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Research and evaluation of appropriate technology for medical and Prevention integration of hypertension management based on Internet Plus Artificial intelligence

Informed Consent Form

We are going to conduct a study with the aim of using a knowledge-based hypertension management system ("hypertension management System") to provide decision support for hypertension diagnosis and treatment and improve the standardization of hypertension diagnosis and treatment process for primary doctors. To evaluate the effect of hypertension management system on the blood pressure management of hypertension residents in the community, improve the structure of the current auxiliary decision-making system, improve the penetration rate, and better manage and prevent hypertension for community residents. You are eligible to participate in this study, so we would like to invite you to participate in this study. This informed consent will introduce to you the purpose, steps, benefits, risks, inconvenience or discomfort that may be caused to you, etc. Please read it carefully before making a decision on whether to participate in the study. When the staff member explains and discusses the informed consent form to you, you can ask questions at any time and ask him/her to explain to you what you do not understand. You can discuss it with your family and friends before making a decision.

The project leader is Shenzhen Hospital, Fuwai Hospital, Chinese Academy of Medical Sciences. Contact information can be found at the top of the page. An estimated 1,100 participants will volunteer for the study, which is scheduled to start in October 2024 and end in October 2026. The study has been reviewed and approved by the Biomedical and Clinical Trial Ethics Committee of Shenzhen Hospital, Fuwai Hospital, Chinese Academy of Medical Sciences.

1. Why did this study take place?

Cardiovascular and cerebrovascular diseases, which are among the most significant chronic noninfectious diseases, are the leading causes of death in China. Hypertension is an important risk factor for cardiovascular and cerebrovascular diseases, as well as chronic kidney diseases. It has also been the main source of cardiovascular disease burden in China. Hypertension is also an important public health problem in our city, and the control of hypertension is one of the important means to curb the burden of chronic diseases. Therefore, improving the professional ability and efficiency of primary medical staff in our city is crucial for enhancing the level of hypertension management. The purpose of this study is to improve the standardization of the hypertension diagnosis and treatment process for primary doctors and to better prevent and manage hypertension among community residents.

2. Who will be invited to participate in the study?

Choice of research institution:

This study included 12 community health service centers under the Third People's Hospital of Longgang District, Shenzhen.

Selection of subjects:

Subjects must meet the following 6 inclusion criteria and not meet any of the exclusion criteria.

1. Subject Inclusion criteria:

- (1) Age ≥ 35 years old.
- (2) Permanent residents of Shenzhen (duration of residence ≥ 6 months).
- (3) Patients with clear diagnosis of essential hypertension (systolic blood pressure (SBP) ≥ 140 mmHg and/or diastolic blood pressure (DBP) ≥ 90 mmHg on three different days, and secondary causes have been preliminarily excluded).
- (4) Signed a family doctor contract in the community health center participating in this study and visited the doctor regularly (completed at least 3 standardized follow-up visits, including at least 1 outpatient follow-up visit, from January 1, 2024 to December 31, 2024).
- (5) Blood pressure at the most recent follow-up was higher than 140/90 mmHg.
- (6) Those who signed the informed consent.

2. Subject exclusion criteria:

- (1) Patients eligible for referral.
- (2) Unwilling to take blood pressure medication.
- (3) Intolerance to 2 or more of 4 antihypertensive drugs, including A, B, C or D.
- (4) Chronic kidney disease diagnosed by a doctor or self-reported by the patient, $\text{eGFR} < 60 \text{ mL/min} \cdot 1.73\text{m}^2$, or receiving dialysis.
- (5) Other serious medical conditions diagnosed by other doctors or self-reported by patients, such as malignant tumors or liver insufficiency.
- (6) Patients with atrial fibrillation who self-reported having been diagnosed by a specialist.
- (7) Participants who are in the acute phase of any disease or whose condition is unstable.
- (8) There are cognitive and communication barriers.

3. Number and content of participants in this study?

This study is a stepped wedge randomized controlled trial, which intends to include 12 community health service centers under the Third People's Hospital of Longgang District, Shenzhen, and these centers are divided into 4 groups according to the distance and the scale of contracted patients. Each community health center recruited 92 qualified hypertensive patients over the course of the study, based on the inclusion and exclusion criteria. In the intervention stage, both Internet of Things blood pressure monitoring and an intelligent hypertension management system were adopted to assist diagnosis and treatment measures. That is, after patients signed the informed consent form to participate in the study, all subjects were issued a unified model of internationally certified upper arm sphygmomanometer with data upload function, requiring patients to carry out home blood pressure monitoring once a week, with two measurements each in the morning and evening, separated by a 1-minute interval. The intelligent hypertension management system was used for diagnosis, treatment, and follow-up, and the decision support for hypertension diagnosis and treatment was provided to clinicians through an interactive interface to assist in optimizing diagnosis and treatment plans. In the control stage, patients were treated and followed up according to standard clinical practice.

4. When you participate in the study, you may be terminated from the study and the reasons:

1. Dropout

Dropout in this study refers to the inability of the subjects to complete the entire process specified in the trial due to various reasons after signing the informed consent form and being screened and qualified to enter the study.

The subjects who meet one of the following conditions will be regarded as dropout cases:

- (1) The subjects are unwilling to continue to participate in the study for various reasons during the trial and request to withdraw from the clinical trial in advance;
- (2) The subjects change the primary medical institution for treatment due to moving or other objective reasons, or cannot complete the follow-up in the current institution;
- (3) Lost to follow-up;

2. Exclusion

The subjects who meet the following conditions will be excluded from the analysis:

- (1) The subjects are found to be not in compliance with the inclusion criteria or meet the exclusion criteria after being included in the trial;
- (2) The intervention group did not use the uniformly distributed blood pressure monitor to carry out the home blood pressure manager;
- (3) There is no data after random grouping.

5. How long will the study last?

The study will begin in October 2024 and end in October 2026.

6. What are the risks of participating in the study?

The intervention measures in this study are based on China's current hypertension management guidelines, as well as health education and treatment decision-support systems for doctors in primary health care institutions. Only diagnostic and treatment recommendations are provided; however, the final medical decision remains with the doctors. Therefore, there is no risk of adverse reactions that might be caused by clinical treatment measures. The intervention measures will not interfere with the routine treatment of hypertension patients in the outpatient department. The study's follow-up investigation consisted of the patient's routine outpatient visits and posed no risk to the patient. Patients can skip any questions they do not wish to answer during the follow-up. Patient information will be stored and transmitted securely with encryption, minimizing the risk of disclosure.

7. What are the benefits of participating in the study?

For patients in the control stage, the study used the Hangchuang system, which is used in routine diagnosis and treatment at Shenzhen Community Health Service Center, to collect comprehensive information about hypertension treatment. For patients in the intervention stage, the hypertension decision-making support system developed in the study provides treatment drugs, hypertension treatment plans, and health education based on the patient's individual information. This system is based on the hypertension prevention and control management guidelines and other cardiovascular-related guidelines. It not only helps doctors to be familiar with and understand the principles and guidelines for hypertension diagnosis and treatment, but also is expected to promote the standardized management of hypertension, especially by reminding doctors to provide patients with timely and standardized health education, drug treatment, and referral recommendations. This is of great significance in improving the rational use rate of antihypertensive drugs, thereby improving the control rate of hypertension and reducing the risk of long-term complications for patients. For all selected patients, the study will prompt doctors to arrange

regular follow-up. This will help patients and medical staff better understand their blood pressure control and the presence of other comorbidities, choose appropriate preventive treatment measures, and promote their treatment effects.

This study aims to improve the blood pressure control rate among patients with hypertension. The results may help enhance the management of primary hypertension through a simple and feasible method, enabling these patients to receive higher quality medical services in the future. Patients participating in this study are likely to benefit from the improved quality of medical care resulting from this study.

8. Do I have to participate in and complete the study?

Your participation in this project is entirely voluntary. If you do not wish to participate, you can decline without any negative impact on your current or future medical treatment. Even after you agree to participate, you may change your mind at any time and withdraw from the study by notifying the investigator via email, phone, or in person. Your withdrawal will not affect your access to normal medical care. In principle, after you withdraw from the study, the researcher will keep your relevant information confidential until final destruction, during which the information will not be used or disclosed. However, in the following rare cases, the researcher may continue to use or disclose your information even after you have withdrawn from the study or the study has ended. These circumstances include:

- Removing your information would compromise the scientific integrity of the research results or the evaluation of data security;
- Providing limited information for research, teaching, or other activities (this information will not include your name, ID number, or other personal identifiers);

The sponsor or regulatory authority may also terminate the study during the study period. In the event of early termination of the study, we will notify you promptly.

9. Are participants paid to participate in the study?

Participants in this study will not receive any direct financial compensation or immediate benefits. However, the data collected during the study will be used to improve medical services in the future, and participants may benefit from the enhanced quality of care resulting from the study's findings. The sphygmomanometer used in this study is part of the national basic public health service project and is provided free of charge to residents when they access services at the Community Health Service Center.

10. How to deal with research-related injuries?

The intervention measures in this study are based on the current guidelines for hypertension management in China, as well as health education for doctors in primary health care institutions and a treatment decision-support system. The final medical decision remains with the doctors, and there is no risk of adverse reactions that might be caused by clinical treatment measures. The intervention measures will not interfere with the routine treatment of hypertension patients in the outpatient department. The study's follow-up investigation consisted of the patient's routine outpatient visits and posed no risk to the patient. Patients can skip any questions they do not wish to answer during the follow-up. Patient information will be stored and transmitted securely with encryption, minimizing the risk of disclosure.

11. Will the results of the study be fed back to you?

The results of this study will not be given to you immediately, but will be published online in the form of a report, but the results of your examination will be given to you later.

12. Will my information be kept confidential?

If you decide to participate in the study, your participation and your personal data (including case information) will be kept confidential. Any information that could identify you will not be disclosed to

anyone outside the study group without your permission. All research members and parties involved will keep your identity confidential as required. Your file will be kept securely and will only be accessible to researchers.

To ensure that the study is conducted in accordance with regulations, government administrators, school authorities, or members of the unit responsible for the clinical study may access your personal data at the research unit, as required. No personal information about you will be disclosed at the time of publication of the results of this study.

13. Anything else to add?

The Research Coordination Center will provide the collaborating unit with the necessary equipment (such as a unified model of blood pressure monitor) and documentation for your examination. The project leader of the collaborating unit will be responsible for ensuring that the research equipment is properly maintained and used exclusively for the study, and that the research documentation materials are used and maintained according to the study Standard Operating Procedures (SOPs).

14. Who do I contact if I have questions or difficulties?

If you have any questions related to this study, please contact the Project Manager Guan Hongtian. The specific contact details are:

Tel: 0755-82180028-5060

Email: 1209709386@qq.com

Address: Shenzhen Hospital, Fuwai Hospital, Chinese Academy of Medical Sciences, 12 Langshan Road, Nanshan District, Shenzhen

If you have questions related to your own rights and interests, you may contact the following clinical research units:

Name of the unit responsible for clinical research	Contact number	Email
Chinese Academy of Medical Sciences Fuwai Hospital Shenzhen Hospital	0755-82180028	578409677@qq.com
Ethics Committee of Shenzhen Hospital, Fuwai Hospital, Chinese Academy of Medical Sciences	0755-82180028-8833	szfwyyirb@126.com

Researcher Statement

“ I have informed the subject of the study's reliability, background, purpose, procedures, risks, and benefits. I have given them sufficient time to read the informed consent form, discuss it with others, and answer any questions they may have about the study. I have also informed them of who to contact at any time if they have questions related to the study, including the Ethics Committee of Fuwai Hospital, Chinese Academy of Medical Sciences, Shenzhen Hospital. I have provided accurate contact information. I have informed the subject that they may withdraw from the study at any time. I have also informed them that they will be provided with a signed copy of this informed consent form. ”

The investigator who received the informed consent signed :

Data :

Subject Statement

“ I have been informed of the reliability of the study, its background, purpose, procedures, risks and benefits. I was given ample time and opportunity to ask questions, and I am satisfied with the answers. I was also told who to contact when I had questions, difficulties, concerns, suggestions for research, or wanted further information or help with research. I have read this informed consent form and agree to participate in the study. I understand that I may withdraw from the study at any time during the study period without any reason. I was told I would be given a copy of this informed consent form. ”

Subject Signature :

Date :