Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 2026

Comparison of the efficacy group discussion based on a healthy lifestyle in two methods family-centered and patient-centered on the control of hypertension

Protocol summary

Summary

Objectives: This study aims to compare the effectiveness of group discussion based on a healthy lifestyle in two methods family-centered and patient-centered. Design: The present study is a randomized controlled clinical trial. Major inclusion and exclusion criteria: Ability to participate in the study; willingness to participate in the study; age between 30 to 60 years; absence of any underlying hard disease; being on medication for hypertension; and living in the city of Urmia will be entry requirements. The exclusion criteria will be: unwillingness to participate further; moving to another city; moving to another city; and cure hypertension. Setting and conduct: The subjects consisted of 100 of the patients with hypertension at the clinical-educational center of Sayyed-Al Shohada, Urmia, who met the study criteria. Will select based on the convenience method, the samples will be randomly divided into two groups: the family-centered group, and the patient-centered group. Intervention: The subjects in the patient-centered group will discussion in four sessions of group discussion with 10 patients in each group for one hour a week for four weeks, and the subjects in the family-centered group, intervention will done in partnership with five patients and five members of their immediate family in four sessions of group discussion with 10 patients in each group for one hour a week for four weeks. Outcome measures: Blood pressure.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015122317059N4**
Registration date: **2016-07-11, 1395/04/21**
Registration timing: **prospective**
Last update:
Update count: **0**

Registration date

2016-07-11, 1395/04/21

Registrant information

Name

Masoume Hemmati Maslakpak

Name of organization / entity

Urmia University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Urmia University of Medical Sciences

Expected recruitment start date

2016-12-30, 1395/10/10

Expected recruitment end date

2018-01-30, 1396/11/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy group discussion based on a healthy lifestyle in two methods family-centered and patient-centered on the control of hypertension

Public title

Group discussion effect on blood pressure

Purpose
Prevention

Inclusion/Exclusion criteria
Major inclusion and exclusion criteria: Ability to participate in the study; aged between thirty and sixty years; lack of underling disease; residence in the city of Orumieh; the use of drugs to control blood pressure will be entry requirements. The exclusion criteria will be: not wanting to continue cooperation; change location to another town; cure hypertension.

Age
From **30 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

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
University of Medical Sciences

Street address
Urmia, Seru Road. Pardis Nazlu Urmia West Azarbayjan Iran, Islamic Republic Of

City
Urmia

Postal code

Approval date
2015-12-21, 1394/09/30

Ethics committee reference number
IR.umsu.iric.1394.275

Health conditions studied

1

Description of health condition studied
Hypertension

ICD-10 code
110

ICD-10 code description
Essential (primary) hypertension, Secondary hypertension

Primary outcomes

1

Description
blood pressure

Timepoint
Five times

Method of measurement
Mercury sphygmomanometer

Secondary outcomes

1

Description
Sweating , nausea , impotency , headaches

Timepoint
Two times

Method of measurement
questionnaire

Intervention groups

1

Description
Intervention group 1: In patient-centered group discussion, group discussion sessions for an hour a week for four weeks in hospital clinics will be held. It is noteworthy that in this group of 50 subjects will be. For control and useful discussion group, the 10-member group will be divided into 5 subgroups. Group discussion revolving around the nature of the topics covered in blood pressure, healthy eating, physical activity, smoking, stress management, diet, regular visits to the clinic for blood pressure control and regular drug use will be recorded.

Category
Lifestyle

2

Description
Intervention group 2: In family-centered group discussion, 50 patients and 50 members of the immediate family (spouse, child, sister, brother, parents) will participate. Group discussion sessions for an hour a week for four weeks in hospital clinics will be held. It is noteworthy that in this group of 100 people will participate in group discussions. For control and useful discussion group, the 10-member group will be divided into 10 subgroups. Group discussion revolving around the nature of the topics covered in blood pressure, healthy eating, physical activity, smoking, stress management, diet, regular visits to the clinic for blood

pressure control and regular drug use will be recorded.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinical-Educational Center of Sayyed-Al Shohada

Full name of responsible person

Iraj Mohebi

Street address

Postal Code: 571478334, Orjhans Street, Resalat Blvd, Urmia West Azarbayjan

City

Orumieh

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Urmia University of Medical Sciences

Full name of responsible person

Iraj Mohebi

Street address

Postal Code: 571478334, Orjhans Street, Resalat Blvd, Urmia Urmia West Azarbayjan Iran, Islamic Republic Of

City

Urmia

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, Urmia 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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Urmia Medical University

Full name of responsible person

Masumeh Hemmati Maslakpak

Position

Ph.D

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Urmia Medical University

Full name of responsible person

Rezaei Behrooz

Position

Nursing graduate student

Other areas of specialty/work

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Urmia,km 11 road,building cedar,campus Nazloo Nursing and Midwifery

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Fax

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Web page address

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