

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

Effect of use health promotion Pender's Model on Adherence to Treatment and Blood Pressure in Patients with Hypertension

Protocol summary

Study aim

Determining the Impact of Pender's health promotion model on adherence to treatment and Blood pressure in patients with hypertension in Shahid Beheshti health center in Kashan, 1396

Design

In this research, 80 Hypertensive patients referring to Shahid Beheshti health center in Kashan were chosen purposefully and a code was allocated to each one of them. Then, patients were randomly divided into two control and intervention groups.

Settings and conduct

After approval of the research project by the Research Council of the University of Medical Sciences and obtaining permission from the Ethics committee of the University of Medical Sciences, and coordination with the officials of the Shahid Beheshti Hospital, the researcher referred to Shahid Beheshti Medical Center Clinic during the week, morning and evening and with the help of the Center staff, after expressing the research goals and ensuring patients are kept confidential and obtain informed written consent from them, select patients who have been admitted to the study and after sampling, patients are assigned randomly between intervention and control groups. The content of perceptual intervention in blood pressure control from valid sources based on the constructs of the Pender Health Promotion Model and validated by 10 nursing and cardiologists. in the intervention group, educational intervention in accordance with Pender model with routine care during 6 sessions of 45-60 minutes for 6 weeks in small groups of 4 to 6 people with group discussion and question and answer in Shahid Beheshti Medical Center will be done. Meanwhile, both groups receive routine training from the center, which includes the presentation of an educational pamphlet based on the Guideline on Blood Pressure Control in Iran. Measurement of adherence to treatment in the first session (at the time of admission), the sixth session (the end of training) and one month and two

months after the end of education is performed by the questionnaire of treatment of peasant and colleagues. Meanwhile, control of patients' blood pressure during the first session (on arrival), the third session (during training), the sixth session (the end of training) and one month and two months after the end of training together with the full compliance of the 7th JNC Guideline with the German manufacture of Bosch mercury device Germany. Educational intervention and distribution and completion of questionnaires by researcher-designer who was a master student of Surgical Internal Nursing and receives the necessary training in the field of the project, according to the previous planning.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Being a citizen of Iranian and Persian languages 2. The ability to communicate verbally 3. Age 20 to 65 years old 4. Having a primary hypertension with cardiologist confirmed 5. At least 6 months have passed since the diagnosis of the disease 6. Patients who score questionnaire based on their adherence to treatment adherence is less than 86. 7. The lack of physical and mental debilitating diseases known for example, MR, depression and cancer 8. Location in Kashan 9. Along the patient is literate 10. The desire and informed consent to participate in the study Exclusion criteria: 2. Unwillingness to continue cooperation during the study 2. The absence of training sessions (more than one session) 3. Changes in the course of illness and patient's therapies so that the type of drug or dose of his medication changes. 4. Having a disease or complication that leads to hospitalization during the study, such as heart attacks, stroke, kidney failure, etc.

Intervention groups

Patients are invited to participate in the study and as knowledge and purpose of the study are aware, after obtaining informed consent in the intervention and control groups sorted but they are not aware of this classification in the control or intervention group. 1- Intervention group: (Education Based on Pender Health Promotion Model) The content of perceived cessation of blood pressure control from valid sources is based on the

Pender Health Promotion Model constructs and Validated by 10 nursing and cardiologists. In this group, educational intervention according to Pender model with routine care during 6 sessions of 45-60 minutes for 6 weeks in groups of 4 to 6 people with group discussion and question and answer in Shahid Beheshti Medical Center will be done. The center's routine training also includes the presentation of an educational pamphlet based on the Guideline on Blood Pressure Control in Iran. 2- Control group: (Routine training in medical center) The routine training of the center includes the presentation of an educational pamphlet based on the Guideline on Blood Pressure Control in Iran.

Main outcome variables

Systolic blood pressure Diastolic blood pressure Median Arterial Pressure (MAP) Kind of treatment of hypertension score of Adherence to treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100829004655N7**

Registration date: **2018-01-22, 1396/11/02**

Registration timing: **registered_while_recruiting**

Last update: **2018-01-22, 1396/11/02**

Update count: **0**

Registration date

2018-01-22, 1396/11/02

Registrant information

Name

Mohsen Taghadosi

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 5554 0021

Email address

taghadosi_m@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-20, 1396/10/30

Expected recruitment end date

2018-07-21, 1397/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of use health promotion Pender's Model on Adherence to Treatment and Blood Pressure in Patients

with Hypertension

Public title

Effect of use health promotion Pender's Model on Adherence to Treatment and Blood Pressure in Patients with Hypertension

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Being a citizen of Iranian and Persian languages The ability to communicate verbally Age 20 to 65 years old Having a primary hypertension with cardiologist confirmed At least 6 months have passed since the diagnosis of the disease Patients who score questionnaire based on their adherence to treatment adherence is less than 86. The lack of physical and mental debilitating diseases known for example, MR, depression and cancer Location in Kashan Along the patient is literate The desire and informed consent to participate in the study

Exclusion criteria:

Unwillingness to continue cooperation during the study The absence of training sessions (more than one session) Changes in the course of illness and patient's therapies so that the type of drug or dose of his medication changes. Having a disease or complication that leads to hospitalization during the study, such as heart attacks, stroke, kidney failure, etc.

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

The sampling method is continuous and patients are divided into 4 randomized blocks between intervention and control groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients are invited to participate in the study and as knowledge and purpose of the study are aware, after obtaining informed consent in the intervention and control groups sorted but they are not aware of this classification in the control or intervention group.

Placebo

Not used

Assignment

Parallel

Other design features

Individuals in the intervention and control groups, randomly allocated blocks (blocks 4-procurement and selection will be based on them)

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kashan University of Medical Sciences

Street address

Ghotb Ravandi Blvd, Kashan

City

Kashan

Province

Isfahan

Postal code

8715981151

Approval date

2018-01-08, 1396/10/18

Ethics committee reference number

IR.KAUMS.NUHEPM.REC.1396.25

Health conditions studied

1

Description of health condition studied

Hypertension

ICD-10 code

I10

ICD-10 code description

Essential (primary) hypertension

Primary outcomes

1

Description

Adherence to Treatment

Timepoint

Baseline, 1 and 2 months after completion of intervention

Method of measurement

treatment adherence questionnaire for patients with hypertension (TAQPH) Persian version

2

Description

blood pressure

Timepoint

Baseline, weeks 1, 3, 5 and 1and 2 month after the intervention

Method of measurement

In compliance with all standards of JNC 7 using a mercury manometer adults model F.BOSCH (GERMANY), which was calibrated with mercury healthy.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Education Based on Pender Health Promotion Model. The content of perceived cessation of blood pressure control from valid sources is based on the Pender Health Promotion Model constructs and Validated by 10 nursing and cardiologists. In this group, educational intervention according to Pender model with routine care during 6 sessions of 45-60 minutes for 6 weeks in groups of 4 to 6 people with group discussion and question and answer in Shahid Beheshti Medical Center will be done.The center's routine training also includes the presentation of an educational pamphlet based on the Guideline on Blood Pressure Control in Iran.

Category

Behavior

2

Description

Control group: Routine training in medical center. The routine training of the center includes the presentation of an educational pamphlet based on the Guideline on Blood Pressure Control in Iran.

Category

Behavior

Recruitment centers

1

Recruitment center**Name of recruitment center**

Research Center of Kashan University of Medical Sciences

Full name of responsible person

Taghadsai Mohsen

Street address

Arctic Blvd Ravandi, Kashan University of Medical Sciences

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Province

Isfahan

Postal code

87159/81151

Email

hossein1396@chmail.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Hamidi Gholamali

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Mohsen Taghadosi

Position

Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Mohsen Taghadosi

Position

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Latest degree

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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

Hossein Nouri Perkhastani

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

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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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
The total potential data can be shared after
unidentifiable people
**When the data will become available and for how
long**

Start the access period 6 months after printing the
results
To whom data/document is available
Only available to scholars working in academia and
academia.
Under which criteria data/document could be used
If you observe the trust and mention the source, data is
available for researchers.
From where data/document is obtainable
Send the following e-mail to the following address:
taghadosi_m@kaums.ac.ir
**What processes are involved for a request to access
data/document**
After receiving the letter via email, your request will be
reviewed within 2 weeks and the data will be sent to the
applicant at the discretion.
Comments