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 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)

##### Phone

+98 17 3324 9837

##### Email address

najmeimanzadeh@gmail.com

##### 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

**Street address**

Golestan University of Medical Sciences, At the beginning of Shast Kola Road, Gorgan

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Gorgan University of Medical Sciences

**Full name of responsible person**

Dr mohammadreza Honarvar

**Street address**

Golestan University of Medical Sciences, The beginning of Gorgan-Kordkoy road, Shast Kola road, Gorgan

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honarvar@goums.ac.ir

**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 scientific inquiries****Contact****Name of organization / entity**

Gorgan University of Medical Sciences

**Full name of responsible person**

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**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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**Person responsible for updating data****Contact****Name of organization / entity**

Gorgan University of Medical Sciences

**Full name of responsible person**

Najme Imanzadeh

**Position**

Master student of geriatric nursing

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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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