


BMJ Open Simplified regimen for the management of hypertension with telemedicine and blood pressure self-monitoring (SIMPLE): study protocol for a randomised controlled trial

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ABSTRACT

Introduction Telemedicine and blood pressure (BP) self-monitoring conduces to management of hypertension. Recent hypertension guidelines highly recommended single pill combination (SPC) for the initial treatment of essential hypertension. Based on this fact, an SPC-based telemedicine titration regimen with BP self-monitoring could be a better way in managing hypertension. This trial aims to elucidate whether telemedicine combined with BP self-monitoring is superior to self-monitoring alone during hypertension management.

Methods and analysis This study will be a multicentred, open-labelled, randomised controlled trial. A minimum sample of 358 hypertensive patients with uncontrolled BP from four centres will be included. The intervention group will include BP self-monitoring and tele-monitoring plus a free SPC-based telemedicine titration therapy for 6 months, they will be recommended to take BP measurements at least once every 7 days, in the meantime, researchers will call to give a consultation on lifestyle or titration advice once a fortnight. The control group will be required to self-monitor BP at the same time interval as intervention group, without any therapy change. Primary outcome of the trial will be the difference in systolic blood pressure at 6-month follow-up between intervention and control group, adjusted for baseline variables. Secondary outcomes such as BP control rate, major adverse cardiovascular events, medication adherence, quality of life will be investigated.

Ethics and dissemination Ethics approval was granted by Ethical Committee of Shanghai Tenth People's Hospital (SHSY-IEC-4.1/20-194/01). The results will be disseminated in peer-reviewed literature, and to policy-makers and healthcare partners.

Trial registration number ChiCTR2000037217.

INTRODUCTION

Hypertension is the leading remediable risk factor for cardiovascular disease (CVD), hypertension and its mediated organ damages are the cause of increased morbidity

Strengths and limitations of this study

- This trial will investigate whether single pill combination-based simplified telemedicine regimen is superior to self-monitoring alone, and advantages of clinic-free hypertension management.
- Although the trial is multicentred, but all four of them are in urban area. Meanwhile, potentially eligible participants for this trial are not universal, exclusion criteria are strictly designed, this may limit the generalisation and application of the study results to a broader population.
- It is possible that high frequent blood pressure (BP) measurement may result in BP elevation due to anxiety.
- Mean home BP and office BP will be used as outcomes in this trial, not 24 hours ambulatory BP.
- This trial may have spillover effect more or less when at the clinician or clinic level owing to the individualised randomisation plan.

and mortality worldwide.¹⁻³ The number of adult patients with hypertension increased from 594 million in 1975 to 1.13 billion in 2015 (226 million of whom in China).⁴ In sharp contrast with the increasing prevalence of hypertension, the well-controlled rate of hypertension is still far below expectations.⁴ Despite the availability of effective treatment, only 31.3% of the hypertensive patients with pharmacologic therapies have controlled blood pressure (BP) in low-income and middle-income countries (38.0% of whom in China,⁵ while 40.7% of the patients were well-controlled in high-income countries.⁶ One of the main reasons for this problem could be the poor medication adherence.^{7 8} Another reason for the poor control rate could be the imbalance between the number of patients



and physicians. Hence, it is necessary to develop an easy and effective way to improve control of BP in management of hypertension. Self-monitoring and telemedicine have been proved to reduce BP and improve adherence to antihypertensive medication.^{9–15} The Chinese Hypertension Guidelines¹⁶ stressed that home BP (HBP) self-monitoring can be used to improve patients' compliance, and it is expected to become a new model of BP management in the future. Meanwhile, hypertension guidelines proposed by the International Society of Hypertension (ISH),¹⁷ National Institute for Health and Care Excellence,¹⁸ in Europe¹⁹ and China¹⁶ all recommended single pill combination (SPC) for initial treatment, and the first step of antihypertensive therapy is to choose ACE inhibitors/angiotensin receptor blockers and calcium channel blocker, which can improve adherence to treatment. On the basis of the self-monitoring and telemedicine, an SPC-based simplified titration regimen according to the latest hypertension guideline^{16 17 19 20} was developed in this study.

This trial investigates whether SPC-based telemedicine combined with BP self-monitoring is superior to self-monitoring alone during hypertension management.

METHODS AND DESIGN

Study setting

The Simplified regimen for the Management of hypertension with telemedicine and blood pressure self-monitoring study will be an open-labelled, two-arm, parallel, randomised controlled trial to compare SPC-based telemedicine combined with BP self-monitoring to usual care in the management of hypertension. This trial will take place in four centres: Shanghai 10th People's Hospital, Shanghai Xuhui Central Hospital, Shanghai Putuo People's Hospital and Shanghai Putuo Central Hospital. Recruitment started on 21 December 2020 and this study is planned to end on 30 June 2022.

Eligibility criteria and recruitment

Internet-based advertising and clinic visit will be used for recruitment, participants who were previously diagnosed with essential hypertension and taking antihypertensive agents, but with uncontrolled BP (office BP >140/90 mm Hg) are considered as potentially eligible. Considering high frequent of BP measuring may lead to BP elevation caused by anxiety, it is not recommended for patients with high anxiety to self-monitor HBP.¹⁶ Detailed inclusion and exclusion criteria are listed in **box 1**. At first visit, potentially eligible participants will undergo a 2-week screening phase, they will be trained to record their HBP on a paper diary at least twice a day (online supplemental file 1), their previous antihypertensive drugs will be replaced with SPC-based titration regimen which is equivalent to their previous ones following specified regimen exchange plan (online supplemental file 2) and also by physicians' experience to verify drug adherence and compliance. Participants who managed to fill at least three quarters

Box 1 Inclusion and exclusion criteria

Inclusion criteria

1. Age 18 and 75 years.
2. Willing to participate the study and sign informed consent.
3. Essential hypertension under medical treatment with uncontrolled blood pressure (systolic blood pressure (SBP) >140 mm Hg or diastolic blood pressure >90 mm Hg).

Exclusion criteria

1. Office SBP >180 mm Hg.
2. Essential hypertension.
3. Taking over three different antihypertensive agents.
4. Atrial fibrillation or other malignant arrhythmias.
5. Any diagnosed type I or II diabetes, renal dysfunction, coronary heart disease, heart failure or a history of stroke or myocardial infarction.
6. Any serious medical condition.
7. Participation in any other trial.
8. Amnesia or dementia.
9. Diagnosed with severe valvular heart disease.
10. Pregnancy or expecting to get pregnant.
11. Spouse already participated in the study.
12. Not own a mobile phone for remote communication.
13. Conditions determined unfit for the study by investigators.
14. Participants who were either not tolerated or had no response to similar antihypertensive therapies.

of the whole BP diary, also without any drug side effects will be considered as fully eligible, randomisation will be performed by senior researchers, physicians will be blinded during the trial process.

Office BP measurement

The day before office BP measurement, participants will be informed to avoid smoking and caffeine. Office measurement will be performed with automated electronic sphygmomanometer (RBP-9802, Raycome Health Technology Corporation, Shenzhen) by nurses or physicians in a quiet room, 3 measurements with at least 1 min interval, average of second and third readings will be recorded.¹⁷

HBP uploads

Participants will be trained to use the automated electronic sphygmomanometer (RBP-9802, Raycome Health Technology, Shenzhen), which will upload the HBP readings to data centre via 2G network (online supplemental file 3). The BP monitors will be given for free, participants are allowed to keep it even after the trial ended. A notification for BP measuring will be sent to the participants at 9:00 am and 21:00 pm via private message or social app. A minimum of once a 7-day measurement is recommended. All participants may review their uploaded BP history.

Control (self-monitoring) group

Usual care group will remain their own management plan without further intervention, HBP measurement is required but without interventional monitoring.

Intervention group

Intervention group will conclude both self-monitoring and tele-monitoring, plus telemedicine, they will take antihypertensive agents following the prespecified titration regimen based on uploaded HBP. Every 2 weeks, researchers will check patients' uploaded HBP records, and give a consultant call under supervision of physicians (patients' personal information censored). After the call, based on the prespecified BP titration regimen, the physician will prescribe the antihypertensive tablets for the future 2 weeks, and all the medications will be delivered within 24 hours to patients. Participants who suffered long time side effects of any drugs prescribed by this trial will be discontinued immediately. Participants who are using spironolactone will receive free blood check monthly to monitor blood potassium level.

Outcome assessment

The primary outcome of the trial will be the difference in systolic BP (SBP) (office BP, mean of second/third readings, mm Hg) at 6-month follow-up between intervention and control group, adjusted for baseline variables.

Secondary outcomes are as follows:

1. Difference in diastolic BP (DBP) (office BP, mean of second/third readings, mm Hg) at follow-up point (3 months and 6 months) between intervention and control group adjusted for baseline variables.
2. Difference in mean BP (uploaded HBP, mm Hg) during the trial (6 months) between intervention and control group.
3. Difference in mean BP (uploaded HBP, mm Hg) during the trial (3 months) between intervention and control group.
4. Percentage of weeks which mean HBP $\leq 135/85$ mm Hg in total weeks by the end of third month and sixth month follow-up.
5. Adverse events: clinical events; the State-Trait Anxiety Inventory;²¹ side effects.

6. Medication outcomes: Medication Adherence Rating Scale,²² Beliefs about Medicine Questionnaire,²³ The Stanford Expectations of Treatment Scale.²⁴
7. Life habits: alcohol use disorders identification test-concise,²⁵ diet, exercise, smoking.
8. Quality of life, EuroQol-5-Dimensions-5-Level (EQ-5D-5L)²⁶ scores.

Participant timeline

As shown in figure 1, a screening phase is set to check participants' eligibility following the inclusion and exclusion criteria. After signing informed consent, the participants will receive a 2-week screening. Subjects who failed screening will be signed to the registered (real world) cohort, they will not be asked to self-monitor or receive any interventions, but will be invited to follow up for office BP measuring by the end of third month and sixth month, mainly to investigate how they manage their BP without any interventions, compared with control group.

During the follow-ups, participants in the intervention group will receive remote contact from physicians of each centre at the end of every 2 weeks, including medication titration plan (based on HBP uploads), lifestyle change suggestion (diet, smoke, alcohol etc.). Senior researchers will also receive feedbacks from participants during the teleconsultant. Participants in the control group will remain their own choice for clinic visit without further interventions. An office visit is required at the end of third and sixth month for both groups, trial-related information or data will be obtained as well (table 1).

Sample size calculation

According to the previous studies, the intervention group lowered the average BP of patients by about 5 mm Hg compared with the control group, the SD of the patients' BP was around 15 mm Hg.²⁷ Based on a two-tailed test of two independent means, with a significance (α) level of 0.05% and 90% power, 155 patients were selected for each

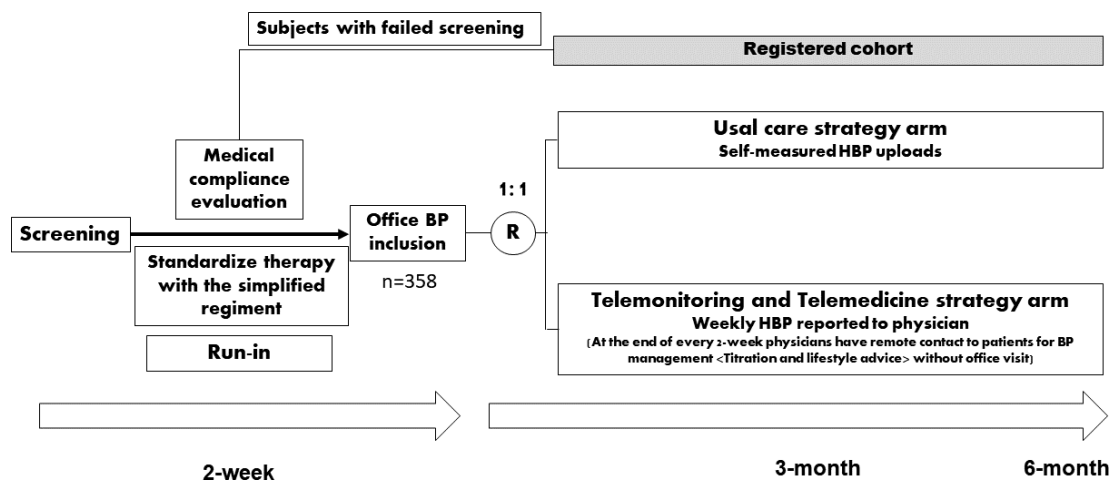


Figure 1 Schematic representation of the simple trial. During the screening phase, participants' drug adherence will be fully evaluated. Participants who failed the screening will be directed to registered cohort. Participants who passed the screening will be stratified by centre during randomisation. There will be two office visits for all participants during run-in phase. Maximum duration of this trial will be 6 months. BP, blood pressure; HBP, home blood pressure.

Table 1 Measurements and data collection

	Enrolment (21 December 2020)	Screening visit	3 months	6 months
Demographic questions	×			
Office BP measurement	×		×	×
Duration of hypertension and antihypertensive treatment	×			
Smoking habits and alcohol intake	×		×	×
Biochemical measurements		Optional*	Optional*	Optional*
HBP 2-week hand-written record		×		
HBP telemonitoring reports			×	×
EQ-5D-5L ²⁶ questionnaire		×	×	×
SETS ²⁴ questionnaire		×		×
MARS ²² questionnaire		×		×
BMQ ²³ questionnaire		×	×	×
Lifestyle: Audit-C, ²⁵ diet, exercise, smoking		×		×
Adverse effects, anxiety (STAI) ²¹ and side effects of medication		×	×	×
Technical difficulties during trial			×	×

*Only participants who are using spironolactone need to check blood monthly to monitor blood potassium level.

BMQ, Beliefs about Medicine Questionnaire; BP, blood pressure; EQ-5D-5L, EuroQoL-5-Dimensions-5-Level; HBP, home blood pressure; MARS, Medication Adherence Rating Scale; SETS, Stanford Expectations of Treatment Scale; STAI, State-Trait Anxiety Inventory.

group. It was assumed that the drop-out rate of this study is no more than 15%, the study requires a total sample of 179 patients to be recruited in each group with a total of 358 patients.

Randomisation

Eligible patients are randomly assigned to the control and intervention group using a competitive design in clinical trial sites. Randomisation will be done after screening, ensuring that the assessing occupational therapist will not be biased at this time by knowing the group assignment. A random number will be generated before the start of this study. The random number list will be kept by the third party and uploaded into a random data assigned system. When participants are recruited, they will be assigned a random number by the system sequentially. If a patient is later excluded for any reason, the participant's position in the randomisation list will not be replaced by any new participants. Senior researchers will generate the allocation sequence online and assign participants to interventions. Physicians will be blinded to both intervention and usual care group, considering usual care participants' clinical visit may bring contaminations to the trial.

Target BP and titration of medication

At the end of every 2-week remote follow-up, titration will be prescribed based on the 2-week average HBP in the intervention group under supervision of physicians. Antihypertensives titration regimen is shown in figure 2, referring to ISH 2020 guide.¹⁷ Three different types of anti-hypertensive drugs were used in this trial: a SPC containing perindopril arginine 10mg and amlodipine 5mg (COVERAM, Servier, France); a thiazide-like diuretic indapamide (NATRILIX, Servier, France) and

a mineralocorticoid receptor antagonist spironolactone 20mg (Yatai, China).

As shown in figure 2, if average HBP is below 135/85 mm Hg and above 115/65 mm Hg, the BP is in the green zone without any medication modification. Participants will keep their current medications. If average HBP is between 135/85 mm Hg and 155/105 mm Hg, antihypertensive agents will be upgraded (eg, T1→T2); if average HBP is between 155/105 mm Hg and 170/110 mm Hg, antihypertensive agents will be upgraded two level (eg, T1→T3); if average HBP is below 115/65 mm Hg, antihypertensives will be downgraded (eg, T2→T1); if average HBP is below 100/50 mm Hg or above 180/115 mm Hg, a visit to clinic will be required, event will be recorded,

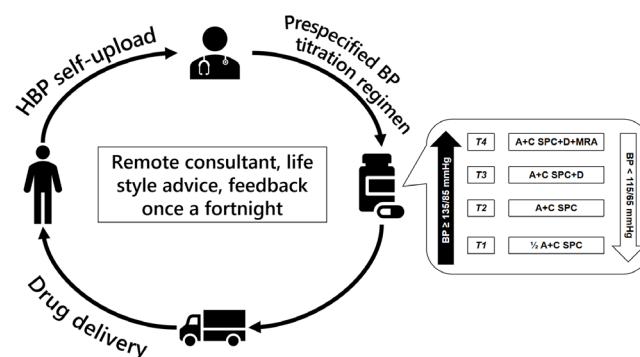


Figure 2 Antihypertensives titration regimen of the simple trial. A+C SPC: ACEI +CCB SPC. T1: half dose of an SPC pill; T2: a full dose of SPC; T3: a full dose of SPC plus diuretic; T4: a full does of SPC plus diuretic plus MRA. ACEI, ACE inhibitor; HBP, home blood pressure; CCB, calcium channel blocker; MRA, mineralocorticoid receptor antagonist; SPC, single pill combination.

participants may choose whether continue or leave the trial.

Statistical analysis and data management

Statistical software R (V.4.0.2) is used for analyses. Analyses will be conducted on an intention-to-treat (ITT) and per-protocol population basis. Data for each assessment will be summarised for each treatment group and the descriptive statistics will be calculated depending on the data distribution for each assessment. Outcomes will be collected at the times defined in the study protocol. ITT analysis will be used to deal with the missing data for the primary outcome. An unpaired t-test will be used to analyse the difference between office SBP at baseline and office BP at 6-month follow-up between the intervention group and the control group. Subgroup factors include the elderly, men, smokers, patients with grade 2 hypertension and patients with poor compliance. A general linear mixed model will analyse the primary outcomes using data collected during 3-month and 6-month follow-up, adjusting for baseline variables. A $p < 0.05$ will be considered to indicate statistical significance.

Clinical Research Institute of Shanghai Jiao Tong University Medicine School will be responsible as the data monitoring committee and for auditing trial conduct. The questionnaires are collected by researchers and recorded into the research electronic data collection system, which will be used as an electronic data collection (EDC) system for long-term data storage and management. Only authorised researchers can obtain these data. Data in the EDC system will be checked by built-in algorithm, monitored when some modification is required, and traceable to source data. Due to patient confidentiality and the possibility of access to EDC system, the collected clinical data will not be shared with the public.

Patient and public involvement

There was no patient or public involvement in the study design.

Ethics and dissemination

Ethics approval was granted by Ethical Committee of Shanghai Tenth People's Hospital (SHSY-IEC-4.1/20-194/01). The results will be disseminated in peer-reviewed literature, and to policy-makers and healthcare partners. Any major modifications in protocol will be kept written record, protocol version will be updated, investigators, RECs, participants trial registries and journal regulators will be informed by email or phone call. Senior researchers will obtain and archive informed consent or assent from potential trial participants or authorised surrogates, participants may keep a copy or take photos of informed consent at their own discretion.

DISCUSSION

This trial focuses on the feasibility of SPC-based telemedicine combined with BP self-monitoring compared with

self-monitoring alone during hypertension management, also assesses whether the regimen is safe and effective for BP control of patients with uncontrolled hypertension and no other severe diseases.

The management of hypertension faced great challenge while COVID-19 pandemic²⁸ hit the globe. During the pandemic, the number of clinical tests and consultations dramatically dropped, not only in China, but in well-developed European countries.²⁹ Telemedicine and self-monitoring are not novel approach in hypertension management, since large randomised controlled trials proved their feasibility in control of BP, but there is still great challenge, which came from two different directions. One of them is patients' low awareness of hypertension mediated organ damage and low compliance in taking BP measurements, for telemedicine requires patients' higher activeness in management of hypertension. The other one comes from policy-makers, for they know little about how much benefit and the cost-effectiveness does telemedicine could bring, as a result, a systematic assessment on how to run a telemedicine procedure and how much the public can be benefited is urgently needed.

This study will investigate a simple strategy for BP managing, which may further lead to prevention of CVD and other severe complications.³⁰ It may also help bring better quality of life by enabling better use of their time instead of spending much of it waiting in the hospitals on the premise that the technical difficulty related to telemedicine can be solved sufficiently.³⁰ Especially in areas with large number of hypertension patients. It is always difficult for patients to visit doctors owing to the disproportion of numbers of doctors and patients in these countries.

Moreover, a clinic-free, simplified and unified telemedicine plan may help lighten the burden of public health both in cost and management of hypertension, especially during COVID-19 pandemic. Predictively speaking, with the rise of artificial intelligence, we hope that someday telemedicine and hypertension management can be greatly benefited from advanced technology, and we hope that this study can more or less contribute to this great goal.

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approved the final manuscript as submitted and agreed to be accountable for all aspects of the work.

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