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Personalized management of high blood pressure in Anhui, China

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

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?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number

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

Study type(s)
Quality of life

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

Key secondary outcome(s))
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

Completion date
30/07/2025

Eligibility

Key inclusion criteria
1. Aged ≥18 years
2. Living in the selected villages for ≥6 months/year
3. Diagnosed with hypertension

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
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Sponsor information

Organisation
National Natural Science Foundation of China

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

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?
Results article		31/05/2025	30/06/2025	Yes	No
Protocol article	protocol	12/03/2021	15/03/2021	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Statistical Analysis Plan	version 1	21/03/2024	18/06/2025	No	No