

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 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 Taghadasi

**Street address**

Ravand street, Shahid Beheshti Hospital

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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

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Ravand Street, Kashan University of Medical Sciences

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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 Taghadasi

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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

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**Full name of responsible person**

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**Position**

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**Latest degree**

Ph.D.

**Other areas of specialty/work**

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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

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