

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Investigation the effect of educational program based on Orem self-care model on quality of life and health- promoting lifestyle in patients with hypertension

Protocol summary

Study aim

Investigating the effect of educational program based on Orem self-care model on quality of life and health-promoting lifestyle in patients with hypertension

Design

This study is a randomized controlled clinical trial without blinding. Participants in this study are 80 patients with hypertension referred to the heart clinic of Vali Asr Hospital affiliated to Fasa University of Medical Sciences. The sampling method is simple random assignment, 80 cards were prepared, including 40 cards labeled A (intervention group) and 40 cards labeled B (control group). These 80 cards will then be put in an envelope, and each patient will be asked to draw out one card randomly.

Settings and conduct

This study is a clinical trial without blinding. Participants in this study are patients with hypertension referred to the heart clinic of Vali Asr Hospital affiliated to Fasa University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with hypertension; having a minimum literacy (being able to read and write); age between 30 and 55 years; no speech or hearing impairment. Non-inclusion criteria: severe mental and emotional disorders.

Intervention groups

Intervention group: The educational intervention consists of five 60-minute training sessions once a week. For the intervention group, a researcher based on the Orem self-care model will use group discussion, questions and answers, as well as PowerPoint and educational pamphlets. The control group will only receive routine training. They will also be provided with a training booklet.

Main outcome variables

Quality of life; health- promoting lifestyle

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190917044802N4**

Registration date: **2022-04-04, 1401/01/15**

Registration timing: **prospective**

Last update: **2022-04-04, 1401/01/15**

Update count: **0**

Registration date

2022-04-04, 1401/01/15

Registrant information

Name

Mostafa Bijani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 5331 5012

Email address

bizhani_mostafa@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-21, 1401/02/01

Expected recruitment end date

2022-07-23, 1401/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation the effect of educational program based on Orem self-care model on quality of life and health-promoting lifestyle in patients with hypertension

Public title

The effect of educational program on quality of life and lifestyle in patients with hypertension

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with hypertension Having a minimum literacy (being able to read and write) Age between 30 and 55 years No speech or hearing impairment

Exclusion criteria:

Suffering from severe mental and emotional disorders

Age

From **30 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

We put 80 cards in an envelope with letter A on 40 cards and letter B on remaining 40 cards. Then patients who meet the inclusion criteria are asked to take one card. If they take card A they will be allocated to the intervention group and if they take the B card, they will be put in the control group. This process will continue until the sample size is completed.

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 Fasa University of Medical Sciences

Street address

Fasa University of Medical Sciences; Ibn Sina Square

City

Fasa

Province

Fars

Postal code

7461686688

Approval date

2022-02-23, 1400/12/04

Ethics committee reference number

IR.FUMS.REC.1400.153

Health conditions studied

1

Description of health condition studied

Hypertension diseases

ICD-10 code

I10

ICD-10 code description

Essential (primary) hypertension

Primary outcomes

1

Description

Quality of life

Timepoint

Before, immediately, one month later and three months later

Method of measurement

SF-36 Quality of Life Questionnaire

2

Description

Health- promoting lifestyle

Timepoint

Before, immediately, one month later and three months later

Method of measurement

Walker Health Promoting Lifestyle Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For the intervention group, educational program based on the Orem self-care model is presented in the form of six two-hour sessions in groups (two groups of twenty) through lectures, questions and answers, and the presentation of an educational pamphlet. According to the COVID-19 pandemic, training sessions will be held in compliance with social distance and all health protocols. Educational content based on the Orem self-care model includes: definition of blood pressure, definition of hypertension, risks of hypertension, influencing factors On blood

pressure, consequences and complications of high blood pressure, self-care definition, self-care training in hypertension including: physical activity, nutrition, weight loss, relaxation, deep breathing, yoga, meditation, training on how to measure blood pressure at home, lack Smoking and alcohol consumption, follow-up treatment and training in the use of drugs.

Category

Lifestyle

2**Description**

Control group: will receive only routine training. They will also be provided with a training booklet.

Category

Lifestyle

Recruitment centers**1****Recruitment center****Name of recruitment center**

Vali Asr Hospital affiliated to Fasa University of Medical Sciences

Full name of responsible person

Dr. Mojabi Farjam

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Vice Chancellor for Research, Fasa University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Fasa University of Medical Sciences

Full name of responsible person

Dr. Mostafa Bijani

Position

Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

The data file will be shared after the confidential information is removed for use by other researchers for future research

When the data will become available and for how long

After the publication of the study results, access will be possible

To whom data/document is available

Researchers working in academic and scientific institutions and health system policy makers

Under which criteria data/document could be used

Documentation will be available by requesting and using the results and data of the study

From where data/document is obtainable

Send email to the responsible author

What processes are involved for a request to access data/document

Submit the request and the reason for using the documents to the responsible author

Comments