Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Sep 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

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Mahnaz Ashoorkhani
Name of organization / entity
Tehran University of Medical Sciences
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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 (BPMap=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 Sciences

Full name of responsible person

Mahnaz Ashoorkhani

Position

PhD Candidate in Health Education and promotion

Other areas of specialty/work

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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