Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigationg 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 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
Investigationg 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

Street address

Fasa University of Medical Sciences; Ibn Sina Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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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
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