

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

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Name of organization / entity

Shiraz University of Medical Sciences

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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.

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