

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 2026

### Investigating the effect of education based on Roy's adaptation model on adherence to the treatment and medication regimen of patients with hypertension in comprehensive health centers affiliated of Shahid Beheshti University of Medical Sciences in Tehran in 2022

#### Protocol summary

##### Study aim

Determination the effect of education based on Roy's adaptation model on adherence to the treatment and medication regimen of patients with hypertension in comprehensive health centers affiliated of Shahid Beheshti University of Medical Sciences in Tehran in 2022

##### Design

Clinical trial with 2 randomized parallel groups on 134 patients

##### Settings and conduct

comprehensive health care centers of Shahid Beheshti University of Medical Sciences

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with hypertension; administration of antihypertensive medications.  
Exclusion criteria: Unwillingness to participate in the study; patients who can't be educated due to psychological disorders.

##### Intervention groups

In intervention group, participants will be educated based on Roy's Adaptation Model. Participants in control group will be educated based on the routine of the health center.

##### Main outcome variables

Adherence to medication regimen, adherence to treatment plan, Blood Pressure

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220502054719N1**

Registration date: **2022-05-27, 1401/03/06**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-05-27, 1401/03/06**

Update count: **0**

##### Registration date

2022-05-27, 1401/03/06

##### Registrant information

###### Name

Amirmohamad Amidi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 44 3348 1678

###### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-05-15, 1401/02/25

##### Expected recruitment end date

2022-06-05, 1401/03/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigating the effect of education based on Roy's adaptation model on adherence to the treatment and medication regimen of patients with hypertension in comprehensive health centers affiliated of Shahid Beheshti University of Medical Sciences in Tehran in 2022

**Public title**

Investigating the effect of RAM on adherence to treatment and medication regimen of hypertensive people

**Purpose**

Other

**Inclusion/Exclusion criteria****Inclusion criteria:**

Diagnosed as a hypertensive patient by a physician  
Taking anti-hypertension medications  
Being able to read and write  
Covered by a comprehensive health center  
Minimum age 18 years old and maximum age 60 years old

**Exclusion criteria:**

Unwillingness to participate in the study

**Age**

From **18 years** old to **60 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **134**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Cluster randomized method will be used in this clinical trial. At first a list of health care centers affiliated to Shahid Beheshti University of Medical Sciences will be attained (North, Shemiranat and East). Then a zone will be chosen randomly and 2 health care centers will be chosen by draw randomly as clusters. Name of health centers will be put into same balls and they will be put into a pot, after mixing the balls one ball will be chosen randomly and first ball chosen will be the health center considered as the cluster which interventions group will be chosen from there. The second ball chosen will be the health center considered as the cluster which control group will be chosen there. Then participants will be chosen from each cluster by random table number. It means intervention group and control group are chosen before using random number table. So random number table will not determine which patient will be in intervention group or control group because intervention group and control group has been chosen by draw before. One health center is the intervention group and the other one is the control group by draw as explained. Therefore it is clear that each health center is chosen as a cluster and it is clear that which cluster contains intervention group and the other cluster contains control group. Then among all patients available for intervention or control group 67 patients will be chosen for each group by random number table. In the end in each of intervention and control groups a number will be given to all patients available then the numbers will be organized in columns or rows and researcher will choose randomly the starting point by eyes closed and a pen and first numbers chosen by eyes closed will be considered as chosen samples. By choosing each number the next number will be chosen among bigger numbers. Then

choosing numbers randomly will be continued by eyes closed until 67 patients be chosen for each group.

**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**

Iran national committee for ethics in biomedical research

**Street address**

Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town, Tehran, Iran.

**City**

Tehran

**Province**

Tehran

**Postal code**

ندارد

**Approval date**

2022-04-26, 1401/02/06

**Ethics committee reference number**

IR.SBMU.PHARMACY.REC.1401.031

**Health conditions studied****1****Description of health condition studied**

Hypertension

**ICD-10 code**

I15.9

**ICD-10 code description**

Secondary hypertension, unspecified

**Primary outcomes****1****Description**

Adherence to treatment plan

**Timepoint**

Before intervention and after intervention

**Method of measurement**

Hill-Bone High Blood Pressure Compliance Scale

## 2

### **Description**

adherence to medication regimen

### **Timepoint**

Before intervention and after intervention

### **Method of measurement**

Morisky Medication Adherence Scale (mmas-8)

## 3

### **Description**

Blood Pressure

### **Timepoint**

Before intervention and after intervention

### **Method of measurement**

Sphygmomanometer available in the health care center.

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: People with hypertension are randomly divided into 4 groups, each group includes 8 or 9 patients. Each session lasts 45-60 minutes. In each session patients will be educated about one mode of Roy's adaptation model. Based on data collected from Pre-test session patients will be educated about each mode of Roy's model in separate sessions. In session 2 patients will be educated about physiologic mode like: education about the effect of medications in controlling hypertensive situations. Education about when can they stop taking their medications and about exercising and its effects and also what can happen if they spontaneously stop taking their medications. In session 3 Patients will be educated about self-concept mode: The effect of managing stress and anxiety in preventing of hypertensive situations, talking about stressful factors to intimate people and friends to lessen anxiety, talking about stress managing skills. In session 4 patients will be educated about role function mode: Educating about the importance of being among family and in society and taking advise from successful people in controlling hypertension. Educating about controlling blood pressure twice a week and taking to their physician each 3 week about status of hypertension and medications they take. In session 5 patients will be educated about interdependence mode: Educating about talking about stressful factors to family members to reduce stressful moments, importance of gaining support from family and the effect of family members and friends in improving adherence to treatment plan and medication regimen. And educating about how religious beliefs parallel to care plan can improve the adherence to treatment and medications. At the end of sessions a needs assessment form will be given to participants to see if they need more education or not.

#### **Category**

Lifestyle

## 2

### **Description**

Control group: People with hypertension. In this group, clients will be educated about hypertension same as the routine of that health center.

### **Category**

Lifestyle

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Not chosen yet

##### **Full name of responsible person**

Not chosen yet

##### **Street address**

Not chosen yet

##### **City**

Tehran

##### **Province**

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##### **Postal code**

تا زمان اخذ مجوز نمو

##### **Phone**

+98 21 2248 7057

##### **Email**

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## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Shahid Beheshti University of Medical Sciences

##### **Full name of responsible person**

Dr. Afshin Zarghi

##### **Street address**

Chamran blvd, yemen st. building 2

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

مشخص نیست

##### **Phone**

+98 21 2243 9780

##### **Email**

info@sbmu.ac.ir

#### **Grant name**

#### **Grant code / Reference number**

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

No

#### **Title of funding source**

Thesis Budget

#### **Proportion provided by this source**

70

**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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Amirmohamad Amidi

**Position**

Master of Public Health Nursing Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available