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Internet-based patient– primary care physician–cardiologist integrated management model of hypertension in China: study protocol for a multicentre randomised controlled trial

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ABSTRACT

Introduction The control rate of hypertension is low in China, especially in rural, western and minority areas. This is related to poor medical skills among physicians in primary care institutions and low levels of trust among patients. However, primary healthcare institutions are the main battleground for the prevention and treatment of hypertension. It is worth exploring how to most effectively integrate patients, primary care physicians and cardiologists in tertiary hospitals, to build a long-term mechanism for the prevention and treatment of hypertension. In this study, we aim to evaluate the clinical effectiveness and conduct a health economic evaluation of an internet-based patient–primary care physician–cardiologist integrated management model of hypertension in areas of China with different socioeconomic levels.

Methods and analysis This is a 12-month, multicentre, randomised controlled trial involving patients with hypertension in urban communities and rural areas of Sichuan Province, China. Each primary healthcare institution will cooperate with their tertiary hospital through the Red Shine Chronic Disease Management System (RSCDMS). Patients will be randomly assigned 1:1 to two groups: (1) a traditional care group; (2) an intervention group in which primary care physicians and cardiologists can share patient data and manage patients together through the RSCDMS. Patients can upload their blood pressure (BP) values and communicate with physicians using the system. The primary outcome is the change in systolic BP over a 12-month period. Secondary outcomes are changes in diastolic BP, BP control rate, values of 24-hour ambulatory BP monitoring, difference in cost-effectiveness between the groups, patient satisfaction, medication adherence and home BP monitoring compliance. All data will be recorded and stored in the RSCDMS and analysed using IBM SPSS V.26.0.

Ethics and dissemination This study has been approved by the Biomedical Research Ethics Committee of the West China Hospital of Sichuan University in Sichuan, China (No. 2020-148). Written informed consent will be obtained from all participants. The results of this study will be disseminated to the public through academic conferences and peer-reviewed journals.

Trial registration number ChiCTR2000030677.

Strengths and limitations of this study

► This 12-month, multicentre, randomised controlled trial will explore the effectiveness of a comprehensive hypertension management model that incorporates telemedicine technologies.

► Each primary healthcare institution will cooperate with their tertiary hospital through the Red Shine Chronic Disease Management System.

► The Red Shine Chronic Disease Management System will be used as a tool to integrate patients, primary care physicians and cardiologists.

► This study will be conducted in southwest China, including patients with hypertension in urban communities and rural areas of Sichuan Province, to test the clinical effectiveness and cost-effectiveness of the model in areas with different socioeconomic levels.

► The study will only be conducted in southwest China, whether this model can be generalised to other regions remains uncertain.

INTRODUCTION

Hypertension is a major risk factor for cardiovascular disease. The latest survey suggests that the prevalence of hypertension in China is 27.9%,[1] with just a 16.8% control rate.[2] The current situation of hypertension is at a rather low level, especially in rural, western and minority areas, causing a heavy disease burden.[1 3] Studies have shown that actively preventing and controlling hypertension is a core strategy in restraining the development of cardiovascular and cerebrovascular diseases.[4 5] Nearly 90% of China's population with hypertension are distributed throughout

primary hospitals, that is, urban and rural community health centres.[6 7] Therefore, primary hospitals are the main battleground for the prevention and treatment of hypertension.[8 9] At present, the traditional management model requires that patients be followed up in primary hospitals according to their blood pressure (BP) level.[2] However, patients have low levels of trust in the medical facilities and treatment in primary hospitals. Thus, the treatment measures and lifestyle advice received from primary care physicians (PCPs) are not effectively implemented and maintained by patients. Routine follow-ups are not carried out in time, affecting BP control.[7 10] Therefore, the current situation of hypertension management in primary hospitals must be improved.

Previous studies have shown that patients are more satisfied with diagnoses and treatment provided by doctors in tertiary hospitals.[11 12] With the participation of specialists in community hypertension management, the control of BP is superior to that under traditional care management.[13 14] Although China is working hard to strengthen the training of PCPs to improve their professional level, the integration of professional knowledge is a gradual and long-term process. PCPs might lack the ability to deal with some patients who have poor BP control. Therefore, it is feasible for specialists to go into the community to provide consultations. However, the busy work schedule of these specialists renders the long-term operation of this management model unfeasible.

Based on these problems with the traditional hypertension management model, it is worth exploring how to most effectively integrate patients, PCPs and cardiologists in tertiary hospitals, to build a long-term mechanism for the prevention and treatment of hypertension.

With the advent of the information era, studies have focused on the effects of telemedicine on chronic disease management.[15–17] Guidelines recommend that telehealth strategies can be a useful method to improve hypertension control by implementing remote BP recordings, e-prescriptions, health education and e-counselling.[15] These methods could improve patients' access and participation in hypertension management. Using e-counselling strategies is an effective way to improve BP, which led to a decrease of systolic BP (SBP) by 10.1 mm Hg compared with 6.0 mm Hg in the control group of one study.[17] Until now, nearly 200 smartphone applications have been developed for hypertension management.[18] However, these lack validation of their effectiveness and the involvement of healthcare professionals in the app-development process. In addition, none of these apps has established an integrated link with high-quality medical resources among patients, PCPs and specialists. Therefore, these apps cannot be effectively implemented in hypertension management.

Based on the above situation, our team developed an internet-based hypertension management system, the Red Shine Chronic Disease Management System (RSCDMS), with the cooperation of cardiologists and software technicians. Through this system, patients can receive effective management by physicians under the guidance of specialists, and PCPs can improve their skills in practice. In this trial, we aim to evaluate the clinical effectiveness and conduct a health economic evaluation of this internet-based three-level integrated management model of hypertension in areas of China with different socioeconomic levels.

METHODS AND ANALYSIS
Study design
This study is designed as a 12-month multicentre trial among patients with hypertension in urban communities and rural areas. The study design will be described in accordance with the Standard Protocol Items: Recommendations for Interventional Trials 2013 checklist[19 20] (online supplemental material 1 and table 1).

Patient and public involvement
This trial is designed to evaluate the clinical effectiveness and health economics of an internet-based patient–primary care physician–cardiologist (PPC) integrated management model of hypertension in areas of China with different socioeconomic levels. The RSCDMS will be used as a tool to execute the management process. Participants will be recruited from six primary hospitals managed by three tertiary hospitals. However, they will not be directly involved in the design, recruitment or execution of the study. After the trial is completed, the results of this study will be disseminated to the public via conference presentations and peer-reviewed journals. When the manuscript is published, we will summarise the results and text them to all trial participants in a brief message.

Study outcomes
Primary outcome
The primary outcome is the difference between the last mean office SBP value and baseline office SBP after 12 months of intervention.

Secondary outcomes
The secondary outcomes are:
1. Changes in mean office diastolic BP from baseline.
2. Office BP control rate (controlled BP is defined as BP <140/90 mm Hg or <130/80 mm Hg (for patients with diabetes or renal diseases) following the Chinese guidelines[2]).
3. Changes related to body metabolism (weight, waist circumference, blood lipid levels and blood glucose level).
4. Changes from baseline in values of 24-hour ambulatory blood pressure monitoring (ABPM): mean 24-hour, daytime and night-time BP.
5. Difference in cost-effectiveness between groups.
6. Changes from baseline in patient satisfaction evaluated using the European Task Force on Patient Evaluations of General Practice.[21]

Table 1 Study timelines overview of all visits and tests scheduled in the trial

Study period					
	Enrolment	Follow-up			
Timepoint	Visit 0 week 1	Visit 1 month 1	Visit 2 month 3	Visit 3 month 6	Visit 4 month 12
Enrolment					
Eligibility screen	×				
Informed consent	×				
Allocation	×				
Interventions					
Control group		×	×	×	×
Intervention group		×	×	×	×
Assessments					
Medical history	×				
Physical examination	×	×	×	×	×
BP measurement	×	×	×	×	×
Treatment plan	×	×	×	×	×
Lab tests					
Blood routine	×			×	×
Serum lipids	×			×	×
Hepatic function	×			×	×
Renal function	×			×	×
FPG	×			×	×
Urine routine	×			×	×
ABPM	×	×			×
EUROPEP	×	×	×	×	×
BMQ	×	×	×	×	×
EQ-5D	×	×	×	×	×
Cost information	×	×	×	×	×
Home BP monitoring compliance	×	×	×	×	×
Adverse events		×	×	×	×

Hepatic function refers to total bilirubin; alanine aminotransferase; aspartate aminotransferase; gamma glutamine transferase; alkaline phosphatase and albumin. Renal function refers to serum creatinine; blood urea nitrogen and blood uric acid.
ABPM, 24-hour ambulatory blood pressure monitoring; BMQ, Brief Medication Questionnaire; BP, blood pressure; EQ-5D, EuroQol five-dimensional; EUROPEP, European Task Force on Patient Evaluations of General Practice; FPG, fasting plasma glucose.

7. Changes from baseline in the antihypertensive medication adherence evaluated by a derived version of the Brief Medication Questionnaire.[22]
8. Home BP monitoring compliance including the frequency of home BP measurements per month (derived from RSCDMS or logbook), and the proportion of months when a home BP reading is obtained.[23]

Eligibility criteria
Inclusion criteria
1. Age between 18 and 80 years.
2. Newly diagnosed hypertension, or with a history of hypertension and uncontrolled BP in the past 3 months (≥140/90 mm Hg or ≥130/80 mm Hg if the patient has diabetes/renal disease), currently taking or about to take antihypertensive drugs.
3. Able to use a smartphone.

Exclusion criteria
1. Secondary hypertension.
2. Heart failure.
3. Hospitalised for acute myocardial infarction within the past 6 months.
4. Severe hepatic or renal disease (serum aspartate aminotransferase/alanine aminotransferase levels three times above the normal limit or glomerular filtration rate <30 mL/min) or serum creatinine >221 µmol/L).
5. Planning to undergo surgery within 6 months.

6. History of malignant tumours.
7. Cognitive dysfunction or unable to take care of self.
8. Participating in other clinical trials.

Study setting and recruitment

Participants will be recruited from six primary hospitals managed by three tertiary hospitals in Sichuan Province, China, and be randomised according to three areas. According to their economic development level, three areas will be included:

1. Economically and medically developed areas in Sichuan Province.
2. Regions with average socioeconomic and medical resource levels.
3. Economically and medically underdeveloped areas in Sichuan Province.

Potential participants will be identified by screening electronic medical records in primary hospitals, roughly following the eligibility criteria. Eligible participants are then to be screened by telephone to determine their interest in participation, experience using smart phones and willingness to sign a consent form (online supplemental material 2). Those who remain eligible will be invited to their primary hospital to attend a screening session with PCPs and cardiologists. Eligible patients will be randomised to the control or the intervention group. Participants in the intervention group will be instructed in how to use the WeChat applet during management. The recruitment process is expected to take 5 months to complete, from May to September 2020.

Interventions

Participants in each primary hospital will be divided into two groups. Group 1 will receive traditional care that complies with China's Hypertension Prevention and Treatment Guideline 2018,[2] but PCPs will not intervene in participants' health-seeking behaviour. Group 2 will additionally receive internet-based PPC-integrated management, which will include coordinated management executed by PCPs and cardiologists (figure 1).

Group 1: control group, traditional care model

After recruitment, group 1 will be managed by their PCPs. Patients will receive the usual management and follow-up
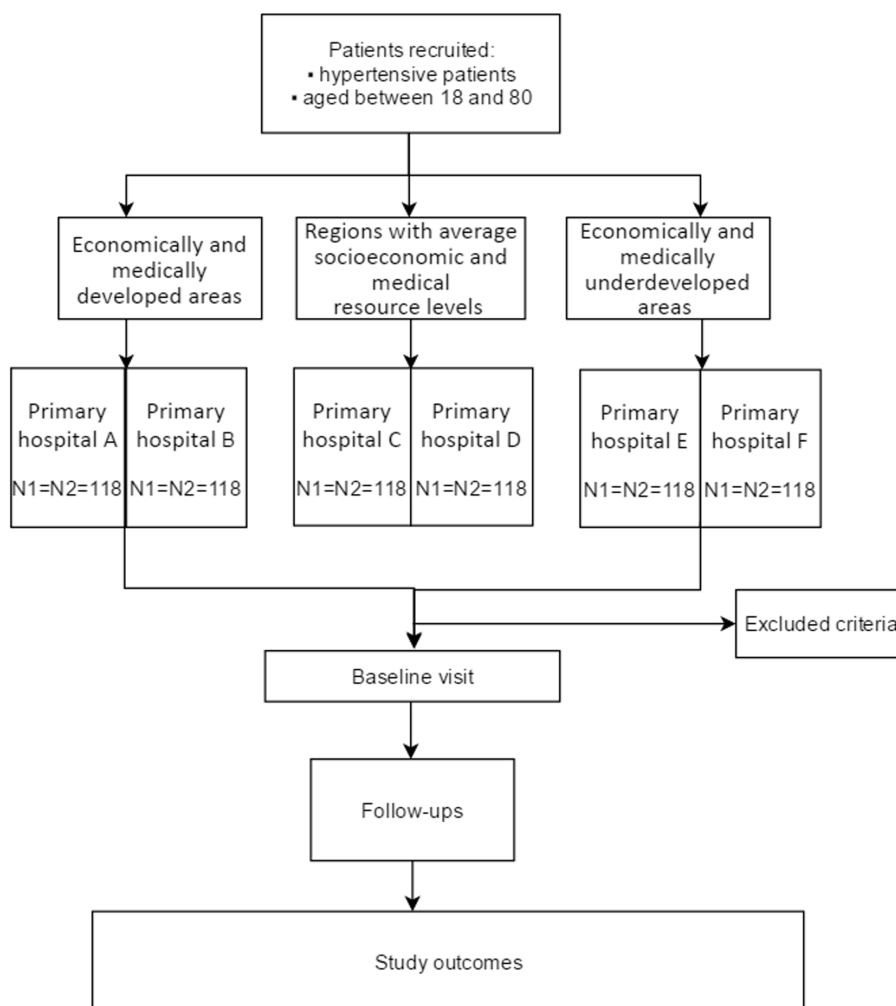
Figure 1 Study design and flow diagram.
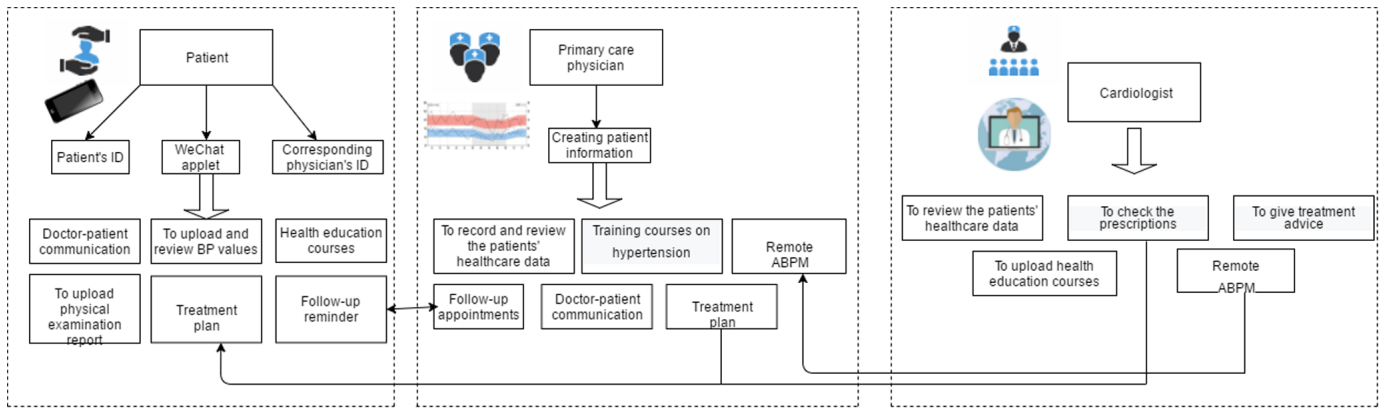
Figure 2 Function of the Red Shine Chronic Disease Management System. ABPM, 24-hour ambulatory blood pressure monitoring.

in compliance with the national guideline. This model includes designated follow-ups by PCPs once every 2–4 weeks if BP is not controlled, and once every 3 months if BP is within the normal range. Patients will be encouraged to record their home BP readings using a logbook and to present the results during their visit. Physicians will provide medication prescriptions and lifestyle advice, as suggested in the guidelines. Follow-ups are to be conducted through outpatient visits and by telephone.

Figure 3 The screenshot for the module of the patients.

Group 2: intervention group, internet-based PPC-integrated management model

Patients in this group will be managed by PCPs together with cardiologists using the RSCDMS. The system consists of three modules (figures 2–4).

1. The first module is a WeChat applet for patients to upload their BP values, communicate with PCPs about their condition and browse through health education courses uploaded by cardiologists. This applet will also serve as a reminder for patients to complete their follow-up appointments on time.
2. The second module is a website for PCPs to record and review patients' medical data, provide treatment plans, make follow-up appointments, communicate with patients and upload ABPM data.
3. The third module is a website for cardiologists to review patients' medical data, check prescriptions provided by PCPs and give suggestions, upload health education information using short videos or popular science articles, and analyse the ABPM data.

Cardiologists will review patients' health data and provide treatment suggestions within 2 days after the patient is enrolled and during each follow-up visit. If the patient's condition worsens or hypertension complications occur, the system can be used to coordinate referral to a tertiary hospital.

The RSCDMS is used as a tool to integrate patients, PCPs and cardiologists. Using the three functional modules, synchronous online management and a real-time hierarchical medical system can be delivered by PCPs and cardiologists in tertiary hospitals.

Data collection and management

The processes of data collection, storage and delivery are achieved through the RSCDMS (http://39.105.211.76:3000/doctor/index). Researchers will manually record the medical information in this internet-based system. Data from the same patient will be entered by one investigator and verified by another investigator to avoid missing, duplicate and erroneous data. A trial inspector will visit each site regularly to check the

Figure 4 The screenshot for the website of the physicians.

research progress and ensure that the trial strictly adheres to the protocol.

Venous blood will be drawn in the morning after an 8-hour fast, and the levels of blood glucose, liver enzymes, creatinine and the serum levels of lipids including triglycerides, total cholesterol, low-density lipoprotein (LDL) cholesterol and high-density lipoprotein cholesterol will be evaluated. Office BP will be measured using a validated Omron upper-arm electronic sphygmomanometer (HBP-9020; Omron Co., Dalian, China), according to the 2018 European Society of Cardiology/European Society of Hypertension (ESH) guidelines.[24] Two or three readings of the heart rate and BP are to be taken and the mean recorded.[24] Home BP monitoring will be carried out by the patients themselves using their own upper-arm electronic sphygmomanometer (meeting criteria of the Association for the Advancement of Medical Instrumentation/ESH/International Organization for Standardization),[25] and BP values will be manually entered into the WeChat applet. Patients will be taught when and how to conduct home BP monitoring by PCPs and cardiologists during the screening sessions, according to the guidelines.[25]

Adverse events include syncope, falls, hypotension, coronary heart disease, stroke and heart failure. Cost information will be collected during each follow-up, including direct costs and indirect costs. Direct costs refer to direct medical costs (antihypertensive drugs, laboratory tests, examinations during follow-up and treatment, and hospitalisation owing to cardiovascular, cerebrovascular and renal events) and direct non-medical costs (transportation, meals and other expenses that arise owing to illness). Indirect costs refer to loss-of-life costs and economic losses caused by illness and missed work.

All patients, PCPs and cardiologists will have a unique account number and password. The account number of each patient corresponds to a PCP and a cardiologist, and the account number of each cardiologist corresponds to the account number of two to three PCPs. The

research staff is only provided with read permission for the database.

Study timeline
A diagram summarising the timeline is presented in table 1.

Randomisation
Participants will be sequentially allocated to the intervention or control group with a 1:1 ratio using centre-stratified block randomisation. The random allocation sequence will be generated by a statistician prior to study initiation using SAS V.9.4. To limit selection bias, the allocation sequence is to be concealed from all study researchers in well-sealed, opaque envelopes until the interventions are assigned. Owing to the nature of the study, this will be an open-label trial for all participating patients, physicians and inspectors at each site.

Sample size calculation
Sample size calculation is based on the primary outcome, namely, differences in the change of SBP between the two groups at 12 months. This study is powered to detect a difference of at least 10 mm Hg in SBP.[26 27] We assume that the SD for the difference in SBP from baseline to 12 months is 10 mm Hg.[28 29] Using a two-sample comparison of the mean change between group 1 and group 2, a sample size of 100 patients per group is required to have more than 99% power. Accounting for an estimated drop-out rate of 15%, the sample size is adjusted to 118 participants per group for each site (6 sites, 2 groups per site, 1416 in total). To reduce potential drop-out, if a patient chooses to discontinue the trial, we will contact them and determine their reasons for dropping out. According to the situation, we will attempt to persuade the patient to continue their participation in the study.

Statistical analysis
Statistical analysis will be performed using IBM SPSS V.26.0. Baseline data will be presented using descriptive

statistics (mean±SD for normally distributed continuous variables, median and IQR for non-normally distributed continuous variables, and frequency and percentage for categorical variables). For comparisons between two groups, a t-test or rank-sum test will be used for quantitative variables, and the X^2 test or Fisher's exact test will be used for qualitative variables. The primary outcome of this study, differences in the change of SBP, will be estimated using a safety set in which all randomised participants with data for at least one follow-up visit will be analysed. A covariance analysis model will be fitted for the primary outcome, adjusting the baseline using the following covariates, as appropriate: baseline SBP, age, sex, body mass index, drinking status, smoking status, fasting blood glucose, total cholesterol and LDL cholesterol. Only those covariates found to be statistically significant for the outcomes will be selected as explanatory variables for inclusion in the final model. Data will be presented as adjusted mean difference (95% CI) and corresponding p values. We will conduct further analysis to evaluate secondary outcomes using the identical methods described above for the primary outcome analysis. For cost-effectiveness analysis, R software will be used for construction of a decision tree (The R Project for Statistical Computing, Vienna, Austria).

Ethics and dissemination

This study has been approved by the Biomedical Research Ethics Committee of the West China Hospital of Sichuan University in Sichuan, China (No. 2020-148). Written informed consent will be obtained from all participants. The results of this study will be disseminated to the public through academic conferences and peer-reviewed journals.

DISCUSSION

The disease burden of hypertension in China is experiencing a growing trend, with a large number of patients who have hypertension and limited physicians in primary hospitals. Tertiary hospitals in China are overcrowded and usually dealing with complicated diseases, leaving physicians less time to manage patients with hypertension. The key to better prevention and control of hypertension lies in the primary hospitals as they are more easily accessible. However, the limited number of PCPs makes patient management inefficient in routine visits.

Recent studies have shown that the use of comprehensive multidimensional hypertension management among low-income populations with relatively limited medical resources can significantly improve the BP control rate.[28–30] In China, implementing a hierarchical medical system and improving the hypertension management capacity of physicians in areas with underdeveloped medical resources is especially important.[31 32] However, the busy schedules of PCPs in primary hospitals, as well as their limited capacity to deal with complex diseases, lead to a hierarchical medical system becoming an armchair strategy.[33 34]

Meta-analyses have shown that telemedicine can help improve the BP control rate and cardiovascular event outcomes.[16 35 36] It can also compensate for physical distance between patients in remote areas and major medical institutions. In addition to these benefits, telemedicine can provide considerable economic benefits.[37] Data from 25 182 teleconsultation visits suggest that a total of US$9 175 132, and 1 876 146 hours (213.1 years) in chronic disease management have been saved with the use of telemedicine in low-income and middle-income countries.

In the context of a national hierarchical medical system, a comprehensive hypertension management model based on telemedicine is worth exploring for use in urban communities and remote rural areas. The present model is designed to fit within the current conditions in China's community healthcare system, to support the hypothesis that extending the role of specialists and making them more available for community healthcare services can enhance the effectiveness of patient management. Previous studies have demonstrated that under the guidance of specialists, BP control can be improved in primary care institutions.[13 14] However, in these studies, researchers have provided consultation in the community, which necessitates that specialists travel from their workplace to communities. This method is effective but also consumes time and energy. Moreover, this approach could go on for a time, but a high rate of BP control cannot be sustained in the long run. Ours is the first multicentre study focusing on use of the internet to connect patients, PCPs and cardiologists in different regions and with differing socioeconomic levels. This study will shed light on web-based management of hypertension in China and provide future guidance on the implementation of a hierarchical medical system.

In addition to assessing the efficacy of the above intervention, this study will have several other impacts. First, through use of this internet system, the difficulties with visiting a doctor in a tertiary hospital experienced by residents in the community and in remote areas could be resolved by reducing the number of times patients must travel to and from hospitals, in addition to improving patient data management. Second, the patient data can be shared between the primary healthcare institution and tertiary hospital in real time, improving the management efficiency. Third, we can determine whether the internet-based management model is suitable for different kinds of institutions and regions. Fourth, physicians in underdeveloped areas can learn from specialists through cooperation, improving medical standards in practice.

There are also some limitations in our study. First, our study will only be conducted in southwest China, although we will include regions with different socioeconomic levels. Thus, whether this model can be generalised to other regions remains uncertain. Second, the sample size is relatively small considering the actual

number of patients with hypertension in clinical practice. It is therefore necessary to explore whether this model can function when the number of patients increases to the normal levels in clinical practice as well as in the long term. Third, the home BP monitoring values will be manually uploaded to the WeChat applet by patients rather than being automatically uploaded via Bluetooth. Currently, many electronic sphygmomanometers lack the ability to transmit BP data automatically. We aim to test this internet-based model over the long term, such that participants will be able to continue to use their own electronic sphygmomanometers and record their BP using the WeChat applet. Fourth, we did not provide BP monitors for patients as home BP monitoring values are not an outcome measure. Thus, the BP monitors used by participants will differ and the uploaded BP values may lack consistency. However, we will ask patients to regularly calibrate their BP monitors, to minimise this difference.

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