

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jun 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 4254 7375

##### Email address

stud2392002274@sums.ac.ir

#### 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.

**Other areas of specialty/work**

**Street address**

Hazrat-e-Fatemeh nursing and midwifery college, Namazi hospital, Namazi Sq. Shiraz

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#### Person responsible for scientific inquiries

#### Contact

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**Other areas of specialty/work**

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#### Person responsible for updating data

#### Contact

**Name of organization / entity**

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**Full name of responsible person**

Zahra khademian

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**Other areas of specialty/work**

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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*