Personalized management of high blood pressure in Anhui, China

Submission date 12/07/2020	Recruitment status No longer recruiting	[X] Prospectively registered[X] Protocol
Registration date 17/07/2020	Overall study status Completed	[X] Statistical analysis plan[X] Results
Last Edited 30/06/2025	Condition category Circulatory System	Individual participant data

Plain English summary of protocol

Background and study aims

High blood pressure (or hypertension) can be caused and influenced by a number of factors including lifestyle and aging. When blood pressure is consistently too high this means that the heart has to work harder to pump blood around your body. Therefore, high blood pressure that is not managed can lead to diseases like a heart attack or stroke. In order to control high blood pressure, behavior modifications and/or treatment using medication may be required. Management may continue as a lifetime endeavor, and often changes to management plans will be needed in response to changing conditions for individual patients. The complexity of causes and long-term dynamics of controlling high blood pressure make personalized management necessary.

Personalized hypertension management (PHMA) is a method which aims to prevent hypertension from harming the health of the patient using eight objective behaviors including: 1. Attending and responding to project messages/contacts

- 2. Performing self-monitoring and reporting
- 3. Modifying unhealthy diet habits/practices
- 4. Maintaining adequate physical exercise/activities
- 5. Containing tobacco and alcohol consumption
- 6. Addressing emotion and sleep problems
- 7. Using clinical checkups and treatment
- 8. Facilitating family engagement and support.

The aim of this study is to test how effective PHMA is for managing high blood pressure and to identify key facilitators, barriers, and corresponding strategies in disseminating and implementing PHMA.

Who can participate?

Adult patients with a diagnosis of hypertension living in the selected villages in Anhui with participating general practices for over 6 months each year

What does the study involve?

Participants will either receive their usual hypertension care or over the study period.

Participants blood pressure and data about their use of healthcare services, health complications, and quality of life using structured questionnaires will be collected at the start of the study and every 12 months for the 5 years following.

What are the possible benefits and risks of participating?

There are not thought to be any risks involved with participating in the study. A possible benefit could be that participants will learn how to better control their hypertension.

Where is the study run from? 60 general practices in Anhui (China)

When is the study starting and how long is it expected to run for? From February 2020 to July 2025

Who is funding the study? National Natural Science Foundation of China (China)

Who is the main contact? Miss Xingrong Shen xinrongshen@sina.com

Contact information

Type(s) Scientific

Contact name Miss Xingrong Shen

ORCID ID https://orcid.org/0000-0002-9708-9659

Contact details Anhui Medical University 81 Meishan Road Hefei China 230032 +86 0551-65116395 xinrongshen@sina.com

Additional identifiers

EudraCT/CTIS number Nil known

IRAS number

ClinicalTrials.gov number Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

Personalized Hypertension Management (PHMA) based on serial assessment and telemedicine in Anhui, China

Acronym

PHMA

Study objectives

1. Compared to those in the control condition, hypertension patients in the personalized hypertension management (PHMA) intervention arm will demonstrate: lower systolic and diastolic BP; higher scores on objective behaviors including self-monitoring, medication adherence, healthy diet, physical activities, tobacco/alcohol consumption, anxiety/insomnia coping, and family engagement; and reduced use of medical care due to hypertension and its complications

2. Key facilitators, barriers, and corresponding strategies in disseminating and implementing PHMA will be identified

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 01/03/2020, Anhui Medical University Biomedical Ethics Committee (Anhui Medical University, 81 Meishan Road, Hefei, Anhui, China; +86 0551-65161053; renzhenhua@ahmu.edu. cn), ref: 20200936

Study design

Multi-centre cluster randomized controlled trial using control and synchronous intervention arms

Primary study design Interventional

Secondary study design Cluster randomised trial

Study setting(s) GP practice

Study type(s) Quality of life

Participant information sheet No participant information sheet available

Health condition(s) or problem(s) studied Hypertension

Interventions

The study adopts a cluster randomized controlled trial (RCT) design involving a total of 60 site communities with 12 in the control arm and 48 in the intervention arm. The control arm maintains existing hypertension patient management; while the intervention arms, personalized hypertension management (PHMA). Project evaluation applies to all arms using the same data collection methods and by the same field data collectors. And detailed intervention in intervention arms varies from patient to patient due to the personalized approach. So, the uneven distribution of site communities between the control and intervention arms were designed to enable detection of potential differences between the control arm and three to four main subgroups with different intervention ingredients in the intervention arm. The analysis and reporting of the trial will be in accordance with the CONSORT guidelines.

The overall goal of PHMA is to prevent hypertension from harming the health of the patient under concern. This goal is reached by eight objective behaviors including:

- 1. Attending and responding to project messages/contacts
- 2. Performing self-monitoring and reporting
- 3. Modifying unhealthy diet habits/practices
- 4. Maintaining adequate physical exercise/activities
- 5. Containing tobacco and alcohol consumption
- 6. Addressing emotion and sleep problems
- 7. Using clinical checkups and treatment
- 8. Facilitating family engagement and support.

These objective behaviors are promoted through two intervention stages and four intervention measures. The four intervention measures are: support for self-monitoring (I1), personalized daily message (I2), supervised machine counseling (I3), and signed quarterly feedback (I4). The design of these measures is guided by proven theories or strategies including system synergy, health belief model, social cognition theory, motivational interviewing, nudging strategies, and computerized tailoring. Detailed intervention varies from patient to patient due to the personalized nature of the intervention.

Intervention Type

Behavioural

Primary outcome measure

Systolic BP/Diastolic BP measured using mercury sphygmomanometer at baseline and every 12 months after baseline for 5 years

Secondary outcome measures

1. Quality of life

2. Occurrence of hypertension-related complications (such as cerebral hemorrhage, coronary heart disease, myocardial infarction, cerebral infarction)

- 3. Healthcare utilization
- 4. Scores of objective behaviors

All secondary outcome measures will be measured using structured questionnaires at baseline and every 12 months after baseline for 5 years

Overall study start date

01/02/2020

Completion date

30/07/2025

Eligibility

Key inclusion criteria

Aged ≥18 years
 Living in the selected villages for ≥6 months/year
 Diagnosed with hypertension

Participant type(s)

Patient

Age group Adult

Lower age limit 18 Years

Sex Both

Target number of participants 3,420

Total final enrolment 2392

Key exclusion criteria Previous diagnosis of mental illness, serious illness, or disability

Date of first enrolment 01/08/2020

Date of final enrolment 30/07/2025

Locations

Countries of recruitment China

Study participating centre Anhui Medical University 81 Meishan Road Hefei China 230032

Sponsor information

Organisation

National Natural Science Foundation of China

Sponsor details

83 Shuangqing Road Haidian District Beijing China 100085 +86-10-62327001 bic@nsfc.gov.cn

Sponsor type Government

Website http://www.nsfc.gov.cn/publish/portal1/

ROR https://ror.org/01h0zpd94

Funder(s)

Funder type Government

Funder Name National Natural Science Foundation of China

Alternative Name(s)

Chinese National Science Foundation, Natural Science Foundation of China, National Science Foundation of China, NNSF of China, NSF of China, , National Nature Science Foundation of China, Guójiā Zìrán Kēxué Jījīn Wěiyuánhuì, NSFC, NNSF, NNSFC

Funding Body Type Government organisation

Funding Body Subtype National government

Location China

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

30/07/2026

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	12/03/2021	15/03/2021	Yes	No
<u>Statistical Analysis Plan</u>	version 1	21/03/2024	18/06/2025	No	No
<u>Results article</u>		31/05/2025	30/06/2025	Yes	No