Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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
City
shiraz
Postal code
Phone
+98 71 3626 7101
Fax
Email
zahrakhademian@yahoo.com
Web page address

Person responsible for scientific 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
City
Shiraz
Postal code
Phone
+98 71 3626 7101
Fax
Email
zahrakhademian@yahoo.com
Web page address

Person responsible for updating data

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
City
Shiraz
Postal code
Phone
+98 71 3626 7101
Fax
Email
zahrakhademian@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