

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jun 2026

The effect of Self-care education through home-visits on blood pressure control and self-care behaviors among middle aged people with primary hypertension

Protocol summary

Study aim

Determining the effect of self-care behaviors training on blood pressure control through home visits in middle aged people with primary hypertension

Design

The study groups included middle-aged people with hypertension who had health records at the health centers of southern Tehran. The research sample consisted of 110 subjects who were selected by simple random sampling. And then they were randomly assigned to two groups of control and intervention.

Settings and conduct

The research environment was the center of comprehensive health services in southern Tehran, providing comprehensive educational, care and medical services to covered individuals.

Participants/Inclusion and exclusion criteria

1- Having reading and writing skills and being able to communicate effectively 2- Age range 30-59 years 3. The definitive diagnosis of the disease and the results of confirmed diagnostic tests 4- Lack of psychological problems with self-declaration of people and approval 1- There is a motor defect that does not have self-care ability. 2. The disease becomes acute and severe. 3. Immigration from the region 4. Do not wish to continue cooperation

Intervention groups

A total of 110 middle-aged patients with hypertension living in southern Tehran were eligible for inclusion in this study.

Main outcome variables

Systolic and diastolic Hypertension, Administration of prescription drugs, Low salt diet, Physical activity, Weight management, Smoking

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190623043985N1**

Registration date: **2019-06-30, 1398/04/09**

Registration timing: **retrospective**

Last update: **2019-06-30, 1398/04/09**

Update count: **0**

Registration date

2019-06-30, 1398/04/09

Registrant information

Name

sara hazratigonbad

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

sarahazrati12123@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-22, 1397/06/31

Expected recruitment end date

2018-11-21, 1397/08/30

Actual recruitment start date

2018-09-22, 1397/06/31

Actual recruitment end date

2018-11-21, 1397/08/30

Trial completion date

2018-11-21, 1397/08/30

Scientific title

The effect of Self-care education through home-visits on blood pressure control and self-care behaviors among middle aged people with primary hypertension

Public title

The effect of Self-care education through home-visits on blood pressure control and self-care behaviors among middle aged people with primary hypertension

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

.Having reading and writing skills and being able to communicate effectively Age range of 30-59 years . Definitive diagnosis of disease and results of confirmed diagnostic tests . No psychological problems with self-declaration of individuals and approval of the health center

Exclusion criteria:

1- There is a motor defect that does not have self-care ability. 2. The disease becomes acute and severe .3. Immigration from the region 4. Do not wish to continue cooperation.

Age

From **30 years** old to **59 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **110**

Actual sample size reached: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

About 156 people were eligible to participate in the study. First, all of these people were contacted. Some people were not accountable, and some did not go to the health center, and some did not want to cooperate. Eventually, the number of people referred to about 138 people. Then, using a simple random sampling method, each person received an identifier and selected 18 draws in a draw. Selected identifiers were excluded from the study and the remaining identifiers were selected as research samples. Approximately 110 individuals were selected. Subsequently, for random assignment of samples to two groups of intervention and control, each study sample was assigned an identifier and according to the table Random numbers were divided into two groups of test and control. In this method, first, according to the sample size (110 people), two columns were included in the random numbers table, then a number as the starting point was randomly selected and proceeded based on it, and the numbers were less than the sample size selected as the intervention group And the remaining numbers were selected as the control group.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of tehran University of Medical Sciences

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no7,parnian ave, rajai blvd, shahrak valiasr

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tehran

Province

Tehran

Postal code

13766-16553

Approval date

2018-07-21, 1397/04/30

Ethics committee reference number

ir.tums.fnm.rec.1397.064

Health conditions studied**1****Description of health condition studied**

hypertension deaseas

ICD-10 code

I10

ICD-10 code description

Essential (primary) hypertension

Primary outcomes**1****Description**

Regular blood pressure control,the measure this blood pressure variable, the subjects were measured before the intervention and one month after the intervention. Also, to check the regular blood pressure control, the frequency of blood pressure measurements during the week was measured by a questionnaire before intervention and one month after intervention.

Timepoint

ONE months after the end of the intervention

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: hypertension disease. In the intervention group, for 3-5 sessions during two months of intervention, self-care behaviors included low salt diet, drug compliance, regular physical activity, non-smoking, weight management and regular blood pressure measurements provided during the home visit program. They also receive routine care for health centers.

Category

Lifestyle

2

Description

Control group: The usual care is provided by health centers.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Health Center of Khakbaz

Full name of responsible person

Dr. Abniki

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No 159, Mowlahadi Ave, Shandiz Ave, Eastern Yafatabad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Shahzad Pashaeipoor

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Sara Hazrati Gonbad

Position

Masters Student

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