Self-Monitoring of Blood Pressure and Feedback via Mobile App in Treatment of Uncontrolled Hypertension: the SMART-BP Randomized Clinical Trial

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Abstract

Objective: To evaluate the effects of mobile apps with tailored recommendations on changes in blood pressure (BP) and drug adherence.

Patients and Methods: This study is a randomized, open-label, multicenter trial to evaluate the efficacy of self-monitoring of blood pressure (SMBP) with a mobile application-based feedback algorithm (SMBP-app with feedback) compared with SMBP-alone. Patients with uncontrolled hypertension aged ≥19 years were randomly assigned. In the control group, the patients only measured their BP at home using the mobile app combined with a Bluetooth BP monitor and received standard care, whereas in the intervention group, the patients could also receive alerts for BP measurement, and additional recommendations from the app using a feedback algorithm in response to the obtained BP value. The primary endpoint was the change in mean home systolic BP at 24 weeks.

Results: From September 2019 to July 2020, 184 patients were randomized into SMBP-app with feedback (n=97) and SMBP-alone groups (n=87). At 24 weeks, the mean home systolic BP reduction from baseline was significantly greater in the SMBP-app with feedback group than in the SMBP-alone group (-22.4±13.5 vs. -17.2±13.3 mmHg, *P*=.02). The SMBP-app with feedback group showed higher drug adherence and proportion of adherence ≥95% than the SMBP-alone group.

Conclusion: The SMBP-app with feedback is superior to SMBP-alone in terms of systolic BP reduction and improved drug adherence in patients with hypertension. Given the high cost of traditional interventions between patients and healthcare providers, feedback through mobile apps could potentially be a useful tool in the management of hypertension.

Trial registration: ClinicalTrial.gov (NCT04470284)

Keywords: hypertension; blood pressure; self-monitoring blood pressure; digital health; mobile applications; feedback; medication adherence

Abbreviations

AI: artificial intelligence

BP: blood pressure

CDSS: Clinical Decision Support System

DBP: diastolic blood pressure

eCRF: electronic case report form

SMBP: self-monitoring of blood pressure

SBP: systolic blood pressure

Background

Hypertension is a major risk factor for cardiovascular disease, whereas blood pressure (BP) levels below the target range have been linked to a reduction in cardiovascular events.[1,2] However, more than half of patients with hypertension cannot achieve their target BP.[3-5] Although various factors contribute to inadequate hypertension control, drug adherence is one of the most crucial contributors, considering that only less than half of all patients with hypertension are adherent.[6,7] Therefore, increasing drug adherence may alleviate the low BP control rate.[8]

Self-monitoring of BP (SMBP) has been known to improve medication adherence and reduction in BP, either through better drug adherence and compliance or lifestyle modification,[9,10] and therefore is recommended by the hypertension practice guidelines.[11-14] However, recent studies have shown that SMBP alone is insufficient to lower BP without other co-interventions, such as drug adjustment and feedback by health care providers, education, and lifestyle counselling.[15,16] The combination of SMBP and medication intensitifcation is associated with improved hypertension control, and the BP-lowering effects of SMBP appear to be proportional to the intensity of the co-intervention.[16,17] Although direct intervention or feedback by health care providers is the most effective means, it is also associated with higher costs, and more manpower and infrastructure, and not easy to implement in real clinical practice

The development of mobile health technology and artificial intelligence (AI) have enabled patient self-care, monitoring, as well as mobile-based feedback via smart phone applications (apps). Recent studies using smartphone apps for the self-management of

patients with hypertension showed that mobile technology intervention was associated with a greater reduction in BP than in control groups.[18-25] However, these previous studies had a small number of participants and limited app functionality. Self-monitoring and feedback are particularly important, and the lack of these critical features limits the interpretation of the effectiveness of hypertension apps. Moreover, a recent study by Morawski et al.[26] showed that smartphone apps only slightly improved self-reported medication adherence, but offered no change in systolic BP (SBP) when compared with control, which was inconsistent with previous studies. There is a possibility that the heterogeneous and diverse functions of mobile intervention, including feedback or level of self-monitoring, might be associated with the benefits of mobile apps.[19-21,27]

Considering the uncertainty of the benefits of mobile apps in reducing BP in patients with hypertension, we developed a mobile health platform to provide tailored recommendations for patients with hypertension. The mobile app provides an alert for BP measurements, records BP, and provides specific recommendations in response to the obtained value using sophisticated feedback algorithms, distinguishing it from previous apps. We evaluated whether this mobile health app with feedback can help reduce BP and increase drug adherence when compared to SMBP-alone in patients with hypertension.

Methods

Study design

Self-Monitoring of Blood Pressure and Feedback using app in Treatment of

Uncontrolled Hypertension (SMART-BP) study is a prospective, randomized, open-label, multicenter trial to evaluate the efficacy of SMBP with a mobile application-based feedback algorithm (SMBP-app with feedback) when compared with SMBP-alone. Enrollment began in September 2019 and was completed in July 2020 at five tertiary hospitals in Korea. The study design has been registered in ClinicalTrial.gov (NCT04470284), and the details of the trial design have been previously published.[28] This clinical trial was approved by the institutional review board of each of the five centers (Seoul National University Bundang Hospital, Kyunghee University Hospital, Korea University Guro Hospital, Samsung Medical Center, and Hallym University Medical Center). The study was conducted in accordance with the Declaration of Helsinki and all patients provided written informed consent upon enrollment.

Study population

We enrolled patients with uncontrolled hypertension aged ≥ 19 years with an SBP of ≥ 140 mmHg or a diastolic BP (DBP) of ≥ 90 mmHg who were receiving at least one antihypertensive medication. Office BP was measured three times on the reference arm in the sitting position, and average values were used. The reference arm was defined as the arm with the higher BP. Only those who could use Android smartphones were screened for inclusion in the study. To identify patients with uncomplicated essential hypertension, we excluded patients with a history of secondary hypertension or suspected secondary hypertension or those whose BP was greater than 200/110 mmHg at the screening visit. We also excluded individuals with uncontrolled diabetes and significant kidney and liver disease. The detailed inclusion and exclusion criteria are listed in Supplemental Table 1. At baseline (Visit 1), all

participants were assessed for sex, age, demographics, BP, comorbidities, and medication use.

Randomization and masking

After enrollment, patients were randomly assigned to the SMBP-app with feedback (intervention) or SMBP-alone (control) groups in a 1:1 ratio. Randomization was performed by the research nurses using restricted block randomization derived from SAS version 9.2 (SAS Institute, Cary, NC, USA). Study participants and investigators including physicians and research nurses interacting with patients were not blinded to group allocation. Data analysts remained blinded until all follow-up data were collected and primary analysis strategies were finalized.

Intervention and application

For the current study, we used a Bluetooth-enabled BP monitor UA-651BLE (A&D Medical, Sidney, Australia), a commercially available BP cuff that is approved for home use because of its high accuracy.[29] According to the five steps of the system development process, we implemented the SMBP platform with a mobile app and the electronic case report form (eCRF)-Lite system (Supplemental Figure 1 and 2). The mobile app could be downloaded from Google Play Store and the eCRF Lite system provided information for physicians to monitor the patients' BP status. Details of the platform were described in a previously published design paper and in the supplemental methods in the Supplemental material.[28]

In summary, the platform was composed of four parts: (i) BP recorder, (ii) Knowledge Base Reasoner, (iii) Database Lite, and (iv) the eCRF-Lite system (Supplemental Figure 3). The “BP Recorder” comprised a BP-monitoring app, equipped with 5 different functionalities, such as user authentication, user registration, dashboard, BP monitoring graph, and recommendation screens (Supplemental Figure 4). The recorder connected the smartphone application with the BP-monitoring device via Bluetooth. When the users measured their BPs, the SBP, DBP, and heart rate values were sent to the mobile app. The app then activated the reasoner to provide recommendations based on the calculated values. The “Knowledge Base Reasoner”, a core component of the Clinical Decision Support System (CDSS), was used to create shareable, interoperable, and executable clinical knowledge. It asks the users about their BP measurement, drug intake and symptoms (e.g., dizziness). The embedded algorithm in the Knowledge Base Reasoner analyzes the data input and generates recommendations for users, for example, an alarm message, if an abnormal BP is detected. “Database Lite” uses the SQLite database for the mobile app and the SQL Server for permanent storage on a cloud, and it stores the patients’ information using Data Model Manager, which controls the schema. Additionally, the Data Access Object Management stores, modifies, and deletes data instantly. The "eCRF-Lite system” displayed vital signs, which were sent from the BP monitoring app to the physicians via vital sign screening. The physicians were easily able to observe BP trends (daily, weekly, monthly, yearly, etc.) of the participants. In the case of abnormalities being detected in patients’ data, the physicians could communicate with the individual patients (Supplemental Figure 5).

After randomization, both groups downloaded the applications from Google Play Store and installed it on their smartphones. After installation, the applications were paired automatically with a Bluetooth BP monitor provided by the researchers. Patients in both the

intervention and control groups measured their BP at home using the mobile app coupled with a Bluetooth BP monitor. The mobile apps varied in that patients in the SMBP-app with feedback group were provided alerts for BP measurement and received instructions or feedback from the mobile application in response to the obtained BP value (Supplemental Table 2). More specifically, the SMBP-app with feedback asked the patients whether the patient took the prescribed BP medication and whether their measured BP was high, normal, or low to enhance awareness, vigilance, and drug adherence (Supplemental Figure 6). Additionally, the SMBP-app with feedback advised patients to re-measure their BP if it was significantly out of the normal range. In the SMBP-alone group, the patients performed only home BP measurements through the app paired with the Bluetooth BP monitor and received standard care according to the Korean hypertension guidelines.[14,30,31] SMBP-alone group were not able to receive BP measurement alerts and feedback.

Follow-up visits were scheduled at 12 (visit 2) and 24 (visit 3) weeks after randomization The Korean hypertension guidelines recommend that the BP target for the general hypertensive population is 140/90 mmHg or lower, but certain conditions may require a lower BP.[14,31] In our study, instead of setting specific BP targets and BP medication adjustment protocols for a patient population, we allowed individual physicians to make decisions based on the patient's condition. If the BP values were not considered to be within the target range by the physicians, the BP medication could be changed at the discretion of the treating physicians.

Study outcomes

The primary endpoint of the study was the change in mean home SBP from baseline to 24 weeks (visit 3). The mean home BP was the average value of the BP recorded in the mobile application. The mean home BP at 12 weeks (visit 2) was defined as the average value of BP from baseline to 12 weeks, and the mean home BP at 24 weeks was defined as the average value of BP from 12 weeks to 24 weeks. We assumed that the average home BP measured over a period of time would best reflect the patient's actual BP and have the greatest clinical significance. Therefore, we decided to use the average home BP over 12 weeks as the primary endpoint. Baseline BP was defined as office BP at randomization, because mean baseline home BP could not be measured in this study.

The key secondary endpoint was adherence to antihypertensive medications at 24 weeks. Other secondary endpoints were as follows: change in mean home SBP at 12 weeks or office SBP at 12 or 24 weeks from baseline, change in mean home DBP at 12 or 24 weeks or office DBP at 12 or 24 weeks from baseline, and drug adherence at 12 weeks.

Clinical data including baseline characteristics, BP, medications, and endpoints were collected by research nurses. The frequency of app use was defined as the percentage of days when BP was recorded in the mobile application, which ranged from 0 to 100%. The drug adherence was assessed with the “pill-count” method. The patients brought the remaining tablets to each scheduled visit, and trained and certified research nurses counted the number of returned drugs and calculated drug adherence as follows:

$$\text{Drug adherence} = \frac{number\ of\ pills\ dispensed - number\ of\ pills\ returned}{number\ of\ days\ between\ dispensing\ data\ and\ follow\text{-}up\ date}$$

We set drug adherence of 95% for adequate adherence.

Sample size and statistical analysis

We assumed that the mean difference in home SBP change would be 3.4 mmHg with a standard deviation of ± 7.5 mmHg, after considering previous studies.[32,33] With a two-tailed alpha of 0.05, power of 0.80, and drop-out rate of 15%, 180 patients (90 patients in the intervention group and 90 patients in the control group) were required.

Categorical variables are reported as frequencies (percentages), and continuous variables are expressed as mean ± standard deviation or median with interquartile range. Categorical variables were compared using Pearson's chi-square test or Fisher's exact test, and continuous variables were compared using Student's *t*-test or Mann–Whitney *U* test.

Intention-to-treat analyses included all randomized patients. Efficacy endpoints were mainly analyzed using the full analysis set, which included all randomly assigned participants who completed at least one home BP measurement using the app paired with the Bluetooth BP monitor. We also performed a per-protocol sensitivity analysis including all patients who completed the study protocol. For the analysis of mean home blood pressure, we utilized existing data to calculate the mean home BP, even for patients who discontinued the study early. Other missing data at 12 and 24 weeks were not imputed and these missing data were not included in the primary analysis. In the subgroup analyses, we evaluated the differential effects of the intervention on the primary outcomes with respect to sex, age, obesity, baseline BP, and number of antihypertensive medications.

All tests were two-tailed, and a *P* value <.05 was considered statistically significant. Statistical analyses were performed using R version 4.2.0 (The R Foundation for Statistical

Computing, Vienna, Austria).

Results

Patient enrollment and clinical characteristics

From September 2019 to July 2020, 186 patients at five centers were screened for eligibility, and 184 were randomly assigned to the SMBP-app with feedback group (n=97) and SMBP-alone group (n=87) (Figure 1). After allocation, 11 patients (nine in the SMBP-app with feedback group and two in the SMBP group) were excluded because they did not undergo at least one home BP measurement using the app paired with the Bluetooth BP monitor; thus, a total of 173 patients (88 for the SMBP-app with feedback and 85 for SMBP-alone groups) were included in the full analysis set.

The baseline characteristics were well balanced between the intervention and control groups (Table 1). Overall, the mean age was 59.8 ± 11.6 years, 61.2% were male, 16.8% had diabetes mellitus, and 76.3% had dyslipidemia. The number of antihypertensive medications was not significantly different between two groups (2.1 ± 0.9 vs. 2.0 ± 1.0, P = .58). There was no significant difference in the use of each category of antihypertensive medication between the two groups.

Blood pressure

Changes in BP according to treatment group are presented in Table 2 and Figure 2.

Baseline office SBP and DBP were similar between the two groups (148.9 ± 8.4 vs. 150.0 ± 8.7 mmHg, *P* = .393; 85.7 ± 10.1 vs. 86.5 ± 10.3 mmHg, *P* = .57). Regarding the primary end point, mean home SBP reduction from baseline to 24 weeks was significantly greater in SMBP-app with feedback group than in the SMBP-alone group (-22.4 ± 13.5 vs. -17.2 ± 13.3; *P* = .02). Absolute difference in the reduction in mean home SBP was -5.2 mmHg (95% confidence interval (CI), -9.5 to -0.9 mmHg; *P* = .02). Moreover, the reduction in mean home SBP at 12 weeks from baseline was significantly greater in the SMBP-app with feedback group than in the SMBP-alone group (-19.2 ± 13.4 vs. -14.9 ± 12.9 mmHg; *P* = .049). In addition, the reduction in office SBP from baseline to 12 or 24 weeks was significantly greater in the SMBP-app with feedback group compared to the SMBP-alone group, which was consistent with the primary endpoint. However, changes in DBP from baseline were not significantly different between the two groups, regardless of the follow-up period (12 or 24 weeks) or BP measurements (home or office) (Supplemental Figure 7).

Medication adherence

Medication adherence according to the treatment group is presented in Table 3. The SMBP-app with feedback group showed a higher drug adherence value at 24 weeks than in the SMBP-alone group (100% [97.2%-100.0%] vs. 97.6% [94.0%-100.0%], *P* =.03). In addition, the proportion of adequate drug adherence (adherence ≥95%) at 24 weeks was higher in the SMBP-app with feedback group than in the SMBP-alone group (86.1% vs. 68.0%, *P* = .01). After excluding patients with an overall drug adherence of < 75% during the follow-up period, the SMBP-app with feedback group still showed higher medication adherence (100% [97.6%-100.0%] vs. 97.7% [94.2%-100.0%], *P* = .01) and proportion of

adequate drug adherence (adherence ≥95%) (90.7% vs. 70.8%; *P* = .004) at 24 weeks than in the SMBP-alone group. At 12 weeks, drug adherence tended to be higher in the SMBP-app with feedback group (100% [93.5%-100.0%] vs. 96.8% [90.9%-100.0%], *P* = .15), and the proportion of drug adherence ≥95% was significantly higher in the SMBP-app with feedback group (73.9% vs. 57.6%, *P* = .04), which was consistent with the primary analyses.

There were no adverse events associated with the use of the mobile app in this study. Supplemental Table 3 presents the antihypertensive medication status at 24 weeks. No significant difference was observed in the number of antihypertensive medications or the use of each category of antihypertensive medication at 24 weeks between the two groups. In addition, there was no significant difference in the proportion of patients with a change in medication category during follow-up between the two groups (19.3% vs. 14.1%, P = .48).

Sensitivity analysis

A total of 154 patients (79 for SMBP-app with feedback and 75 for SMBP-alone) completed the trial over 24 weeks (per-protocol analysis). Supplemental Table 4 and 5 in the Supplemental material show sensitivity analyses of the per-protocol population. There was a higher SBP reduction from baseline and medication adherence in the SMBP-app with feedback group than in the SMBP-alone group, similar to the primary main analyses.

Subgroup analysis

Figure 3 shows subgroup analyses of the difference between the intervention and

control groups regarding the change of mean home SBP from baseline to 24 weeks. The effect of SMBP-app with feedback on the change of mean home SBP was generally consistent across subgroups, including age, sex, obesity, baseline SBP, and number of antihypertensive medications.

The median value of the frequency of app use in the intervention group was 35.0%. Patients in this intervention group who had a high frequency of app use (≥35.0%) showed similar reduction in mean home SBP compared with patients who had a low frequency of app use (<35.0%) (-23.4 ± 14.1 vs. -21.2 ± 12.9; P = .49). Moreover, medication adherence and the proportion of adequate drug adherence (adherence ≥95%) at 24 weeks were not significantly different between these two groups (100% [97.7%-100.0%] vs. 99.6% [96.7%-100.0%], P = .50; 90.7% vs. 80.6%, P = .33).

Discussion

We developed a mobile health platform for tailored interventions in patients with hypertension. The main findings of the present study are as follows: (1) Mobile application-based feedback algorithm for tailored recommendations (SMBP-app with feedback) resulted in a higher reduction in mean home SBP and office SBP when compared to SMBP-alone; (2) The SMBP-app with feedback group achieved higher antihypertensive medication adherence than that of the SMBP-alone group.

SMBP with co-intervention, such as lifestyle counseling, drug adjustment by health care providers, or feedback, as opposed to placebo, is known to be associated with BP-lowering effects.[15,16] However, these direct interventions or feedback by healthcare providers

require time, financial expenditure, and personnel, and thus are challenging to incorporate in an actual clinical setting. Currently, smartphones are available to most of the general population at an affordable cost. With the advent of mobile technology and advances in AI and CDSS, remote patient monitoring and mobile-based feedback algorithms may be promising strategies to assist in the self-management of chronic diseases, including hypertension or heart failure, with cost-effective and accessible methods.[21,22,34,35]

By using this concept of mobile health platforms for a personalized intervention in patients with hypertension, our mobile application provides alerts for BP measurement reminders, tracks the BP and other biometric measurements, and visualizes the BP trend in easy-to-interpret graphs. It also provides specific instructions in response to the measured BP value, such as taking medication if a high BP is measured. Although interaction between patients and healthcare providers may be an ideal situation, it may not be realizable because of the rising costs of specialized healthcare and shortage of medical personnel. By using this app, we achieved greater blood pressure reduction and improved drug adherence in patients with hypertension at low cost, without the need for additional manpower, and with minimum effort from the healthcare providers.

Previous studies regarding mobile interventions in patients with hypertension have shown inconsistent results. Many studies and meta-analyses showed that using smartphone apps in treating patients with hypertension resulted in a greater reduction in BP than in the control group.[18-21,24,25,34] However, Morawski et al.[26] showed smartphone apps resulted in only a slight improvement in medication adherence, but no change in SBP when compared with the control group. Pletcher et al.[36] recently showed that enhanced SMBP paired with a smartphone application was not superior to the standard SMBP for BP reduction or patient satisfaction. These previous results were slightly different from our results, and we assumed

that these inconsistent results might be due to the different functions and feedback provided by mobile apps. Some apps only had the function of recording SMBP, while other apps also provided alarms for BP measurement, tracking BP, and feedback.[19-21] Although SMBP can reliably measure daily BP, the patient may not know the adequate response to the measured BP value. The SMBP-app with feedback can provide immediate feedback as it captures, archives, and visualizes the BP values unlike other conventional mobile health apps for hypertension, and educates and reminds patients to take their BP medication. We think that these heterogeneous and diverse functions of mobile intervention may influence the benefits and outcomes of mobile apps, and that the self-monitoring and feedback function is especially important for the mobile app's role in BP reduction.

One interesting finding of our study was the lack of difference in DBP reduction between the intervention and control groups. Previous studies showed that the role of SMBP in the reduction of DBP availed little benefit when compared to that of SBP reduction.[10,15,22] In addition, a systematic review of mobile apps for managing hypertension showed that only SBP and not DBP benefited from mobile intervention in some studies[21]; however, we do not know the exact mechanism underlying this difference in SBP and DBP between the SMBP-app with feedback and SMBP-alone groups. We carefully considered the fact that the absolute value of SBP is greater than DBP, and the sample size of the study population could affect these results. Moreover, there was no difference in the outcomes according to frequency of app usage in the intervention group. This is likely a consequence of the small sample size or difference in baseline characteristics; thus, further research with larger study populations is warranted to confirm whether the effect of the SMBP-app with feedback on SBP or DBP is significantly different and whether the frequency of app usage directly affects the outcome.

The proportion of patients achieving adequate medication adherence (≥95%) was higher at 24 weeks than at 12 weeks (Table 3). Medication adherence at 24 weeks was assessed only in patients who completed the full study period; therefore, we believe that the early dropout of some patients (nine in the intervention group and ten in the control group) may have influenced the results. Towards the end of the study, it is possible that those who were more adherent to the smartphone apps and SMBP were also more likely to adhere to their medication regimen.

There is no consensus regarding the standard for adequate drug adherence. Some trials considered adherence rates of ≥80% to be acceptable, whereas others considered rates of ≥95% to be mandatory for adequate adherence.[37-40] In our study, we set drug adherence of 95% for adequate adherence. Both the continuous value of drug adherence and proportion of adequate adherence were significantly higher in the SMBP-app with feedback group than in the SMBP-alone group. This was consistent after excluding patients with drug adherence of less than 75%. We showed that both drug adherence and SBP reduction were better in the SMBP-app with feedback groups; however, it was not clear whether improvement of drug adherence itself only resulted in improved SBP reduction. We believe that lifestyle changes or other mediators by the feedback app might affect the change in BP.

Limitations and strengths

This study had several limitations. First, our results are limited by the small sample size of the study. Second, because we only enrolled patients who had a smartphone and were able to use it, the results of our trial may not be applicable to patients who are not proficient

in smartphone use, such as some elderly individuals. Since a large proportion of patients with hypertension are elderly and may have difficulties using smartphones, excluding them from participation may lead to bias and limit the scope of the study. Third, the true engagement and use frequency of apps and the real responses of participants to feedback could not be analyzed. Also, there is a lack of clarity on exactly how the frequency of app use affects clinical outcomes. We believe that these limitations are commonly observed in studies using mobile apps. Additionally, lifestyle changes such as diet, body weight and physical activity were not assessed during the trial and may affect the change in BP. Fourth, there was a lack of information regarding adherence to antihypertensive medication before randomization. However, we assumed that drug adherence before randomization might be well balanced between the two groups due to the randomization study design. Fifth, there was a lack of information on baseline home BP. Although baseline BP in this study was defined as office BP at randomization and might be well balanced between the two groups, the inability to compare between baseline and follow-up home BP is limiting. Home BP measurements tend to be lower than those obtained by health care professionals, which means that our primary endpoint (the change from baseline office BP to mean home BP at 24 weeks between the two groups) may not accurately reflect the difference in patients' BP. Sixth, the BP medication could be modified at the discretion of each physician, which could be a confounding factor. Although no significant difference was observed in the number of antihypertensive medications or the use of each category of antihypertensive medication at 24 weeks, detailed changes in BP medication doses were not investigated in the current study. Open-label design could affect the outcome of the trial because physicians would be aware of the study group allocation and could adjust the drug more frequently. Finally, data on app satisfaction or quality of life were not examined.

Despite these limitations, this study has certain strengths. First, in our study drug adherence was assessed by the "pill count" method, in which the number of returned pills were counted. Drug adherence by pill count may be more accurate than the drug adherence score,[41,42] and this is a strength of our study compared with previous studies.[22,26] Second, our study evaluated mean home BP as the primary endpoint, which was the average of 12 weeks values of home BP values recorded in the mobile application, and this value could reflect real patients' BP better than office BP. Third, our study was conducted in in-person research visits; however, previous studies used online platform recruitment or self-reported BP measurements.[26,36] To the best of our knowledge, only a few studies have evaluated the effectiveness of SMBP plus co-intervention compared with SMBP-alone. Most previous studies comparing SMBP plus co-intervention and SMBP-alone were performed in the pre-era of smart phones.[15,16] We used a designated mobile health app, which has a dedicated feedback algorithm and a knowledge base to improve BP control, and showed that a mobile health app-based feedback may be an effective solution to control hypertension.

Conclusions

The SMBP-app with feedback is superior to SMBP-alone in terms of SBP reduction and improved drug adherence in patients with hypertension. Considering the high cost of traditional interventions between patients and healthcare providers, feedback through mobile apps could potentially be a useful tool in the management of hypertension.

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Figure legends

Figure 1. CONSORT flow Diagram

SMBP, self-monitoring of blood pressure.

Figure 2. Change of mean systolic blood pressure during trial follow-up in intervention and control groups

(A) Home systolic BP (B) Office systolic blood pressure

The data points and error bars represent the mean BP and the 95% confidence interval, respectively.

*: $P<.05$ by Student's t-test.

†Baseline BP was defined as office BP at randomization because mean baseline home BP could not be measured in this study.

BP, blood pressure; SMBP, self-monitoring of blood pressure.

Figure 3. Subgroup analyses of the difference between intervention and control group regarding the change of mean SBP from baseline to 24 weeks.

BMI, body mass index; CI: confidence interval; SBP, systolic blood pressure.