# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Nov 2026

## Comparison Self- Efficacy and Quality of Life hypertensive patients with and without Orem's self-care education

## Protocol summary

**Summary**

Objective: Evaluating the effects of Orem's self-care program on self- efficacy and quality of life in hypertensive patients. Type of experiment: Randomized. Inclusion criteria: A definitive diagnosis of hypertension by cardiologist; History of taking at least one anti-hypertensive medication for one year; Age of 18-55 years; Having a minimum education level (elementary); Not participated in the same study; Ability in Persian language comprehension and communication; Tendency to participate in the study; Have filled informed consent form; Not working at medical services. Exclusion criteria: Known psychological disorders; History of addiction in past one year; Other chronic diseases; History of major heart surgery during past six months; Method: By randomization, the two groups (intervention and control) are followed in exactly the same way. Population studied: All patients with hypertension referred to Mamasani Valiasr hospital. Target sample size: 80 cases. Interventions: Patients in intervention group will receive four 45 minutes teaching sessions weekly during one month and the manner of educated program adherence will be followed up with a phone call. Primary outcomes of this project is the study of patient's self-efficacy and quality of life.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2015081323606N1**
Registration date: **2016-02-07, 1394/11/18**
Registration timing: **retrospective**

Last update:
Update count: **0**

**Registration date**

2016-02-07, 1394/11/18

**Registrant information**

**Name**
Farzaneh Kazemi Ara
**Name of organization / entity**
Shiraz University of Medical Sciences
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Iran (Islamic Republic of)
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**Recruitment status**

**Recruitment complete**

**Funding source**

Vice Chancellor for Research, Shiraz University of Medical Sciences

**Expected recruitment start date**

2015-06-20, 1394/03/30

**Expected recruitment end date**

2015-07-24, 1394/05/02

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison Self- Efficacy and Quality of Life hypertensive patients with and without Orem's self-care education

**Public title**

The effect of Orem's self-care program on Self- Efficacy and Quality of Life in hypertensive patients

**Purpose**

Supportive

**Inclusion/Exclusion criteria**

Inclusion criteria: A definitive diagnosis of hypertension by cardiologist; History of taking at least one anti-

hypertensive medication for one year; Age of 18-55 years; Having a minimum education level (elementary); Not participated in the same study; Ability in Persian language comprehension $ communication; Tendency to participate in the study; Have filled informed consent form; Not working at medical services. Exclusion criteria: Known psychological disorders; History of addiction in past one year; Other chronic conditions such as: Epilepsy, C.V.A, cancer, physical disability and neurological disorders; History of major heart surgery during past six months; long hospitalization since two years ago.

**Age**
From **18 years** old to **55 years** old

**Gender**
Both

**Phase**
N/A

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **80**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**

**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 Shiraz university of medical Sciences

**Street address**
Seventh floor, Shiraz university of medical Sciences and health services, Zand Blvd.

**City**
Shiraz

**Postal code**
71345-1978

**Approval date**
2015-06-21, 1394/03/31

**Ethics committee reference number**
IR.SUMS.REC.1394.44

## Health conditions studied

### 1

**Description of health condition studied**
Hypertensive diseases

**ICD-10 code**
I10-I15

**ICD-10 code description**
Hypertensive diseases

## Primary outcomes

### 1

**Description**
Quality of life

**Timepoint**
before intervention, exactly after and eight weeks after intervention

**Method of measurement**
Mac new quality of life questionnaire

### 2

**Description**
Self-Efficacy

**Timepoint**
before intervention, exactly after and eight weeks after intervention

**Method of measurement**
SUPPH self-Efficacy questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Patients in intervention group will receive four 45 minutes teaching sessions weekly during one month. The First 3 sessions are personal and fourth session is for solving problems and sharing experiences. Also quality of life and Self-efficacy questionnaire will be filled in fourth session. Final intervention step includes phone call follow-up in order to evaluate the applying taught issues by cases, answer their questions and encourage them for active participation in self-care activities.

**Category**
Other

### 2

**Description**
Control group: No Intervention

**Category**
Other

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Mamasani Valiasr Hospital
**Full name of responsible person**
Farzaneh Kazemi ARA
**Street address**
Mamasani
**City**
Mamasany

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Vice chancellor for research, Shiraz University of Medical Sciences
**Full name of responsible person**
basir hashemi
**Street address**
Seventh floor, Shiraz university of medical Sciences and health services, Zand Blvd.
**City**
Shiraz
**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, Shiraz 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**
Shiraz university of medical sciences
**Full name of responsible person**
Zahra Khademian
**Position**
Nursing ph.d.
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## Person responsible for scientific inquiries

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## Person responsible for updating data

**Contact**
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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*