

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Effect of self-management training program using peer support on adherence and self-management behavior in patient with hypertention

Protocol summary

Study aim

The effect of self-management training program using peer support on adherence to treatment and self-management behavior in hypertensive patients in Kashan in 2019

Design

A clinical trial with a parallel control group, randomized

Settings and conduct

This study will be performed in Shahid Beheshti Hospital in Kashan. Patients will be divided into two groups: intervention and control. First, two questionnaires of adherence to treatment and self-management will be completed by the two groups of intervention and control. Then each group receives a specific training by the peer person introduced. The training will include 5 sessions of 45 to 60 minutes. There is no intervention in the control group and they will receive routine blood pressure control training.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having Iranian citizenship, Ability to communicate verbally, Age 20 to 65 years, Hypertension of primary type with the approval of a cardiologist, At least 6 months have passed since the disease diagnosis, Lack of known mental and physical disability, Not participating in another study at the same time, Willingness and informed consent to participate in the study; Exclusion criteria: Systolic blood pressure more than 170 mm Hg.

Intervention groups

Intervention group: Patients in the intervention group are will divided into three subgroups. In each subgroup, self-management training in blood pressure control will be performed by peers in 5 sessions of 45 to 60 minutes during 5 weeks. In the Control group, no intervention will not perform during 5 weeks.

Main outcome variables

Adherence to treatment; Self-management behavior

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100829004655N11**

Registration date: **2020-05-06, 1399/02/17**

Registration timing: **retrospective**

Last update: **2020-05-06, 1399/02/17**

Update count: **0**

Registration date

2020-05-06, 1399/02/17

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

2019-07-23, 1398/05/01

Expected recruitment end date

2019-11-21, 1398/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of self-management training program using peer support on adherence and self-management behavior in patient with hypertension

Public title

Effect of using peer support on adherence and self-management behavior

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Having Iranian and Persian citizenship
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
The lack of physical and mental debilitating diseases known for example, MR, depression and cancer
Location in Kashan
Do not attend another study at the same time
The desire and informed consent to participate in the study

Exclusion criteria:

Patients with systolic blood pressure more than 170 mm Hg

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

The sampling method will be convenience and based on inclusion criteria. Random allocation in two groups of intervention and control will be simple randomization. Randomization is carried out by creating a random sequence of numbers using an online tool (<https://www.randomizer.org>).

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 kashan University of Medical Sciences

Street address

Ravand Street, Kashan University of Medical Sciences.

City

kashan

Province

Isfahan

Postal code

8715981151

Approval date

2019-07-16, 1398/04/25

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1398.046

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

Before training, after training and 45 days after completion of intervention

Method of measurement

Treatment adherence questionnaire for patients with hypertension

2**Description**

Self Management Behavior

Timepoint

Before training, after training and 45 days after completion of intervention

Method of measurement

Self-management questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Patients in the intervention group are will divided into three subgroups. In each subgroup, self-management training in blood pressure control by peers in 5 sessions of 45 to 60 minutes, once a week for five weeks will be

performed. The content of the sessions will include the following. The first session includes the definition of hypertension and its cause; The second session includes risk factors for high blood pressure and ways to control it; The third session includes the general principles of hypertension treatment and its pharmacological treatments; The fourth session includes training the daily weight control, diet and proper physical activity; The fifth session includes stress management and non-smoking and alcohol consumption.

Category

Prevention

2

Description

Control group: Receive the routine training of the center and answer the questions that the researcher asks in writing by questionnaire. The routine training of the center consists of providing a training pamphlet based on the national guidelines for blood pressure control in Iran.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti hospital, Kashan university of medical sciences

Full name of responsible person

Mohsen Taghadosi

Street address

Ravand street, Shahid Beheshti Hospital

City

Kashan

Province

Isfahan

Postal code

87159/81151

Phone

+98 31 5554 6633

Email

Taghadosi_m@kaums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Hamidreza Banafshe

Street address

Ravand Street, Kashan University of Medical Sciences

City

Kashan

Province

Isfahan

Postal code

87159/81151

Phone

+98 31 5554 0021

Email

Taghadosi_m@kaums.ac.ir

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

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Ravand Street, Kashan University of Medical Sciences

City

Kashan

Province

Isfahan

Postal code

87159/81151

Phone

+98 31555 0021

Fax

+98 31 5546 6333

Email

Taghadosi_m@kaums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Mohsen Taghadosi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Ravand Street, Kashan University of Medical Sciences

City

Kashan

Province

Isfahan

Postal code

8715988141

Phone

+98 36 1555 0021

Fax

+98 31 5546 6333

Email

Taghadosi_m@kaums.ac.ir

Postal code

87159/81151

Phone

+98 31 5263 9807

Email

Hamidehfatahpour@gmail.com

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

Information about the main outcome can be shared.

When the data will become available and for how long

Start the access period 4 months after publishing the results

To whom data/document is available

Researchers working in academia

Under which criteria data/document could be used

Use data to complete clinical trial studies

From where data/document is obtainable

trauma nursing research center, Kashan University of Medical Sciences Research Center

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

After the investigation of researcher request and presentation of required documents will be accessible.

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

Hamideh fatahpour

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Ravand Street, Kashan University of Medical Sciences

City

Kashan

Province

Isfahan