

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 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 Maslakkpak

###### Name of organization / entity

Urmia University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 44 1365 9031

###### Email address

hemmati\_m@umsu.ac.ir

##### 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 underlying 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.irc.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 Maslarpak

**Position**

Ph.D

**Other areas of specialty/work**

**Street address**

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

**City**

Urmia

**Postal code**

5714783734

**Phone**

+98 44 3365 9031

**Fax**

**Email**

hemmatma@yahoo.com

**Web page address**

**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**

**Street address**

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

**City**

Urmia

**Postal code**

**Phone**

008736210308

**Fax**

**Email**

b.rezaei2014@yahoo.com

**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*