

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 2026

### Designing a mobile app for the control of essential hypertension, based on the PRECEDE-PROCEED model, and evaluation of its effectiveness on patients' self-management compared to the usual care

#### Protocol summary

##### Summary

This study will be conducted with the goal of designing and developing Self-management education & support package for hypertensive patients, in the form of a mobile app. Moreover, it aims to evaluate its effectiveness against the usual care. The study will be conducted as a controlled clinical trial. The participants will be selected from the patients attending the Tehran Heart Center Clinic and will be randomly assigned to two groups of intervention and control. Inclusion criteria: The diagnosis of essential hypertension –without its complications, patients aged 30 – 60 years, having a Smartphone and/or tablet, the ability to read Persian, inclination to participate in the study, being medically treated for hypertension, intention to reside in the site of the study for the next 6 months. Exclusion criteria: presence of other cardiovascular diseases, diabetes mellitus, physical disability. The intervention consists of an educational – support package in the form of a mobile app for controlling the determinant factors of hypertension and adherence to treatment. The content of this application has been developed based on a 'needs assessment' performed on hypertensive patients receiving medical treatment. The participants of the intervention group will keep receiving their medical treatment as well as being given the package. The outcomes of this study include adherence to hypertensive drug therapy, adherence to the DASH diet and sodium reduction, regular monitoring of blood pressure, predisposing –enabling & reinforcing factors of adherence to the treatment of primary hypertensive patients, hypertension, the usability of the application, rate of satisfaction of the application.

#### General information

##### Acronym

Blood Pressure Management application(BPMap)  
**IRCT registration information**  
IRCT registration number: **IRCT2015111712211N2**  
Registration date: **2016-01-01, 1394/10/11**  
Registration timing: **prospective**

Last update:  
Update count: **0**  
**Registration date**  
2016-01-01, 1394/10/11

**Registrant information**  
**Name**  
Mahnaz Ashoorkhani  
**Name of organization / entity**  
Tehran University of Medical Sciences  
**Country**  
Iran (Islamic Republic of)  
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+98 21 8897 5660  
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ashoorkhani@farabi.tums.ac.ir

**Recruitment status**  
**Recruitment complete**  
**Funding source**  
The study will be conducted with the financial support of Tehran University of Medical Sciences and Tehran Heart Center..

**Expected recruitment start date**  
2016-02-04, 1394/11/15  
**Expected recruitment end date**  
2016-05-04, 1395/02/15  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**

empty

### Scientific title

Designing a mobile app for the control of essential hypertension, based on the PRECEDE-PROCEED model, and evaluation of its effectiveness on patients' self-management compared to the usual care

### Public title

Evaluation of the effectiveness of a mobile app for self-management of hypertension

### Purpose

Supportive

### Inclusion/Exclusion criteria

Inclusion criteria: The diagnosis of essential hypertension, without its complications, such as cardiovascular accidents etc ; Being medically treated for hypertension ; Age of patients between 30 and 60 years ; Having a Smartphone and/or tablet ; The ability to read Persian ; Inclination to participate in the study ; Intention to reside in the site of study for the next 6 months Exclusion criteria: Presence of other cardiovascular diseases ; Diabetes mellitus ; Physical disability

### Age

From **30 years** old to **60 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **132**

### Randomization (investigator's opinion)

Randomized

### Randomization description

### 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 Tehran University of Medical Sciences

##### Street address

Tehran University of Medical Sciences, Central Building, Qods St., Keshavarz Blvd., Tehran, Iran.

##### City

tehran

### Postal code

### Approval date

2015-10-04, 1394/07/12

### Ethics committee reference number

IR.TUMS.REC.1394.872

## Health conditions studied

### 1

#### Description of health condition studied

primary hypertension

#### ICD-10 code

I10

#### ICD-10 code description

Essential (primary) hypertension

## Primary outcomes

### 1

#### Description

Adherence to hypertensive drug use

#### Timepoint

Before the intervention - two months after the intervention - 6 months after the intervention

#### Method of measurement

Hill bone questionnaire

### 2

#### Description

adherence to the DASH diet and sodium reduction

#### Timepoint

Before the intervention - two months after the intervention - 6 months after the intervention

#### Method of measurement

questionnaire

### 3

#### Description

hypertension

#### Timepoint

Before the intervention and upon every visit - the blood pressures recorded in the application

#### Method of measurement

Mercury sphygmomanometer

### 4

#### Description

regular monitoring of blood pressure

#### Timepoint

three times in week

#### Method of measurement

register in application

### 5

#### Description

predisposing -enabling & reinforcing factors of

adherence to treatment of primary hypertensive patients

### **Timepoint**

Before the intervention – two months after the intervention – 6 months after the intervention

### **Method of measurement**

questionnaire

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

Interventions: Intervention group: Intervention group one, in addition to the usual care, the educational – supportive intervention (usual care plus intervention) will be carried out by installing the software on the Smartphone. This application has been developed with the goal of allowing self-management for the optimum detection and control of the determinant factors of hypertension and overcoming the barriers to adherence (BPMapp=blood pressure management application). The items available in the application are: reminder for drug use, the doctor's appointment, physical activity, blood pressure measurement • Reminder for drug use, doctor's appointment, physical activity, blood pressure measurement • Knowledge information on the disease, its etiology, causes of disease, influential factors of disease control • Knowledge information, encouragement and reminders for quitting and reduction of smoking • Guidance and provision of a healthy nutritional diet (DASH and low-salt diet) and a weight reduction diet based on BMI and other personal characteristics • The recording of blood pressure in the application and provision of advice appropriate to the recorded rate • Delivery of data to the physician and researcher A session will be held during which the intervention group's participants will be briefed on the goals of the study and the research team's expectations. The application will be installed on their mobile phones and they will be taught how to operate it. Based on their drugs and individual characteristics, the patients will then set their applications accordingly. They will operate the application in the presence of the research team, so that, if any problem arises it may be resolved by the research team. The patients will then be examined at the clinic once every two weeks. Control group: The second group will receive the usual care. The usual care consists of blood pressure measurement, responding to the patient's questions, prescription of earlier drugs or changing the drug used and explaining its method of use, in accordance with the patient's circumstances and the specialist's opinion.

#### **Category**

Prevention

## **Recruitment centers**

### **1**

#### **Recruitment center**

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

Tehran Heart Center Hospital

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

Dr. Ali Bozorgi

##### **Street address**

Tehran Heart Center Hospital- North Kargar-Ave ,  
Tehran-Iran

##### **City**

Tehran

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

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

Tehran University of Medical Sciences

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

Dr Masoud yunesian

##### **Street address**

Deputy of Research and Technology, Tehran  
University of Medical Sciences, 6th floor, Central  
Building, Qods St., Keshavarz Blvd., Tehran, Iran.

##### **City**

Tehran

#### **Grant name**

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

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

Yes

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

Tehran University of Medical Sciences

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

100

#### **Public or private sector**

*empty*

#### **Domestic or foreign origin**

*empty*

#### **Category of foreign source of funding**

*empty*

#### **Country of origin**

#### **Type of organization providing the funding**

*empty*

## **Person responsible for general inquiries**

#### **Contact**

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

Faculty of Health-Tehran University of Medical  
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##### **Full name of responsible person**

Mahnaz Ashoorkhani

##### **Position**

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##### **Other areas of specialty/work**

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ashoorkhani@farabi.tums.ac.ir

**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*