

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Sep 2026

The effect of the educational program on adherence of patients with high blood pressure

Protocol summary

Summary

Objectives: Determining the effectiveness of educational program on adherence of patient with high blood pressure in Sayyad Shirazi educational hospital Design: Controlled clinical trial (single blind) Setting and conduct: 196 qualified patients with hypertension, will be selected through convenience sampling to detect patients' adherence compliance of patient, then 98 patients with low adherence will allocate into two intervention and control group by using stratified random allocation. Lifestyle modification education will be took place in heart clinic unit by trained practitioners based on lifestyle modification guideline in intervention group. Patients' adherence and blood pressure will be measured before and after intervention in both groups for comparing. Major Inclusion and Exclusion criteria: Inclusion criteria will include age from 18 to 65 years; having the ability to read and write; having systolic blood pressure more than 140 and less than 169; having diastolic blood pressure more than 90 and less than 109; at least 6 months history of treatment; having complete alertness; hearing and speech ability; don't be pregnant; not having known psychiatric disorders and chronic illness; not using opium or alcohol. Exclusion criteria will include don't want to continue participation and travel or migration during study. Intervention: Two hours face to face education will be done twice a week for two weeks based on lifestyle modification guideline. Main outcome measures: Patients' adherence to treatment and blood pressure

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2014070117237N4**

Registration date: **2015-08-15, 1394/05/24**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-08-15, 1394/05/24

Registrant information

Name

Mahnaz Modanloo

Name of organization / entity

Country

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Recruitment status

Recruitment complete

Funding source

Deputy of Research & Technology, Golestan University of Medical Sciences

Expected recruitment start date

2015-07-03, 1394/04/12

Expected recruitment end date

2015-11-04, 1394/08/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of the educational program on adherence of patients with high blood pressure

Public title

The effect of the education on adherence

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: age from 18 to 65 years; having the ability to read and write; having Systolic Blood Pressure more than 140 and less than 169; having Diastolic Blood Pressure more than 90 and less than 109; at least 6 months history of treatment; having complete alertness; hearing and speech ability; don't be pregnant during participating in study; not having known psychiatric disorders; don't have chronic illness such as cancer, lupus, advanced heart failure, ARDS, CVA and diabetes; not using opium or alcohol. Exclusion criteria: don't want to continue participation; travel or migration during study.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Patients will allocate into two intervention and control group by using stratified random allocation.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Golestan University of Medical Sciences

Street address

Deputy of Research and Technology, Golestan University of Medical Sciences, Hirkan Boulevard, Gorgan

City

Gorgan

Postal code

4934174515

Approval date

2015-06-07, 1394/03/17

Ethics committee reference number

ir.goums.rec.1394.44

Health conditions studied

1

Description of health condition studied

Hypertention

ICD-10 code

I10

ICD-10 code description

Essential (primary) hypertension

Primary outcomes

1

Description

Adherennce

Timepoint

Before intervention and two weeks after intervention

Method of measurement

Using checklist to measur adrerent to treatment in diets, excercise and drug

Secondary outcomes

1

Description

Level of blood pressure

Timepoint

Before intervention and two weeks after intervention

Method of measurement

Using sphygmomanometer

Intervention groups

1

Description

Intervention group: Two hours face to face education based on lifestyle modification guideline will be done twice a week for two weeks.

Category

Other

2

Description

Control group: without any intervention

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Sayyad Shirazi Educational Hospital

Full name of responsible person

Saeid Amirkhanloo

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Sayyad Shirazi Blv., Bahonar Square, Gorgan,
Golestan, Iran

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

Vice Chancellor for research of Golestan University of
Medical Sciences

Full name of responsible person

Masood Khoshnia

Street address

Deputy of Research and Technology, Golestan
University of Medical Sciences, Hirkan Bulvar, Gorgan,
Iran

City

Gorgan

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Vice Chancellor for research of Golestan University of
Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Golestan University of Medical Sciences

Full name of responsible person

AtharAlsadat Mirkarimi

Position

MS Student of Critical Nursing Care

Other areas of specialty/work**Street address**

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty