

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

The effect of self-care program of family-oriented on compliance with the drug regimen and diet in Patients with hypertension

Protocol summary

Study aim

The effect self-care program of family-oriented on compliance with the drug regimen and diet in Patients with hypertension

Design

Two arm parallel group randomised trial with postoperative care and outcome assessment

Settings and conduct

In the intervention group: Using two training sessions in the training sessions, in the hospital, the training will be given to improve the compliance of the diet and dietary regimen and will help the patient and his or her family with three sessions of home visits to correct lifestyle. Then the patient is evaluated In the control group: the questionnaires are filled in at home

Participants/Inclusion and exclusion criteria

Inclusion criteria : Diagnosis of hypertension by the doctor Failure to receive home visits in the past Have a reading and writing literacy Exclusion criteria: Dialysis being admitted to the hospital No family or friend

Intervention groups

In the intervention group, after filling out the dietary questionnaires and following Medication Adherence Scale -8 and regimen Scale, two group training sessions will be provided with family support for self-care home-based self-care programs for observing the diet and the diet to patients and families, followed by three home visits and Questionnaires are filled in immediately and two months later and statistics are evaluated. In the control group, Medication Adherence Scale -8 and regimen Scale was filled in three stages of the diet and follow-up, and a group training session was given to patients after evaluation of the statistics.

Main outcome variables

Adherence to drug use

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180116038389N1**
Registration date: **2018-12-26, 1397/10/05**
Registration timing: **retrospective**

Last update: **2018-12-26, 1397/10/05**

Update count: **0**

Registration date

2018-12-26, 1397/10/05

Registrant information

Name

Zahra Givpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3775 9350

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-22, 1397/04/01

Expected recruitment end date

2018-07-23, 1397/05/01

Actual recruitment start date

2018-06-22, 1397/04/01

Actual recruitment end date

2018-07-23, 1397/05/01

Trial completion date

2019-11-21, 1398/08/30

Scientific title

The effect of self-care program of family-oriented on compliance with the drug regimen and diet in Patients with hypertension

Public title

The effect self- care program of family-oriented on compliance with the drug regimen and diet in Patients with hypertension

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Diagnosis of hypertension by the doctor Failure to receive home visits in the past Not having mental illness and addiction Have a reading and writing literacy

Exclusion criteria:

Hospitalization of the patient Patient dialysis

Age

From **45 years** old to **74 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **66**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization method using table numbers The pair numbers of the intervention group and the individual numbers of 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 Isfahan University of Medical Sciences

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No 17, Bahar Alley, Roodaki Ave

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Postal code

8176946411

Approval date

2017-11-19, 1396/08/28

Ethics committee reference number**Health conditions studied****1****Description of health condition studied**

Hypertension

ICD-10 code

I15

ICD-10 code description

Secondary hypertension

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

compliance with the drug regimen and diet

Timepoint

Before intervention, Immediately later intervention, 2months later intervention

Method of measurement

Morisky Medication Adherence Scale

Secondary outcomes**1****Description**

Better Adherence to Diet and Medicines and Reduce Blood Pressure

Timepoint

For both intervention and control groups :Before intervention, immediately after intervention and two months later intervention

Method of measurement

Morisky Medication Adherence Scale8

2**Description**

Decreased blood pressure

Timepoint

For both intervention and control groups :Before intervention, immediately after intervention and two months later intervention

Method of measurement

with Blood Pressure

Intervention groups**1****Description**

Intervention group: In the intervention group, two groups of group training are taught in 6 groups of patients with the family. Then, using the home visit method, the problems with the use of medications and diet are identified and they are resolved according to the facilities of the family. And leads to better diet and drug

compliance and promotes community health and reduces health care costs

Category

Lifestyle

2

Description

Control group: the questionnaires are filled in before the intervals, before, and two months later, and after the evaluation of a session, they are taught.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Isa ebn maryam hospital

Full name of responsible person

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Recruitment center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Habib Hoseini

Position

Associate professor

Latest degree

Master

Other areas of specialty/work

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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