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Effective and low-cost management of cardiovascular risks at primary healthcare settings in Anhui, China.

Submission date 27/01/2026	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 28/01/2026	**Overall study status** Ongoing	
Last Edited 19/06/2026	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
Cardiovascular diseases are a major and growing health problem, causing illness, deaths, and high healthcare costs. In China, primary healthcare clinics play an important role in preventing and managing these conditions, but they face challenges such as limited training, lack of support, and few incentives. This study aims to test whether a new, costeffective system can help clinicians provide better care and help patients manage their health more effectively.

Who can participate?
People can take part if they live permanently in the communities served by the 32 selected clinics in Anhui Province, are aged 18 or older, and have been diagnosed with hypertension, diabetes, high cholesterol, or any cardiovascular disease. All fulltime clinicians responsible for chronic disease care in these clinics will also participate.

What does the study involve?
The study will include 32 clinics. Half will continue with their usual care, and the other half will use the new care approach. Participants in both groups will have health assessments at the start of the study, after 12 months, and after 24 months.
In clinics using the new approach, clinicians will follow a stepbystep system to decide what support each patient needs. This may include advice on diet, exercise, stopping smoking, reducing alcohol, managing stress, and monitoring blood pressure, blood sugar, cholesterol, or weight. Patients may also receive personalised leaflets to support selfmanagement at home.

What are the possible benefits and risks of participating?
Participants may benefit from receiving more personalised support to manage their health, which could help improve their cardiovascular risk factors. There are no known major risks. Some people may find the extra assessments or lifestyle discussions timeconsuming, but these are expected to be minimal.

Where is the study run from?
The study is being carried out in Anhui Province, China.

When is the study starting and how long is it expected to run for?
The study will run from March 2026 to March 2028.

Who is funding the study?
The study is funded by the National Natural Science Foundation of China.

Who is the main contact?
Associate Professor Xingrong Shen, shenxr@ahmu.edu.cn

Contact information

Type(s)
Public, Scientific, Principal investigator

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Study information

Scientific Title
Cost-effectiveness-oriented management(CEOM) of cardiovascular risks at primary healthcare settings in Anhui, China

Study objectives
The current trial aims to test the efficacy of an integrated and Cost-effectiveness-oriented intervention to overcome the main existing problems and thus improve CVD risk and harm management at primary healthcare settings in Anhui, China.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 07/03/2023, Anhui Medical University Biomedical Ethics Committee (Anhui Medical University, 81 Meishan Road, Hefei, Anhui, 230032, China; +86 0551-65161053; renzhenhua@ahmu.edu.cn), ref: 83230358

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Prevention

Study type(s)

Health condition(s) or problem(s) studied
Cardiovascular disease

Interventions
Participants randomized to the intervention arm will implement an integrated and Cost-effectiveness-oriented management (CEOM) of CVD risks and harms using algorithm or model assisted: standardization of clinical diagnosis and treatment procedures according to guidelines and expert consensus; and promotion of personalized self-management based on the changing health and behavioral conditions of the individual participants under concern.

Randomization will be conducted after the baseline but before the intervention by an independent statistician using the "Sealed Envelope" web-based system. He/she will employ a stratified randomization method by county. More specifically, he/she will randomly assign the two selected village clinics from each county in a 1:1 ratio to either the intervention or control group. While blinding of village clinicians and patients is not feasible due to the nature of the intervention, the statisticians will be kept blinded throughout the analysis process.

Intervention Type
Behavioural

Primary outcome(s)
Incremental Cost-effectiveness ratio (ICER) calculated using the EuroQol 5-Dimension 5-Level (EQ-5D-5L) instrument and cost-utility survey data at baseline and at 12 and 24 months after baseline.

Key secondary outcome(s)
1. Patient knowledge, attitude, and practice (KAP) regarding nutrition/diet, physical activity, smoking and alcohol abstinence, emotional and sleep problems, selfmonitoring, health service use, and treatment adherence is measured using a structured questionnaire at baseline, 12 months, and 24 months
2. Systolic and diastolic blood pressure is measured using a validated automated blood pressure

monitor at baseline, 12 months, and 24 months
3. Fasting plasma glucose is measured using a fasting blood test at baseline, 12 months, and 24 months
4. HbA1c is measured using a laboratory HbA1c assay at baseline, 12 months, and 24 months
5. Lipid profile (LDLC and total cholesterol) is measured using a fasting blood lipid panel at baseline, 12 months, and 24 months
6. Body mass index (BMI) is measured using height and weight measurements at baseline, 12 months, and 24 months
7. Major adverse cardiovascular events (nonfatal myocardial infarction, nonfatal stroke, and cardiovascular death) are measured using routinely collected medical records at baseline, 12 months, and 24 months
8. Quality of life is measured using the EQ5D5L questionnaire at baseline, 12 months, and 24 months
9. Medical costs, including outpatient visits, inpatient admissions, medications, and other direct medical expenditures, are measured using routinely collected healthcare expenditure data at baseline, 12 months, and 24 months

Completion date
30/03/2028

Eligibility

Key inclusion criteria
Current key inclusion criteria as of 01/06/2026:

Clinicians:
1. Hold a valid medical license and work full-time at the participating clinics
2. Are directly responsible for the routine management and clinical care of CVD-related patients
3. Agree to participate in the study and sign the informed consent form

Patients:
1. Permanent residents (residing >6 months/year) aged 35 years or older
2. Diagnosed with hypertension, type-2 diabetes and/or established CVD (specifically coronary heart disease, stroke, or transient ischemic attack)
3. Willing and able to complete follow-up assessments

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Previous key inclusion criteria:

Clinicians:
1. Hold a valid medical license and work full-time at the participating clinics
2. Are directly responsible for the routine management and clinical care of CVD-related cases
3. Agree to participate in the study and sign the informed consent form

Patients:
1. Age 18 years
2. Have clinical diagnosis of CVD-related conditions (including hypertension, diabetes, coronary heart diseases, stroke sequelae, etc.)
3. Are permanent residents (living in the site villages for >6 months a year)
4. Are willing and able to participate and complete the pre-set surveys (e.g., EQ-5D-5L); 5) have signed the informed consent form

Participant type(s)
Health professional, Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
35 Years

Upper age limit
99 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
Current key exclusion criteria as of 01/06/2026:

Clinicians
1. Will retire or plan to leave their current practice within the next 24 months

Patients:
1. Experienced acute cardiovascular events within the past 3 months (such as acute myocardial infarction, unstable angina, or acute stroke)
2. Exhibit severe cognitive, mental, or sensory impairments that preclude smooth follow-up assessments
3. Plan to move out of the study area

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Previous key exclusion criteria:

Clinicians
1. Will retire or plan to leave their current practice within the next 24 months
2. Are participants in other interventional studies which may confound the results of the current trial

Patients:
1. Plan to move out of the selected site villages within the next 24 months
2. Are participants in other interventions that may confound the results of the current trial

Date of first enrolment
01/03/2026

Date of final enrolment

30/03/2026

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

ROR
https://ror.org/01h0zpd94

Funder(s)

Funder type
Not defined

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

De-identified individual participant data will be made available beginning 3 months and ending 5 years following the publication of the primary manuscript. Data will be shared with researchers who provide a methodologically sound proposal to achieve the aims in the approved proposal. To gain access, data requestors will be required to sign a data access agreement. Proposals and requests for clarification should be directed to shenxr@ahmu.edu.cn. The steering committee will consider requests for specific data points provided that such disclosure does not jeopardize future planned publications by the research team.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		18/06/2026	19/06/2026	Yes	No