

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)

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+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 intervention 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

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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

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مشخص نیست

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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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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