Effect of the Blood Pressure Management Application (BPMAP) on Hypertension Self-Management Enhancement: A Randomized Clinical Trial

CURRENT STATUS: UNDER REVIEW

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DOI:
10.21203/rs.2.1820/v1

SUBJECT AREAS
General Medicine
KEYWORDS
Mobile Health, Hypertension, Medication Adherence, Self-Management
Abstract

Background

Self-management of Blood pressure is of great significance given the increasing incidence of hypertension and associated disabilities. With the increased use of mobile health in medicine, the present study evaluated the effect of the self-management application on patient adherence to hypertension treatment.

Methods

This clinical trial was performed on 120 hypertensive patients who were provided with BPMAP for 8 weeks and followed-up to 24th weeks. Data on the primary outcome (adherence to treatment) and secondary outcomes (adherence to the DASH diet, regular monitoring of blood pressure, and physical activity) were collected using a questionnaire and a mobile application, respectively. The inter-group change difference over time was analyzed using repeated measures ANOVA (General Linear Model).

Results

The treatment adherence score increased by an average of 5.9 (95%CI: 5.0-6.7) in the intervention group compared to the control group. Scores of adherence to the low-fat and low-salt diet plans were 1.7 (95%CI: 1.3-2.1) and 1.5 (95%CI: 1.2-1.9), respectively. Moreover, moderate physical activity increased to 100.0 minutes (95%CI: 61.7-138.3) per week in the intervention group.

Conclusion

The treatment and control of blood pressure require a multifaceted approach given its complexity and multifactorial nature. Considering the widespread use of smartphones, m-Health interventions can be effective in self-management and better patient adherence to treatments. Our results showed that BPMAP can be used as a successful tool for hypertension self-management in patients attending public hospitals in developing
countries.

Background

The number of people with hypertension and hypertension-related mortality have increased dramatically over the past 25 years (1). By the year 2025, approximately one out of every three individuals are expected to suffer from high blood pressure (2). The mortality rate of over 140mmhg systolic blood pressure reached 106.3 million in 2015 from 9.97 million in 1990. In addition, the disability-adjusted life year (DALY) has risen from 9.95 million to 143 million during the same period (1). The majority of hypertension-induced problems occur in low- and middle-income countries, imposing great individual and governmental costs on health systems (3).

Despite effective pharmacological and non-pharmacological treatments for hypertension (healthy lifestyle, regular physical activity, avoiding smoking and alcohol, DASH diet, and low-salt diet plan) (2, 4, 5), and ample evidence pointing to the role of blood pressure control and consideration of associated risk factors in hypertension control, patients do not adhere to treatments appropriately (3, 6).

Mobile phones are widely used nowadays by people all over the world. The innovative use of smartphone features can effectively reduce healthcare costs and improve the welfare of all individuals (7).

Mobile phone applications have increasingly reduced disease-related costs in developed countries in the past decade (4, 5, 8, 9). They provide a low-cost method for health intervention, and have been consequently stressed in developing countries (10, 11).

The present study aimed to evaluate the effectiveness of BPMAP in promoting the adherence of hypertensive patients to pharmacological and non-pharmacological treatments visiting a university medical center in Iran.
Methods

Study design
This was a randomized, controlled clinical trial (IRCT2015111712211N2) with two parallel arms designed to demonstrate the effect of BPMAP (Supplementary file1) on self-management of hypertensive patients in adherence to the treatment and control of hypertension risk factors (12). Writing this article is guided by the CONSORT 2010 checklist (See additional file 1).

Study setting
Tehran Heart Center is a third-level cardiovascular subspecialty medical center affiliated to Tehran University of Medical Sciences. The center admits about 113,000 outpatients, 24,000 hospitalized patients, and performs 4,000 open heart surgeries each year (13).

Participants
The participants included patients with primary hypertension diagnosed and confirmed by their physician. Inclusion criteria were the 30-60-year age range, literacy, treatment of hypertension during the past year, possession of and ability to use a smartphone, willingness to participate in the study, and residence in the study region throughout the study. Exclusion criteria were hypertension complications such as myocardial infarction, stroke, other cardiovascular diseases, diabetes, and physical disability.

Interventions
Participants in the intervention group received a mobile application-based educational-supportive intervention, along with the routine treatment. The content and features of the application were prepared based on the educational needs of hypertensive patients (14). The application had the following features; a) recording blood pressure and receiving feedback of the recorded blood pressure, b) saving the recorded blood pressure levels and plotting them as a chart, c) reminding the time of drug consumption, visit date, and blood
pressure measurement, d) healthy diet (DASH and low-salt diet) and weight loss plans, e) knowledge-based information on the nature, control, and treatment of the disease, f) motivational and supportive programs for smoking cessation g) sending notifications or informing one of the patient’s family members of critical blood pressure levels, h) sending general motivational messages and reminders about adherence to treatment to all patients and specific individual messages based on patient characteristics, and i) saving the recorded information by users on the portal for physicians and researchers.

Participants in the comparison arm received the usual treatment including clinical examinations, such as measurement of blood pressure and weight, patient history, laboratory tests and paraclinical services tailored to individuals’ conditions, drug treatment according to the JNC8, recommendations and answers to patient questions.

Outcomes (Primary and secondary)

Adherence to antihypertensive medication was considered as the primary outcome, assessed with the 14-item Hill-Bone Scale (15). The secondary outcomes included clinical and behavioral outcomes, such as adherence to DASH diet, reduced sodium and fat intake, regular blood pressure monitoring, physical activity, predisposing, enabling, and reinforcing factors in adherence to treatment.

Adherence to DASH diet and sodium reduction: The intake of salt, fat, low-fat dairy products, fruits, and vegetables over the past week was evaluated.

Regular blood pressure monitoring: The frequency of blood pressure in the application was recorded in the study period.

Physical Activity: The degree of change in the frequency and time allocated to physical activity was evaluated in two categories of moderate and severe physical activity.

Predisposing, enabling, and reinforcing factors in adherence to treatment: The effect of these factors was evaluated based on the questionnaire items.
**Sample size**

Group sample size of 60 and 60 (120 people in both group) achieve 80 power to detect at least 5 score (SD= 10) difference on the Hill-Bone Compliance to high blood pressure (15) using two sided T test at the significance level of 5%.

**Randomization**

Patients were referred to the physician to assess the inclusion and exclusion criteria after obtaining informed consent. The baseline survey was then completed, and the participants were randomly divided into two groups. Randomization was performed using a randomized website with block sizes of four. The allocation ratio was 1:1 for each arm. Patients from each group were visited at two different schedules.

**Implementation**

Individuals were given one week to review and consult with the family to read and sign the informed consent form. After approval by the assessor physician, the initial assessment questionnaire was completed by a trained interviewer (Fig. 1). The application was installed on the mobile phones of the intervention group and described to individual patients. Patients’ sphygmomanometers were calibrated at the application installation time to ensure correct measurement of blood pressure at home.

**Follow-up assessments**

Participants in both groups had an initial visit and six follow-up visits. The first 5 visits were performed with a two-week interval and the last one 24 weeks after the first visit (Table 1). In both groups, clinical evaluation and the questionnaire completion were done at baseline, eight weeks after receiving the application, and at the 24th week.

**Data collection methods**

The primary outcome was measured by the Hill-Bone Scale and secondary outcomes by a mercury sphygmomanometer and the researcher-made questionnaire.
The questionnaire contained patients’ demographic information, treatment status, some health-related behaviours as the initial assessment. A number of the PRECEDE model constructs (predisposing, enabling, and reinforcing factors), the World Health Organization STEPS questionnaire for monitoring chronic risk factors, (16), the Hill-Bone Compliance Scale, and the Global Physical Activity Questionnaire (GPAQ) guide were used in its design (17). The questionnaire validity and reliability were evaluated and confirmed.

Data management

Patients’ information was obtained from the self-report questionnaire and the application. When connected to the Internet, all user clicks in the application were stored on the portal (Supplementary file 2, table 1). The final databank was prepared in SPSS. A double entry was made to ensure that the data was entered correctly. In the event of any discrepancy, the information entered was verified with the initial data.

Statistical methods

Quantitative variables were reported as mean (standard deviation) and qualitative variables as frequency (frequency percentage). To evaluate the effectiveness and observe the changes over the predicted time, the produced content was used in the form of a piece of software including adherence of hypertensive patients to the pharmacological therapy, adherence to the DASH diet, adherence to regular blood pressure monitoring, knowledge enhancement, attitude improvement, and self-efficacy of the Repeated Measurement ANOVA (GLM) test. Changes in the baseline data were entered as the covariate, and the second and third measurements as the repeated variable. The intervention group was selected as the comparison variable.

Results

This study was conducted from September 2016 to August 2017 on 120 people. One participant in the intervention group was excluded from the study due to immigration. In
terms of gender, 56.9% and 60% of the participants in the intervention and the comparison groups were male, respectively. The mean hypertension duration was about 7 years in the intervention group and about 8 years in the comparison group. The mean arterial pressure (MAP) was 108±13.5 in the intervention group and 115±14.3 in the comparison group. The mean medication adherence score was 58.5± 7.4 in the intervention group and 59±5.0 in the comparison group (Table 2).

Based on the Hill-Bone Scale, the mean adherence medication was 65.1(95%CI: 65.04-65.23) in the intervention group and 59.7(95%CI: 59.60-20.36) in the control group, indicating an improvement of 5.9 points (95%CI: 5.03-6.69) in the intervention group compared to the control group. (Table 3)

Adherence to the DASH diet was examined with 5 items. Three items were related to the dairy, fruit, and vegetable consumption. The findings indicated an increase in dairy, fruit, and vegetable consumption in the intervention group compared to the control group. In addition, subjects in the intervention group adhered to low-fat and low-salt diet plans better than the comparison group, so that the adherence to low-fat and low-salt diet plans increased by 1.7 points (95%CI: 1.30-2.10) and 1.5 points (95%CI: 1.16-1.90), respectively. (For more result see supplementary file 2. table 2).

The MAP decreased over time by an average of 3.4 mmHg (95%CI: 1.6-5.2) in the intervention group compared to the control group.

To monitor the blood pressure measurements, the recorded blood pressure measurements of the intervention group was introduced to the measurement scale software. A recording frequency of 30 times was expected in the intervention group. Recordings of more than 25 times were considered appropriate; 84.7% of the application users (50 people) had recorded their blood pressure in the application more than 25 times during the 2 months. (More result about using part of app was considered in supplementary file 2. table 2).
The mean estimated moderate physical activity over time was 247.3 (95%CI: 223.7-267.5) in the intervention group and 102.7 (95%CI: 100.4-176.8) in the control group, indicating an increase of 100.0 min per week (95%CI: 61.7-138.3) in the intervention group.

The predisposing factors of adherence to treatment (knowledge, attitude, and self-efficacy) in the intervention group led to an improvement of 2.9 points (95%CI: 1.6-4.2) in knowledge, 2.3 points (95%CI: 1.2-3.4) in attitude, and 1.7 points (95%CI: 1.3-2.2) in self-efficacy of patients.

The rate of satisfaction from the application was measured with a scale of 1-20 in each visit. The mean satisfaction rate of users from the application was 18.41 (Min: 16, Max: 20). Also usability was examined by a questionnaire at the end of the study.

(Supplementary file 2. table 3).

Discussion

Adherence to treatment in chronic diseases is of paramount importance, which is estimated at 50-60%. Currently, m-health is an increasingly used solution (18). The results of this study showed that the use of BPMAP by hypertensive patients resulted in an increase of 5.86 points in the patient adherence to medication than the routine treatment. Evidence suggests that 65% of m-health studies can increase the adherence to drug therapy, and in some cases were able to increase self-efficacy and self-care of patients by sending encouraging messages (19, 20). However, most of these studies have used text messages and notifications (20, 21). It seems that the present study had a significant effect on improving adherence to treatment due to paying attention to different aspects of adherence to treatment and the holistic view to it such as access to treatment knowledge, drug reminder, sending knowledge-based and single-sentence encouraging messages, recording of blood pressure measurement at home, and getting feedback about the recorded numbers.
In BPMAP users, the number of dairy, fruit, and vegetable meals was increased and the consumption of salt and fat was reduced. A study was conducted to improve the nutritional status using desktop computers, the results of which indicated an increase in the consumption of vegetables and cereal grains (22). The use of technology to improve the nutritional status appears to be effective. Although these studies have not examined the effect of evidence in the long term, it seems that the use of new technologies along with medical treatment is useful.

Blood pressure monitoring at home is increasingly accepted and used by patients and has appropriate and helpful impact on clinical interventions. In the present study, the effect of a blood pressure measurement reminder and increased knowledge of the disease has led to a regular monitoring of blood pressure at home. About 84.5% of BPMAP users measured and recorded their blood pressure more than 25 times over a period of 2 months. Measurement of blood pressure at home leads to the awareness of individuals of their blood pressure and adherence to treatment, which can lead to an optimal blood pressure control (23).

Regular physical activity is one of the effective factors in controlling hypertension and improving patients’ health. In addition to knowledge about the importance of regular physical activity on appropriate blood pressure control, encouraging messages were sent to the application with three-day intervals, which increased the average physical activity of BPMAP users by 100 minutes per week. A similar finding was found in studies conducted in the United Kingdom (24) and Taiwan (25). Contradictory results were also reported on the ineffectiveness of encouraging messages on increased physical activity in a study by Nguyen in USA (26). Difference in the effectiveness encouraging messages can be attributed to the quality, relevance, and format of the sent messages. Accordingly, it is essential to pay attention to the indicators of effective messages when designing them.
Although pharmacological treatment are as important as non-pharmacological therapies in controlling blood pressure, in clinical settings, especially in non-private healthcare systems with many visits, non-pharmacological recommendations are not sufficiently considered. In these conditions, the use of other methods, such as providing enough and necessary information to patients would improve the level of knowledge, attitude, self-efficacy, and adherence to treatment. A systematic review by Marshall et al in 16 countries revealed that the lack of awareness about the causes and symptoms of hypertension, fear of the drugs side effects, and addiction to them are the major causes of treatment discontinuation and adherence to treatment (27, 28). In this study, BPMAP provided the users with the necessary knowledge which was identified in pre-intervention studies. Increasing the level of knowledge of people about the nature of hypertension and the necessary measures in self-management can help improve the adherence of individuals to pharmacological and non-pharmacological treatments. Therefore, the use of technologies such as mobile applications is recommended in these cases.

Conclusions

Hypertension is a multifactorial disease whose proper control requires a multifaceted approach. In addition to regular consumption of drugs, patients also need to fully adhere to pharmacological and non-pharmacological recommendations. Utilizing smartphone capabilities can be a good alternative to drug therapy given their low costs and high penetration, in order to achieve this multifaceted goal. The present study showed that the proper use of BPMAP is effective in raising the level of knowledge, controlling the factors influencing adherence to treatment, and having access to family support. Considering that the participants of this study were visiting a non-private center in Iran, the authors believe that this approach could be a successful tool for self-management of hypertension in similar settings in many developing countries.
Abbreviations

BPMAP: Blood Pressure Management Application; PRECEDE: Predisposing, Reinforcing and Enabling Constructs in Educational Diagnosis and Evaluation; DASH: Dietary Approaches to Stop Hypertension; IPAQ: International Physical Activity Questionnaire; JNC: Joint National Committee; LDL: Low-density lipoprotein; HDL: High-density lipoprotein; BMI: Body Mass Index; MAP: Mean Arterial Pressure.

Declarations

Ethics approval and consent to participate

The protocol of this study was approved by the Ethics Committee of Tehran University of Medical Sciences with the license number IR.Tums.rec-1394-872. Written informed consent was obtained from all participants at the first visit exactly after observation of physician and appraisal the inclusion criteria.

Consent for publication

Not applicable

Availability of data and material

The data sets used and analysed during the current study are available from the corresponding author on reasonable request. The data cannot be presented, as the most important aspect of the intervention is the application and its online portal, which is in Persian, and is no value to the non-Persian speaking audience.

Competing interests

The authors declare that they have no competing interests.

Founding

This study is supported by Tehran University of Medical Sciences in the form of a PhD. thesis, taken up by Ms. Mahnaz Ashoorkhani, the student of health education and
promotion, under grant no. 94-02-102-29524. It will be conducted in association with the Tehran Heart Center.

Authors' contributions

MA conceived and designed the study, composed the content, conducted the implementation procedures, managed the project, and drafted the manuscript. HE, RM, AB, HH, AY, and AR contributed to the study design and procedures. MA and AB contributed to the intervention content. MA, AB, and HH conducted the recruitment and evaluation. MM contributed as a coding and programming the application. All authors read and approved the final manuscript.

Acknowledgements

This study is supported by Tehran University of Medical Sciences in the form of a PhD. thesis, taken up by Ms. Mahnaz Ashoorkhani, student of health education and promotion, under grant no. 94-02-102-29524. It will be conducted in association with the Tehran Heart Center. We would also like to acknowledge the whole of participants in current study.

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Tables

Table 1: Steps were taken in each visit in both gropes
| Close-out | Post allocation | Allocation | Enrollment |
|-----------|----------------|------------|------------|
| 24±2 days | 8±2 days       | 6±2 days   | 4±2 days   |
| 7th visit | 6th visit      | 5th visit  | 4th visit  |
| 0±2 days  | 0±2 days       | 0±2 days   | 0±2 days   |

| Study period |
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Table 2- Baseline characteristics of the study population
| Characteristics                          | Intervention group | Control     |
|-----------------------------------------|--------------------|-------------|
| **De demo graphic**                     |                    |             |
| Age (year. mean±SD) *                   | 51.9± 5.1          | 51.6± 9.6   |
| Sex (male)                              | 33(56/9)           | 36(60)      |
| Marital status                          |                    |             |
| Alone N (%)                             | 3(5.2)             | 6(10)       |
| Living with family N (%)                | 55(94.8)           | 54(90)      |
| Educational status N (%)                |                    |             |
| Under diploma                           | 7(12.1)            | 7(11.7)     |
| Diploma                                 | 33(56.0)           | 26(43.3)    |
| Bachelor                                | 12(20.3)           | 20(33.3)    |
| Master and above                        | 6(10.1)            | 7(11.7)     |
| **History**                             |                    |             |
| Duration of Disease (year. mean±SD)    | 7.4±6.2            | 8.3±6.3     |
| Duration of taking medication (year. mean±SD) | 5.8± 5.4          | 6.4± 5.8   |
| Number of visits per year for hypertension(mean±SD) | 1.7± 2.3          | 1.9± 1.5   |
| Frequency of home blood pressure measurement N (%) |                    |             |
| A few times a week                      | 10(17.0)           | 8(13.3)     |
| Once a week                             | 7(12.1)            | 10(16.7)    |
| Once a month                            | 2(3.4)             | 9(15.0)     |
| Whenever I feel I'm not good            | 30(51.7)           | 29(48.3)    |
| Never                                   | 9(15.5)            | 4(6.7)      |
| Cholesterol (mg/dl, mean±SD)            | 179.5±39.2         | 196.7±39.2  |
| Triglyceride (mg/dl, mean±SD)           | 155.6±56.3         | 163.0±48.0  |
| LDL(mg/dl, mean±SD)                     | 107.2±24.0         | 105.6±12.0  |
| HDL(mg/dl, mean±SD)                     | 47.5±12.0          | 51.9±15.5   |
| FBS(mg/dl, mean±SD)                     | 96.7±17.4          | 96.8±17.4   |
| MAP*                                    | 108.1±13.5         | 114.9±13.5  |
| BMI(mean±SD)                             | 29.7±3.4           | 28.5±3.1    |
| **characteristics**                      |                    |             |
| Adherence to medication/hill bon checklist(mean±SD) 3* | 58.5±7.4          | 59.1±5.1    |
| Adherence to medication/self-assessment(mean±SD) 2* | 15.2±4.6          | 17.0±3.0    |
| Adherence to low-fat diet (mean±SD)2*    | 16.0±3.0           | 15.8±3.0    |
| Adherence to low-salt diet (mean±SD)2*   | 14.3±5.7           | 15.8±3.0    |
| Vigorous physical activity (mean±SD) 4*  | 162.2±83.2         | 162.0±13.2  |
| Moderate physical activity(mean±SD) 5*  | 169.4±132.8        | 113.0±7.5   |
| Knowledge(mean±SD) 6*                    | 2.7±2.3             | 2.1±1.2     |
| Attitude(mean±SD) 7*                     | 23.1±5.4            | 23.8±4.1    |
| Self- efficacy(mean±SD)2*                | 16.2±2.0            | 14.7±2.0    |

1*(range: 65-30), 2* (range: 1-20), 3* (range: 14-70), 4* (range: 0-150min), 5* (range: 0-300min), 6* (range: 1-7), 7*(range: 1-35),*

Table 3- Outcome variables were taken just before intervention, 8th week and 24th week as final visit, with changes between visits and group differences.
Mean change over time (% 95CI)

|                | 24th week mean ± SD | 8th week mean ± SD | Baseline assessment mean ± SD | Groups               |
|----------------|----------------------|---------------------|-------------------------------|---------------------|
| **5.9 (5.0 - 6.7)** | 66.1 ± 2.00          | 65.1 ± 2.44         | 58.5 ± 7.42                   | Intervention group  |
|                | 59.9 ± 3.51          | 59.7 ± 3.69         | 59.1 ± 5.07                   | Control group       |
| **1.9 (1.5 - 2.3)** | 19.7 ± 0.71          | 19.5 ± 0.86         | 15.3 ± 4.64                   | Intervention group  |
|                | 18.0 ± 1.50          | 18.4 ± 1.91         | 17.0 ± 3.14                   | Control group       |
| **1.5 (1.2 - 1.9)** | 18.59 ± 0.91         | 18.40 ± 1.18        | 14.3 ± 5.7                    | Intervention group  |
|                | 17.12 ± 1.41         | 17.30 ± 1.87        | 15.8 ± 3.4                    | Control group       |
| **1.7 (1.3 - 2.1)** | 18.21 ± 0.78         | 17.86 ± 1.06        | 16.0 ± 3.0                    | Intervention group  |
|                | 16.66 ± 1.72         | 17.13 ± 1.78        | 15.8 ± 3.3                    | Control group       |
| **1.2 (0.77 - 3.2)** | 28.6 ± 3.2           | 29.3 ± 3.5          | 29.7 ± 3.4                    | Intervention group  |
|                | 28.4 ± 3.7           | 30.2 ± 15.5         | 28.5 ± 3.6                    | Control group       |
| **3.4 (1.6 - 5.2)** | 94.8 ± 3.42          | 95.5 ± 3.66         | 108.1 ± 13.5                  | Intervention group  |
|                | 100.1 ± 7.20         | 98.9 ± 6.84         | 114.9 ± 14.30                 | Control group       |
| **97.3 (41.1-153.1)** | 173.3 ± 68.6         | 195.0 ± 79.9        | 162.2 ± 83.2                  | Intervention group  |
|                | 56.7 ± 18.9          | 140.20 ± 69.3       | 162.0 ± 100.8                 | Control group       |
| **100.0 (61.7-138.3)** | 247.3 ± 96.29        | 260.9 ± 115.9       | 169.4 ± 132.8                 | Intervention group  |
|                | 102.7 ± 53.33        | 154.6 ± 135.47      | 113.0 ± 72.9                  | Control group       |
| **2.9 (1.6-4.2)** | 6.4 ± 1.2            | 6.4 ± 1.2           | 2.7 ± 2.3                     | Intervention group  |
|                | 3.1 ± 1.4            | 2.6 ± 1.2           | 2.1 ± 1.2                     | Control group       |
| **2.3 (1.2-3.4)** | 24.55 ± 4.97         | 26.4 ± 2.82         | 23.0 ± 5.43                   | Intervention group  |
|                | 22.68 ± 4.48         | 24.13 ± 3.45        | 23.8 ± 4.47                   | Control group       |
| **1.7 (1.3-2.2)** | 16.9 ± 1.41          | 16.9 ± 1.42         | 16.18 ± 2.03                  | Intervention group  |
|                | 14.6 ± 1.58          | 14.5 ± 1.76         | 14.75 ± 2.30                  | Control group       |

*(range 1-20), 2*(0-150 min) 3* (0-300 min), 4* (range 1-7), 5* (range 1-35)

Figures
Figure 1

Trial flow diagram. The procedure of the study evaluating the impact of the Blood Pressure Management Application (BPMAP).
Supplementary Files

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