Protocol

# Wireless Home Blood Pressure Monitoring System With Automatic Outcome-Based Feedback and Financial Incentives to Improve Blood Pressure in People With Hypertension: Protocol for a Randomized Controlled Trial

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## Abstract

**Background:** Hypertension is prevalent in Singapore and is a major risk factor for cardiovascular morbidity and mortality and increased health care costs. Strategies to lower blood pressure include lifestyle modifications and home blood pressure monitoring. Nonetheless, adherence to home blood pressure monitoring remains low. This protocol details an algorithm for remote management of primary care patients with hypertension.

**Objective:** The objective of this study was to determine whether wireless home blood pressure monitoring with or without financial incentives is more effective at reducing systolic blood pressure than nonwireless home blood pressure monitoring (usual care).

**Methods:** This study was designed as a randomized controlled open-label superiority study. A sample size of 224 was required to detect differences of 10 mmHg in average systolic blood pressure. Participants were to be randomized, in the ratio of 2:3:3, into 1 of 3 parallel study arms :(1) usual care, (2) wireless home blood pressure monitoring, and (3) wireless home blood pressure monitoring with financial incentives. The primary outcome was the mean change in systolic blood pressure at month 6. The secondary outcomes were the mean reduction in diastolic blood pressure, cost of financial incentives, time taken for the intervention, adherence to home blood pressure monitoring, effectiveness of the framing of financial incentives in decreasing nonadherence to blood pressure self-monitoring and the adherence to antihypertensive medication at month 6.

**Results:** This study was approved by SingHealth Centralised Institutional Review Board and registered. Between January 24, 2018 and July 10, 2018, 42 participants (18.75% of the required sample size) were enrolled, and 33 participants completed the month 6 assessment by January 31, 2019.

**Conclusions:** Due to unforeseen events, the study was stopped prematurely; therefore, no results are available. Depending on the blood pressure information received from the patients, the algorithm can trigger immediate blood pressure advice (eg, Accident and Emergency department visit advice for extremely high blood pressure), weekly feedback on blood pressure monitoring, medication titration, or skipping of routine follow-ups. The inclusion of financial incentives framed as health capital provides a novel idea on how to promote adherence to remote monitoring, and ultimately, improve chronic disease management.

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**KEYWORDS**

telemedicine; home blood pressure monitoring; behavior change; hypertension; financial incentive; medication adherence; remote titration

## Introduction

Hypertension is prevalent in Singapore, affecting 23.5% of adults between 18 to 69 years of age [1]. It is a major risk factor for cardiovascular morbidity and mortality [2,3] and is associated with significant health care cost [4,5]. The goal of hypertension management is to lower blood pressure to healthy ranges through lifestyle modifications such as restricting salt and alcohol intake, eating a healthy diet, losing weight, engaging in regular exercise, quitting smoking, and taking antihypertensive medication(s) [6].

For patients whose blood pressure remains high, doctors routinely recommend home blood pressure monitoring for better blood pressure control. Home blood pressure monitoring allows the doctor to monitor response to treatment, detect white-coat hypertension, and predict cardiovascular risk [7,8]. Nonetheless, adherence to home blood pressure monitoring and medication(s) remains low [9]. Even when patients adhere to home monitoring, the readings are not reviewed by the doctor until the patient's subsequent in-person visit, which may be several weeks later. To address this, telemonitoring [10-14] can be employed as it allows for health care providers to monitor and intervene [15], to increase adherence to blood pressure monitoring [16], or titrate blood pressure medication [17] as needed, potentially without requiring an in-person visit [18]. However, systematic reviews [19,20] on telemonitoring reveal that it produces only modest improvements, which suggests that other features are needed [21-25]. For example, features such as automatic reminders [26,27], weekly feedback [28], or clinical interventions in response to concerning blood pressure trends (eg, medication titration), and financial incentives can be considered.

Behavioral economic theory suggests that the high rates of nonadherence to lifestyle modifications result, at least in part, from patients not perceiving a clear cause and effect relationship between greater adherence and reduced likelihood of adverse health consequences (eg, cardiovascular disease and premature death) [29,30]. The financial cost, such as the cost of medication(s), and nonfinancial costs, such as eating healthy, exercising, medication adherence, and blood pressure monitoring efforts, occur today, whereas the benefits, such as reduced risk for major cardiovascular events, often appear distant and uncertain. As a result, and because many individuals with hypertension feel perfectly healthy, they do not internalize the costs of nonadherence until it is too late. This theory suggests that a strategy to improve adherence is by providing a short-term financial incentive—an immediate benefit to offset the costs associated with the behavior change. Similar economic incentives have been used successfully in several adherence-enhancing interventions [31-34].

Therefore, this study aimed to leverage the potential of wireless and mobile technology and introduce financial incentives to improve the effectiveness of home blood pressure monitoring. The primary objective of this study was to determine whether wireless home blood pressure monitoring, with or without financial incentives, is more effective at reducing systolic blood pressure than nonwireless home blood pressure monitoring that relies on patient self-report (usual care). The secondary objectives were to improve adherence to blood pressure monitoring and antihypertensive medication(s).

## Methods

### Trial Design

The study was designed as a randomized controlled open-label superiority study with 3 parallel arms. Patients with hypertension who were on antihypertensive medication were randomized to (1) usual care, (2) wireless home blood pressure monitoring only, and (3) wireless home blood pressure monitoring with financial incentives arms, in a ratio of 2:3:3. Participants were randomly stratified based on whether they had diabetes mellitus (diabetes) and by clinic. The study intervention was to last 6 months. This protocol conforms to CONSORT (Consolidated Standards of Reporting Trials [35]) guidelines; the checklist can be found in Multimedia Appendix 1.

### Study Setting and Eligibility Criteria

Patients were recruited from Bedok and Marine Parade Polyclinics (SingHealth Polyclinics) in Singapore. Bedok and Marine Parade Polyclinics provide primary health care services to the eastern and southern region of Singapore. Hypertension management is one of the key services provided. Participant eligibility was based on the inclusion and exclusion criteria (Textbox 1).

**Textbox 1.** Inclusion and exclusion criteria.

**Inclusion criteria**

Participants had to fulfil all of the following:

- Diagnosed hypertension and on at least 1 antihypertensive medication
- Systolic blood pressure ≥140 mmHg or diastolic blood pressure ≥90 mmHg for patients without diabetes (systolic blood pressure ≥140 mmHg or diastolic blood pressure ≥85 mmHg for patients with diabetes), which was verified by the average of the last 2 of 3 blood pressure readings taken on the day of the screening visit at 3-minute intervals [36] (model: HEM-7130, Omron)
- Age from 21 to 70 years of age
- Singapore citizens or permanent residents
- Able to converse in English
- Has a compatible smartphone (iOS: versions 8.0 and higher, Android: versions 5.0 and higher) with data plan or regular Wi-Fi access
- Ability to perform self-monitoring of blood pressure as assessed by the clinical research coordinator
- Expecting to be a patient of Bedok or Marine Parade Polyclinics for the duration of the trial

**Exclusion criteria**

Patients with any of the following were not enrolled:

- Systolic blood pressure ≥180 mmHg or diastolic blood pressure ≥110 mmHg which was verified by the average of the last 2 of 3 blood pressure readings taken on the day of the screening visit at 3-minute intervals (model: HEM-7130, Omron)
- Started on angiotensin-converting enzyme inhibitors or angiotensin-receptor blockers within the last 3 months
- Clinically unstable heart failure
- Advanced kidney disease (estimated glomerular filtration rate <30 mL/minute CKD-EPI Creatinine formula [37]
- Acute kidney injury (ie, increase in serum creatinine ≥50% from baseline within the past week
- Confirmed glomerulonephritis
- Severe or overt macro albuminuria (urine albumin-to-creatinine ratio >30 mg/mmol or protein-to-creatinine ratio >0.5)
- Known liver disease (eg, liver cirrhosis)
- Atrial fibrillation
- On warfarin or anticoagulants (eg, novel oral anticoagulants)
- Underwent double mastectomy
- Pregnant
- Known allergy to epoxy resin
- Newly referred to specialist outpatient clinics or upon follow-up for complications related to hypertension
- Discharged from hospital within the last 3 months for complications related to hypertension
- Any other major debilitating disease or mental illness that precludes validity of informed consent or would result in the patient being unable to take their blood pressure independently
- Living in a household where another member has been recruited into the trial

## Participant Recruitment, Timeline, and Study Arms

### *Overview*

Participants were recruited via posters and referrals at Bedok and Marine Parade Polyclinics. A screening visit was arranged during which the study's purpose was explained and the screener administered. For eligible patients, the clinical research coordinator went through the participant information sheet, and if the patient agreed to participate, obtained informed consent (Multimedia Appendix 2).

Blood pressure was assessed at baseline and at month 6. Participants wore an ambulatory blood pressure monitor (model 7100, Welch Allyn) for 12 hours while awake (eg, 9 AM-9 PM). A period of 12 hours instead of 24 hours was chosen to reduce participant burden [38]. A diary was also given to participants to record antihypertensive medication adherence and physical activity (Multimedia Appendix 3, Figure S1). Participants were also issued a home blood pressure monitor and advised to monitor their blood pressure 3 times per week during the study. Medication Tracker (eCAP) was also issued, and participants were advised to store their most frequently prescribed antihypertensive medication in it. A demonstration of the study devices was given. The baseline questionnaire was administered (in paper format) at Bedok and Marine Parade Polyclinics, and the participant's responsibilities and adherence goals explained.

The study intervention began on the Monday following the valid baseline ambulatory blood pressure monitoring test (defined as having at least 70% of successful readings [39]). Participants also completed questionnaires at the 6-month assessment. Multimedia Appendix 4 contains the study timeline.

### *Arm 1: Usual Care*

SingHealth Polyclinics have a structured framework for hypertension management. Patients who are newly diagnosed with hypertension would be prescribed antihypertensive medication if deemed necessary by the doctor. All patients are subsequently referred to a nurse who would provide further information on hypertension and come up with a lifestyle modification plan with the patient. Patients are then followed up by the doctors and nurses at 3- to 4-month intervals (or more), based on their blood pressure trend. Further education is given at these visits as needed. Patients with good blood pressure control can teleconsult with a trained nurse, alternating with in-person doctor's consultation at up to 6-month intervals if they monitor their blood pressure at home. There are in-house pharmacists who assist patients in understanding their medication doses and regimens. Regular blood tests (ie, electrolytes, renal function, lipids, and glucose) are also carried out annually to monitor the patient's response to treatment and to detect any disease progression and complications. Patients with evidence of disease progression and complications would be closely monitored and referred to the appropriate specialists if required.

Participants in the usual care arm were advised to use their existing blood pressure monitor. Participants who did not have a home blood pressure monitor were given a blood pressure monitor (HEM 7130, Omron). In order to properly identify the effect of contingent financial incentives, all participants received a participant leaflet (Textbox 2).

The clinical research coordinator also provided advice on self-management and education on how to interpret blood pressure readings according to a standard self-monitoring guideline (Multimedia Appendix 5). The self-monitoring instructions were adapted from the guidelines of the Healthy Singapore website, a website by the Singapore Ministry of Health which was discontinued in September 2016. Elevated blood pressure was defined as clinic-measured systolic blood pressure 140 mmHg or diastolic blood pressure 90 mmHg. Published home-based monitoring protocols however, state that for home blood pressure monitoring, systolic blood pressure ≥135 mmHg or diastolic blood pressure ≥85 mmHg is indicative of elevated blood pressure [40,41]. In addition, SingHealth Polyclinics guidelines recommend home blood pressure monitoring targets of <135/80 mmHg for patients with diabetes, and <135/85 mmHg for those without diabetes. We therefore worked with the SingHealth Polyclinics Telehealth Team to fine-tune the blood pressure cut-offs for the various categories in order to have the same blood pressure cut-offs as the intervention (Table 1).

Participants in Arm 1 recorded their blood pressure readings on the SingHealth Polyclinics home blood pressure charting form (in paper format) as part of usual care. For monitoring adherence to hypertensive medicines, an eCAP (Information Mediary Corp) was used. The eCAP device passively recorded the dates and times the bottle was opened; these data are stored in the memory via an radiofrequency identification tag. Data were extracted by scanning the eCAP device on a reader (CertiScan desktop). Participants were assessed for adherence within specified time windows (eg, if a participant's specified timing is 5 AM to 11 AM and 5 PM to 11 PM, a reading had to be logged within both windows for the participant to be considered adherent for that day).

**Textbox 2.** Participant leaflet.

Aim to achieve blood pressure readings in the normal range

Measure your blood pressure on at least 3 days each week

Recommendations:

1. It is best to measure your blood pressure in the morning, before you take your medication, coffee, tea, smoke or exercise. Please sit for at least 5 minutes before measuring your blood pressure.
2. It is also recommended that you measure your blood pressure before you sleep at night.

Get active

Eat better. Reduce your salt intake

Take your medication as prescribed by your doctor.

**Table 1.** Blood pressure classification.

| Diabetes status | Very low | Low normal | Normal | Slightly high | Very high | Extremely high |
|---|---|---|---|---|---|---|
| **No diabetes** | | | | | | |
| Systolic blood pressure (mmHg) | <90 | 90-99 | 100-134 | 135-159 | 160-179 | ≥180 |
| Diastolic blood pressure (mmHg) | <50 | 50-59 | 60-84 | 85-99 | 100-109 | ≥110 |
| **Diabetes** | | | | | | |
| Systolic blood pressure (mmHg) | <90 | 90-99 | 100-134 | 135-159 | 160-179 | ≥180 |
| Diastolic blood pressure (mmHg) | <50 | 50-59 | 60-79 | 80-99 | 100-109 | ≥110 |

### *Arm 2: Wireless Home Blood Pressure Monitoring System*

Participants in Arm 2 used an asynchronous telehealth system that consisted of a wireless home blood pressure monitor and app (Figure 1). The study app comprised 3 parts: (1) instant home blood pressure monitoring advice, (2) weekly home blood pressure monitoring adherence feedback, and (3) 28-day continuous home blood pressure monitoring assessment.

The participants monitored their blood pressure using a wireless upper arm blood pressure monitor (iHealth KN-550BT [42]). The blood pressure monitor transmitted the readings via Bluetooth and internet to a smartphone app on the participants' smartphones. Participants received training from the clinical research coordinator on how to use the device and to upload their blood pressure readings. This smartphone app was available at no charge to study participants. Data were automatically sent to secure participant accounts, then pushed to a secure study app. The study app then sent feedback SMS text messages to the participants and automatically triggered interventions from the polyclinics depending on the blood pressure readings (Table 2).

**Figure 1.** Wireless home blood pressure monitoring system. BP: blood pressure; CRC: Clinical Research Coordinator; WiFHy: Wireless Monitoring and Financial Incentives for Uncontrolled Hypertension.

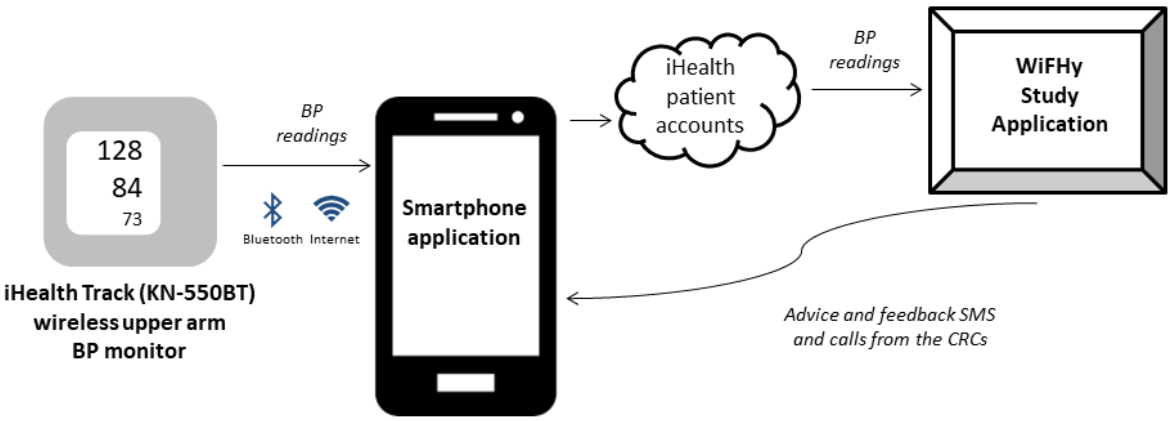

**Table 2.** Blood pressure–related procedures.

| Part | Description |
|---|---|
| Part 1: Instant home blood pressure monitoring advice (Multimedia Appendix 6) | Each blood pressure reading was classified in the order of most abnormal to normal (ie extremely high, very high, slightly high, very low, low normal and normal) and displayed on the study website. Based on the blood pressure classification, the participant received SMS self-management advice. A colour coded protocol (Red protocol)[a] was activated for very low and extremely high blood pressure readings. |
| Part 2: Weekly home blood pressure monitoring adherence feedback (Multimedia Appendix 7) | Participants received automated praise, encouragement, or reminder SMS messages on the Monday of the following week at 8 AM throughout the intervention, with content that were dependent on their adherence to home blood pressure monitoring the week prior. |
| Part 3: 28-day continuous home blood pressure monitoring assessment (Multimedia Appendix 8) | The average of blood pressure readings over the past 28 days was calculated daily based on readings over the preceding 28 days. It was categorized in the order of most abnormal to normal and color coded[a]. The triggering of interventions based on the average blood pressure in the past 28 days is in line with previous studies that recommend using the average of a series of measurements for clinical decisions [43]. The 28-day continuous home blood pressure monitoring assessment occurred when the system detected a minimum of 8 blood pressure readings in the past 28 days. |

[a]Color-coded protocols (Multimedia Appendix 8)—red: for very low and extremely high blood pressure; black: for very low or extremely high average blood pressure; gray: for low normal average blood pressure; green: for average blood pressure within the normal range just before scheduled clinic visit (participants were eligible to skip their upcoming clinic visit on approval of a doctor after review of the participant's clinical history and verification of the participant's current well-being by the clinical research coordinator); pink: for slightly high or very high average blood pressure (remote drug titration for participants on selected drugs); yellow: no readings for the past 28 days (the clinical research coordinator contacted the participant to determine the reason).

### *Remote Titration (Arm 2 and 3 Participants Only)*

To be clinically more responsive to uncontrolled blood pressure, remote titration is integrated in this intervention as per the Joint National Committee 8 [44] recommendation to increase the dose of an initial drug if goal blood pressure is not reached within 1 month of treatment. This protocol for drug titration is based on an unpublished pilot program at Pasir Ris Polyclinic. Participants were eligible for remote titration if they were randomized to Arms 2 and 3 and prescribed (1) nifedipine LA ≤30 mg/day, (2) amlodipine ≤7.5 mg/day, (3) atenolol ≤75 mg every morning or (4) bisoprolol ≤7.5 mg every morning at baseline. For participants who were on more than 1 drug, the study doctor determined the drug to be titrated based on the drug selection workflow (Multimedia Appendix 8, Figure S4) and gave instructions on the dose increase to the participant. The participant was to increase the dose only if contacted by the clinical research coordinator to do so during the intervention. The doctor's instructions were also written in an individualized leaflet (Remote Titration Action Plan–Patient Information Leaflet; Multimedia Appendix 8, Figure A8.4.1.2) and given to the participant for reference. The clinical research coordinator also tagged the drug to be titrated and reinforced the doctor's advice. Participants were prescribed the full duration of the antihypertensive drugs until their next scheduled clinic visit. The drugs selected for remote titration were calcium channel blockers and beta blockers as these do not require monitoring of electrolytes.

On each working day, the clinical research coordinator logged-in to the study website, monitored the dashboard for flags and intervened accordingly. The clinical research coordinator unflagged the flag once the intervention had been carried out.

Study participants had doctor consultations at month 3 and at month 6 during the intervention period. For Arm 1 participants, the clinical research coordinator met with them prior to their doctor consultation and made a copy of their blood pressure readings for record. For Arm 2 and 3 participants, the clinical research coordinator passed them the blood pressure readings captured by the wireless monitoring system on the day of the doctor consultation for review by the doctor; except in cases where the visit was skipped due to good blood pressure control (green protocol).

### *Arm 3: Wireless Home Blood Pressure Monitoring System With Incentives*

Participants in this arm received an intervention identical to those in Arm 2, with the addition of financial incentives for blood pressure monitoring. This arm was subdivided into 2 arms; participants were eligible to receive the same incentive amounts but framed differently. In the instant reward subarm, participants received SGD $3 (an exchange rate of approximately SGD $1 to US $0.75 was applicable at the time of publication) for each day they measured their blood pressure, up to 3 times per week (SGD $9 if they measured their blood pressure on at least 3 different days, SGD $6 if they measured their blood pressure on at least 2 different days, SGD $3 if they measured their blood pressure on at least 1 day, or no financial incentive if they did not measure their blood pressure). In the health capital subarm, participants received an initial health capital of SGD $72. Participants' health capital increased by SGD $6 on each week they measured their blood pressure on at least 3 different days. Participants' health capital decreased weekly by 10% per missing blood pressure reading. Health capital decreased by 10% if the participant measured their blood pressure on 2 different days, by 20% if the participant measures their blood pressure only on 1 day, and by 30% if the participant did not measure their blood pressure. Therefore, at the end of the 24-week intervention, Arm 3 participants could receive incentives up to SGD $216 for blood pressure monitoring.

Noncontingent study payments (Multimedia Appendix 9) to Arm 1 and 2 participants and incentive payments to Arm 3 participants (Multimedia Appendix 7, Table A7.4) in the form of supermarket vouchers were disbursed by the clinical research coordinator at the month 6 assessment.

## Participant Withdrawal

During the study intervention, the clinical research coordinator reviewed the participants' medical records and contacted the participants via phone to determine if there were any serious adverse events, changes in medical condition, hospitalizations, or referrals to specialist outpatient clinics that may require a withdrawal from the study. The study doctor reviewed the participant's medical records and determined when there was a need to do so. Participants who were newly diagnosed with a hypertension related condition or complication or met the following exclusion criteria: clinically unstable heart failure, acute kidney injury, glomerulonephritis, liver disease, atrial fibrillation, prescribed warfarin or anti-coagulants, double mastectomy, pregnant, epoxy-resin allergy, referred to specialist outpatient clinic, or hospitalized for complications were withdrawn. Those who had a progression of an existing condition (eg, impaired kidney function) could remain in the study. For study participants who were withdrawn by the study team, a payment of SGD $80 in compensation for forgoing potential payments that the participant might have received had they remained in the study was given. Participants were free to withdraw their consent and discontinue their participation at any time during the intervention, without prejudice or effect on their medical care; however, all data collected until the time of the participants' withdrawal were kept to allow for a comprehensive evaluation.

## Outcome Measures

The outcome measures and schedule of collection can be found in Multimedia Appendix 10.

### *Primary Outcome*

The primary outcome was the mean reduction in systolic blood pressure in 6 months. This was to be obtained from the participants' month 6 ambulatory blood pressure monitor results. systolic blood pressure is associated with increased risk of cardiovascular disease [45-47].

### *Secondary Outcomes*

Secondary outcomes were mean reduction in diastolic blood pressure in 6 months, obtained from the participants' month 6 ambulatory blood pressure monitor results; mean cost of financial incentives at month 6, calculated as the total financial incentives earned by Arm 3 participants at the end of the intervention and to be used as part of the cost-effectiveness analysis; mean time taken for the intervention at month 6, calculated as the total number of minutes spent by the clinical research coordinator intervening for the colored flags, adherence calculation, and payment of financial incentives for all study arm participants during the month 6 assessment and to be used as part of the cost-effectiveness analysis; mean adherence to home blood pressure monitoring at month 6; effectiveness of the framing of financial incentives in decreasing nonadherence to blood pressure self-monitoring; and mean adherence to antihypertensive medication (prescribed to be taken most frequently) at month 6.

Diastolic blood pressure may have some associations with future systolic hypertension and with increased risk of cardiovascular disease [47-51].

### *Exploratory Outcomes*

Exploratory outcomes were the proportion of participants who have target blood pressure (defined as less than 130 mmHg/80 mmHg) at month 6; mean change from baseline in European Quality of Life-5 Dimensions-5 Levels [52] score at month 6; mean change from baseline in Brief Illness Perception Questionnaire [53] score, which assesses perceptions of hypertension, at month 6; mean change from baseline in the Global Physical Activity Questionnaire at month 6; mean change from baseline in the Dietary Practices Questionnaires [54] at month 6; mean change from baseline in Healthcare Services Expenditure at month 6; and the Treatment Satisfaction on home blood pressure monitoring, which is a modified version of the Treatment Satisfaction Questionnaire for Medication [55], at month 6.

## Sample Size

A key parameter is the systolic blood pressure. To assess this, we computed the sample size to be able to detect differences of 10 mmHg in average systolic blood pressure between study arms at the 5% level with 80% power. To compute the overall sample size, we computed the size of the intervention groups that is required for testing for difference between intervention groups (study arms 2 and 3). After applying a Bonferroni correction (by dividing the test's significance level by 2, which is the number of comparisons that we test in our study for the primary outcome), we found that 68 patients per intervention group is necessary to detect mean differences in systolic blood pressure of 10 mmHg (with 2.5% significance level and 80% power). Given the resulting cumulated sample size for the 2 intervention arms of 136, we then computed the size required for the control group to test the overall effect of the wireless home blood pressure monitoring (with and without financial incentives) with the same effect size, significance level, and power. This computation yielded a size of 45 for the control group. After accounting for 25% attrition in each arm, the resulting sample sizes were 56 for the control group and 84 for each intervention group, resulting in a total of 224 patients. We assumed throughout that the standard deviation of systolic blood pressure is 19 (which is slightly greater than the maximum value reported by a similar size 6-month study of patients with uncontrolled hypertension [56]).

## Randomization

Participants were allocated to 1 of 3 study arms by random assignment. Prior to recruitment, randomization numbers was generated by the principal investigator using Stata software (StataCorp LLC) to create an assignment schedule for block-randomization to allocate eligible participants into 1 of the 3 study arms in a ratio of 2:3:3. Randomized stratification was based on whether the patient had diabetes and study site. The block size was not communicated to SingHealth Polyclinics to minimize the predictability of the random sequence.

Furthermore, in order to test a secondary hypothesis (H5), the patients in the home blood pressure monitoring with financial incentives arm were further randomly divided into 2 equal-size groups, 1 per incentive type. The project coordinator and principal investigator then stored the assignment schedule on a secure server at Duke–NUS Medical School. For allocation concealment, the project coordinator and a Duke–NUS Medical School staff external to the study team enclosed the assignments in sequentially numbered, opaque, sealed randomization envelopes. These were handed over to the clinical research coordinator for participant enrollment and assignment.

### Allocation Blinding

The clinical research coordinators were not blinded to the group allocation during the study intervention as there was a need for the clinical research coordinators to know the participants' arms to assign study devices to the participants and carry out the intervention accordingly and disburse payouts for the incentive arm participants (Arm 3). The site investigators were also not blinded as they had to explain the remote titration action plan and advise on intervention for the colored protocols (Arm 2 and 3).

### Data Management and Monitoring

To maintain confidentiality, all enrolled participants were issued a unique ID based on their randomization number and were referred to via their unique ID thereon. Identifiable data were kept at locked cabinets at Bedok and Marine Parade Polyclinics and only accessible by the SingHealth Polyclinics team. Only deidentified research data were passed to Duke–NUS Medical School, and all data transfers were documented. All keyed in deidentified research data were encrypted, password-protected and stored on a secure server. Blood pressure readings and home blood pressure monitoring adherence data from the mobile app were transmitted automatically to the app via the application programming interface daily. The app did not contain any identifying information, was password protected, and only authorized members of the Duke–NUS Medical School team had access to the website via 2-factor authentication. Investigators have access to the research data collected. All hardcopy research data collected are archived for the next 10 years in compliance with NUS's research data management policies. No Data and Safety Monitoring Board was used for this trial as the study was deemed to be low risk by the investigators as this intervention was modelled after an existing standard of care by the Polyclinics and not involving more than minimal risk to the participants. Compensation was to be considered on a case-by-case basis for unexpected injuries due to nonnegligent causes. This trial was subjected to study review visits and audits to ensure that all investigator-initiated research is conducted effectively and efficiently.

### Ethics

This study was approved by the SingHealth Centralised Institutional Review Board E (2016/2026). Amendments to the protocol or other study-related documents were approved by the institutional review board.

### Data Analysis

All main analyses were to be based on intent to treat. The mean difference in the systolic blood pressure at 6 months was to be assessed in the context of a linear mixed-effects model with a random effect for subject and fixed effects for baseline mean (the same in both arms) and change in mean at 6 months for each treatment arm (one for each arm). The mixed-effects model allows nonmissing data to be used in analysis without imputation. For estimates of the treatment arm effects to be unbiased, data must be missing-at-random. However, it is possible that the analysis of the pattern of attrition would indicate that additional covariates needed to be included in the mixed-effects models. If data are not normally distributed, appropriate transformations will be attempted before resorting to using nonparametric statistical analysis methods.

## Results

Recruitment at Bedok Polyclinic began on January 24, 2018 and at Marine Parade Polyclinic on June 26, 2018. From January 24, 2018 to July 10, 2018, 42 participants (18.75% of the total sample size) were enrolled, and 33 participants completed the 6-month assessment by January 31, 2019. A decision was made to terminate the study prematurely due to unforeseen delays and resulting funding issues. No analysis was carried out due to the lack of sample size and therefore no results are available.

## Discussion

This paper reports a protocol for a randomized trial to determine whether a wireless home blood pressure monitoring system, with or without financial incentives, is more effective at reducing blood pressure than a nonwireless home blood pressure monitoring that relies on patient self-report or best practices.

While the 6-month study intervention is sufficient to detect potential blood pressure improvement that is clinically significant, a longer period would be needed to test for the long-term effectiveness of the intervention. There is currently no prior intervention that has the same components as those in our wireless home blood pressure monitoring system.

Unfortunately, due to unforeseen events the study was stopped prematurely. Regardless, as this study raises an interesting set of research questions, this protocol may be of value to other researchers considering similar efforts for blood pressure control or other behavioral targets. Results of such a study would provide evidence on whether a telemonitoring system with or without financial incentives can improve hypertension management, thereby reducing long-term complications and health care cost. By interacting socioeconomic characteristics with the intervention effect, this study may also have provided evidence on the benefit incidence of interventions involving financial incentives. The framing of financial incentives as reward versus health capital, would also have informed the design of future incentive strategies in hypertension management and other chronic diseases. The study would also have added to telemonitoring knowledge on hypertension self-management in patients and remote clinical management of hypertension,

which is increasingly relevant in light of COVID-19 and an increase in the use of telehealth in managing chronic diseases.

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## Authors' Contributions

MB conceived and designed the study, acquired funding, and supervised the study. AYLK contributed to the study design and was the site principal investigator. IKYP contributed to the study concept and design. NCT contributed to the acquisition of funding and study design. JB contributed to the acquisition of funding, contributed to study design, and was the co-site principal investigator. JB helped amend the study protocol, provided logistical support, and drafted the manuscript. APMB-A contributed to the study design and provided logistical support. EAF contributed to the study concept, acquisition of funding, and provided supervision.

## Conflicts of Interest

None declared.

## Multimedia Appendix 1

CONSORT E-HEALTH checklist.
[PDF File (Adobe PDF File), 944 KB-Multimedia Appendix 1]

## Multimedia Appendix 2

Participant Information Sheet and Consent Form.
[PDF File (Adobe PDF File), 327 KB-Multimedia Appendix 2]

## Multimedia Appendix 3

Ambulatory Blood Pressure Monitoring.
[PDF File (Adobe PDF File), 280 KB-Multimedia Appendix 3]

## Multimedia Appendix 4

Study timeline for participants.
[PDF File (Adobe PDF File), 232 KB-Multimedia Appendix 4]

## Multimedia Appendix 5

Standard guideline for interpretation of blood pressure readings.
[PDF File (Adobe PDF File), 277 KB-Multimedia Appendix 5]

## Multimedia Appendix 6

Instant home blood pressure monitoring advice.
[PDF File (Adobe PDF File), 946 KB-Multimedia Appendix 6]

## Multimedia Appendix 7

Weekly home blood pressure adherence feedback.
[PDF File (Adobe PDF File), 999 KB-Multimedia Appendix 7]

## Multimedia Appendix 8

The 28-day continuous home blood pressure monitoring assessment.

[PDF File (Adobe PDF File), 534 KB-Multimedia Appendix 8]

### Multimedia Appendix 9

Study payment scheme.
[PDF File (Adobe PDF File), 314 KB-Multimedia Appendix 9]

### Multimedia Appendix 10

Outcome measures and schedule of collection.
[PDF File (Adobe PDF File), 210 KB-Multimedia Appendix 10]

### Multimedia Appendix 11

Peer-review report by the National Medical Research Council (Ministry of Health, Singapore).
[PDF File (Adobe PDF File), 708 KB-Multimedia Appendix 11]

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## Abbreviations

**SGD:** Singapore dollar
**SMS:** short message service

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