Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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
Isfehan

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
Taghadsi Mohsen

Street address
Arctic Blvd Ravandi, Kashan University of Medical Sciences

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Isfehan

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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

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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