

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 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 elder 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

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Postal code

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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

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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,
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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

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Reza Negarandeh

Position

Professor

Latest degree

Ph.D.

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Person responsible for updating data

Contact

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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