

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of patient education based on Health Literacy INDEX on medication adherence and hypertension management in elderly patients with primary hypertension

#### Protocol summary

##### Study aim

Determining the effect of Educational Package with the help of the Health Literacy Index (INDEX) on medication adherence and hypertension management in elderly patients with primary hypertension

##### Design

In this research, 120 eligible elderly referring to Cardiovascular clinic were chosen purposefully. Then, patients were randomly divided into two control and intervention groups.

##### Settings and conduct

Among all elderly with hypertension who referred to the Cardiology Clinic of Shaheed Fayyaz Bakhsh Hospital, who have criteria for entering the study, 120 elderly are selected and the study process is briefly explained to them. Then, if the elderly desire, they will receive written informed consent and all elderly people will be asked to complete the demographic profile, health literacy and medication adherence questionnaire. Then all samples will be randomly assigned in two groups of intervention and control. Control group received the usual services from the clinic and the intervention group was divided into small groups (to save time and affordability) and during two sessions attending the clinic in the first and second weeks and four telephone conversations in the third and fourth weeks will be taught. By using content adapted to the level of health of people, with the help of the Health Literacy Index. After fifteen days of last telephone conversation, patients were followed up again, to determine the mean of blood pressure in individuals. For examining possible changes after the test, questionnaires used in Pre-test completing again after intervention. Finally, data collected from the research.

##### Participants/Inclusion and exclusion criteria

including Criteria : Age over 60 years old, using anti hypertensive drugs, ability to speak Persian and able to communicate with researchers, inadequate health

literacy based on helia health literacy questionnaire  
exclusion criteria: Psychiatric disorders (dementia, depression) with patient self-report, drug addiction, hospitalization, patient death, reluctance to continue cooperation, don't complete educational program (one meeting and two telephone calls)

##### Intervention groups

Patient education via using an educational package with the help of the Health Literacy Index

##### Main outcome variables

medication adherence- management of hypertension

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20171227038097N1**

Registration date: **2018-02-26, 1396/12/07**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-02-26, 1396/12/07**

Update count: **0**

##### Registration date

2018-02-26, 1396/12/07

##### Registrant information

##### Name

Farzane Delavar

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6653 5524

##### Email address

f-delavar@razi.tums.ac.ir

##### Recruitment status

**Recruitment complete**

## Funding source

### Expected recruitment start date

2018-01-05, 1396/10/15

### Expected recruitment end date

2018-03-06, 1396/12/15

### Actual recruitment start date

empty

### Actual recruitment end date

empty

### Trial completion date

empty

## Scientific title

The effect of patient education based on Health Literacy INDEX on medication adherence and hypertension management in elderly patients with primary hypertension

## Public title

The effect of educational package with the help of health literacy index on medication adherence and hypertension management in elderly patients with hypertension

## Purpose

Education/Guidance

## Inclusion/Exclusion criteria

### Inclusion criteria:

All people over the age of 60. Elderly who have ability to speak Persian and communicate with scholars. All elderly people who have been suffering from primary hypertension for at least one year before entering the study. All people who are taking antihypertensive medications. Elderly people who have 66 score or less in Helia Health Literacy Questionnaire.

### Exclusion criteria:

Psychiatric disorders (dementia, depression) Addicted people to drugs Hospitalization Death Unwillingness to continue cooperation Do not Complete the curriculum (one meeting and two phone calls)

## Age

From **60 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **120**

## Randomization (investigator's opinion)

Randomized

## Randomization description

After collecting basic information, all samples are randomly assigned block size of 4 in two groups of intervention and control. For generating random sequences used from the randomizer.org website, and for conceal allocation, dark envelopes will be used to specify the group name. Then, according to the order of entering samples, envelope number one is opened for the first sample and the group will be identified.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

### Placebo

Not used

### Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

ethic committee of Tehran University of Medical Sciences

##### Street address

بلوار کشاورز، خیابان قدس، دانشگاه علوم پزشکی تهران

##### City

Tehran

##### Province

Tehran

##### Postal code

0000000000

#### Approval date

2017-10-14, 1396/07/22

#### Ethics committee reference number

IR.TUMS.VCR.REC.1396.3687

## 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

Percentage of People with Hypertension- Medication adherence in morisky questionnaire

#### Timepoint

Measurement of hypertension and medication adherence at the beginning of the study and fifteen days after the end of intervention

#### Method of measurement

Morisky medication adherence Questionnaire - blood pressure monitoring

## Secondary outcomes

empty

## Intervention groups

1

### Description

Control group received the usual services from the clinic and the intervention group was divided into small groups (to save time and affordability) and during two sessions attending the clinic in the first and second weeks and four telephone conversations in the third and fourth weeks will be taught. By using content adapted to the level of health of people, with the help of the Health Literacy Index.

### Category

Other

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

درمانگاه قلب بیمارستان شهید دکتر فیاض بخش

#### Full name of responsible person

Dr Hossein Bayat

#### Street address

next to the Vitana factory, at the beginning of Khayij street, old Karaj road, km 7, Tehran

#### City

Tehran

#### Province

Tehran

#### Postal code

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#### Phone

+98 21 6400 5673

#### Email

h.bayat@sina.tums.ac.ir

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

دکتر محمدعلی صحرائیان

#### Street address

Department of Research and Technology, Sixth floor, Central Organization of the University, Ghods Ave, Keshavarz Blvd

#### City

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#### Province

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#### Postal code

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#### Phone

+98 21 8163 3685

#### Email

m.sahraeian@sina.tums.ac.ir

### Web page address

#### Grant name

-

#### Grant code / Reference number

-

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Tehran University of Medical Sciences

#### Proportion provided by this source

25

#### 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

Tehran University of Medical Sciences

#### Full name of responsible person

Farzane Delavar

#### Position

Msc student

#### Latest degree

Bachelor

#### Other areas of specialty/work

Nursery

#### Street address

Faculty of Nursing and Midwifery, East Nosrat, Tohid squ.

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#### Email

f-delavar@razi.tums.ac.ir

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Reza Negarandeh

#### Position

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**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Farzane Delavar  
**Position**  
Msc student  
**Latest degree**  
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**Other areas of specialty/work**  
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**City**

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**Province**  
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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