BMC Public Health

STUDY PROTOCOL

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Strengthening China's National Essential Public Health Services Package for hypertension and diabetes care: protocol for an interrupted time series study with mixed-methods process evaluation and health economic evaluation

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Abstract

Background Despite major primary health care (PHC) reforms in China with the 2009 launch of the National Essential Public Health Service Package, the country experiences many challenges in improving the management of non-communicable diseases in PHC facilities. "EMERALD" is a multifaceted implementation strategy to strengthen the management of hypertension and type-2 diabetes mellitus (T2DM) in PHC facilities. The study aims to: (1) examine the effectiveness of EMERALD in improving hypertension and T2DM management; (2) evaluate the implementation of the interventions; and (3) use the study findings to model the long-term health economic impact of the interventions.

Methods The EMERALD intervention components include: (1) empowerment for PHC providers through training and capacity building; (2) empowerment for patient communities through multi-media health education; and (3) empowerment for local health administrators through health data monitoring and strengthening governance of local PHC programs. An interrupted time series design will be used to determine the effectiveness of the interventions based on routinely collected health data extracted from local health information systems. The primary effectiveness

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outcome is the guideline-recommended treatment rates for people with hypertension and T2DM. Secondary effectiveness outcomes include hypertension and T2DM diagnosis and control rates, and enrolment and adherence rates to the recommended care processes in the National Essential Public Health Service Package. A mixed-methods process evaluation will be conducted to evaluate the implementation of the interventions, including the reach of the target population, adequacy of adoption, level of implementation fidelity, and maintenance. Qualitative interviews with policy makers, health administrators, PHC providers, and patients with hypertension and/or T2DM will be conducted to further identify factors influencing the implementation. In addition, health economic modelling will be performed to explore the long-term incremental costs and benefits of the interventions.

Discussion This study is expected to generate important evidence on the effectiveness, implementation, and health economic impact of complex PHC interventions to strengthen the primary care sector's contribution to addressing the growing burden of non-communicable diseases in China.

Trial registration The study has been registered on Chinese Clinical Trial Registry at https://www.chictr.org.cn/ (Registration number ChiCTR2400082036, on March 19th 2024).

Keywords Hypertension, Type-2 diabetes, Primary health care, Interrupted time series

Background

Over the past decade, China has invested considerable effort in primary health care (PHC) reforms to address the growing burden of non-communicable diseases (NCDs) [1, 2]. One major reform is the National Essential Public Health Service Package (NEPHSP) [3], which is a publicly funded national program that requires PHC providers, such as general practitioners and public health workers in township hospitals and village doctors (i.e., non-physician rural health workers with basic medical training) in village clinics, to provide routine health services for hypertension and type-2 diabetes mellitus (T2DM), to all residents aged 35 years or older. Despite notable progress and achievements with this reform, major gaps remain in optimizing NCD management in China [4–6]. A recent national cross-sectional study in China found inadequate adherence to recommended guidelines in screening and caring for hypertension, with only 56% of sampled PHC providers meeting guideline standards for blood pressure measurements [7].

One driver of sub-optimal health system performance is the limited capacity of China's PHC providers, both in terms of inadequate supply to meet demand and insufficient skills with many providers receiving insufficient education, training, and ongoing support [4, 5]. On the demand side, despite increasing emphasis on health education and promotion from the Chinese government [8], health literacy levels remain low, with large regional and population disparities [9]. Moreover, studies also suggest some local governments in China have inadequate health governance due to a lack of cross-sectoral collaboration and frequently shifting policy focuses [5]. Subsequently, the uptake of some of the national health initiatives in China, including the NEPHSP, remain suboptimal [5].

There have been several implementation trials in China to address these challenges. A recent cluster-randomised controlled trial (cRCT), conducted in three provinces in rural China (the CRHCP project), found an intensive intervention package including training and performance-based payments for PHC providers (non-physician village doctors) reduced systolic blood pressure by 23.1 mm Hg and diastolic blood pressure by 9.9 mm Hg, and was associated with a 33% reduction of cardiovascular disease events over three years [10, 11]. A cRCT conducted in northern rural China (the SINEMA project) found that training for village clinicians and health education for residents through mobile health technologies reduced systolic blood pressure control by 2.8 mm Hg compared with usual care and was associated with improved quality of life, physical activity, and medication adherence [12]. Another cRCT found community-based programs to improve residents' health literacy in Shanghai, China, reduced glycated haemoglobin (HbA1c) by 0.90% among people with T2DM [13]. Although these trials have demonstrated the effectiveness of PHC-focused interventions in NCD management, the interventions were one-off programs that relied on large research grants and may have limited sustainability in non-research settings. Few trials have been embedded within local governance structures and as part of the NEPHSP or existing health systems. Further, few of these studies examined implementation outcomes to understand how to spread and scale the interventions to other settings in China and beyond.

Following a comprehensive evaluation of China's PHC system for NCD management from the policy, facility, and patient population's perspectives [1, 5, 6], this paper describes the rationale and protocol for an interrupted time series study to evaluate "EMERALD", which stands for "*e*mpower pri*m*ary h*e*alth ca*r*e st*a*keho*ld*ers", a multifaceted intervention package comprising strategies to improve the capacity of PHC providers, promote health education of the patient communities, and to strengthen

local health governance for the management of hypertension and T2DM in China.

Methods

Study aim and objectives

The overall aim of this study is to examine the effectiveness, implementation, and health economic impact of EMERALD in improving hypertension and T2DM management in PHC facilities in selected regions in China. Specific objectives of the study are:

1. To determine the effectiveness of EMERALD in improving the diagnosis, treatment, and control rates for hypertension and T2DM, and people's enrolment in and adherence to the routine care of the NEPHSP;
2. To evaluate the implementation of EMERALD, including the reach of the target population, adequacy of adoption, level of implementation fidelity, and maintenance; and.
3. To explore the long-term incremental health economic impact of EMERALD on hypertension and T2DM management.

Study design

This study includes: (1) an interrupted time series design using routinely collected data from local health systems (2), a mixed-methods process evaluation, and a (3) health economic modelling study. The study has been registered on Chinese Clinical Trial Registry at https://www.chictr.org.cn/ (Registration number: ChiCTR2400082036, on March 19th 2024). This study protocol adheres to the SPIRIT 2013 reporting guideline for clinical trials (Complete checklist presented in Appendix 1).

Study setting

The study will be conducted in four regions: Xiling District from Yichang city of Hubei province in central China, Wenjiang District from Chengdu city of Sichuan province in western China, Acheng District from Harbin city and Jiao District from Jiamusi city from Heilongjiang province in Northern China (Fig. 1). These sites were purposively sampled considering diversity in geographics, population sizes, resident socio-economic characteristics, and previous collaborations. According to China's 7th census data and National Economic and Social Development Statistical Bulletin in 2021 [14, 15], population sizes of study sites vary greatly from 265,340 people in Jiao District to 967,868 people in Wenjiang District. They also vary in the status of rurality, where all residents in

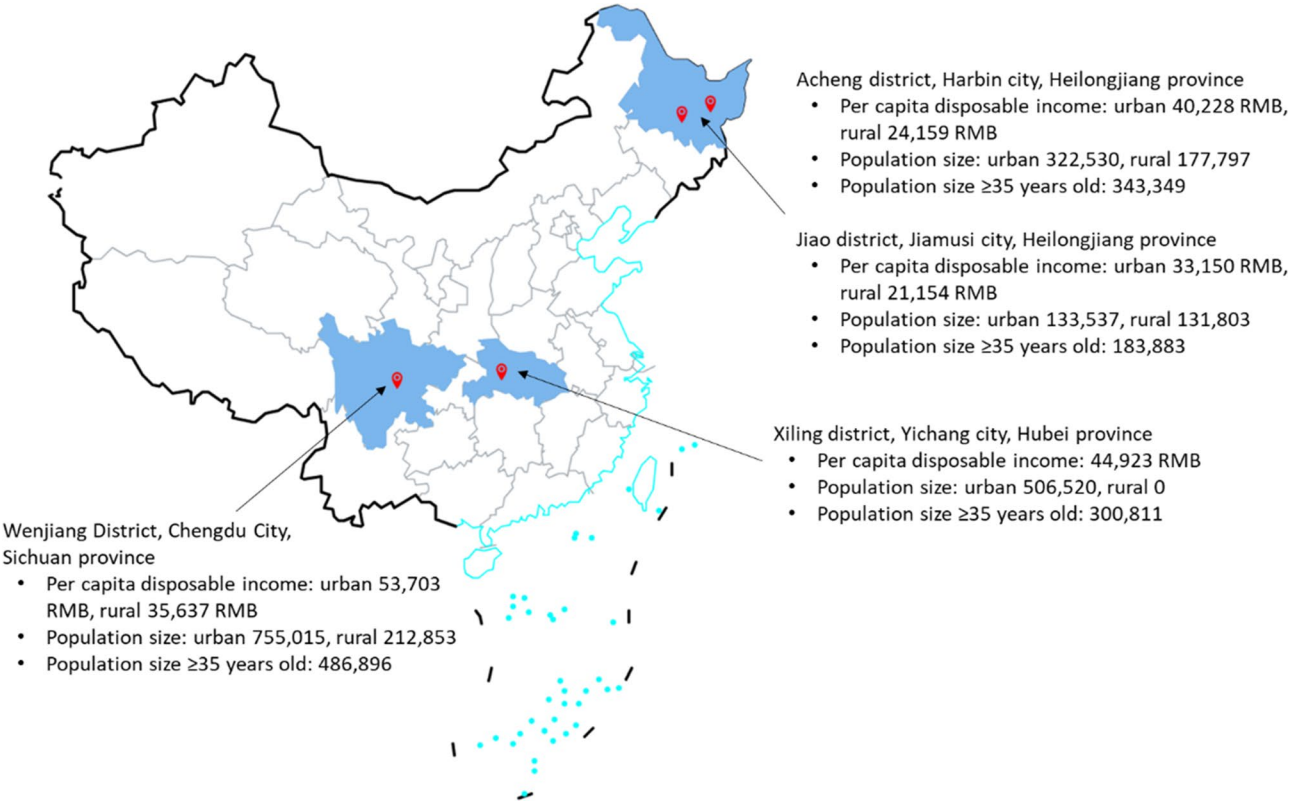

Fig. 1 Geographic locations and basic demographic information of selected study sites in China

Xiling District are considered urban, while half the population in Jiao District are rural. Figure 1 shows the geographic locations and basic demographic information of the selected sites in China.

Theoretical frameworks

EMERALD is aligned with the World Health Organisation (WHO) five strategies for integrated people-centred care (Fig. 2). This framework provides five interwoven recommendations on how to strategically optimise the health system toward universal health coverage [16], including engaging and empowering people and communities, strengthening governance and accountability, reorienting the model of care (towards community and primary care), coordinating services within and across sectors, and creating an enabling environment for all the above strategies.

We will use the RE-AIM framework to guide the evaluation (Fig. 2). RE-AIM was developed to assess and address failures in the translation of scientific evidence into practice and policy, and it contains five key dimensions including reach and effectiveness (individual level), adoption and fidelity (staff, setting, system, and policy levels), and maintenance (individual, staff, setting, system, and policy levels) [17]. RE-AIM has been widely used in program evaluation, especially in public health and health behaviour change research, and gaining increasing attention in diverse fields in clinical, community, and corporate settings [18].

The EMERALD interventions

The following descriptions for the interventions follows the TIDIeR reporting guideline (Appendix 2) [19]. The EMERALD interventions consist of three major components for empowering PHC stakeholders (Figs. 2 and 3). First, on the supply side (i.e., empowering PHC providers), we aim to increase PHC provider capacity primarily through monthly training sessions across all study sites, to be delivered in a hybrid mode both online and in-person. Contents of the training sessions are focused on improving provider capacity in screening, diagnosis, and management for hypertension and T2DM, as well as enhancement for "soft skills" focused on person-centeredness such as patient-provider communications and shared decision making with patients and their families. The training modules are provided by a group of clinical experts, supervised by the local centres for disease control and prevention (CDCs). After the training sessions, the PHC providers will also receive multi-media educational materials for ongoing access to the content from the training sessions.

Second, on the demand side (i.e., empowering patient communities), we aim to enhance patient health literacy through weekly multi-media health education messages and monthly offline health education seminars across all study sites. The health education messages will be delivered on multiple social media platforms including TikTok and WeChat, mainly in the format of videos and short-message services. Both the multi-media messages and health education seminars will be focused on improving residents' knowledge and skills for disease

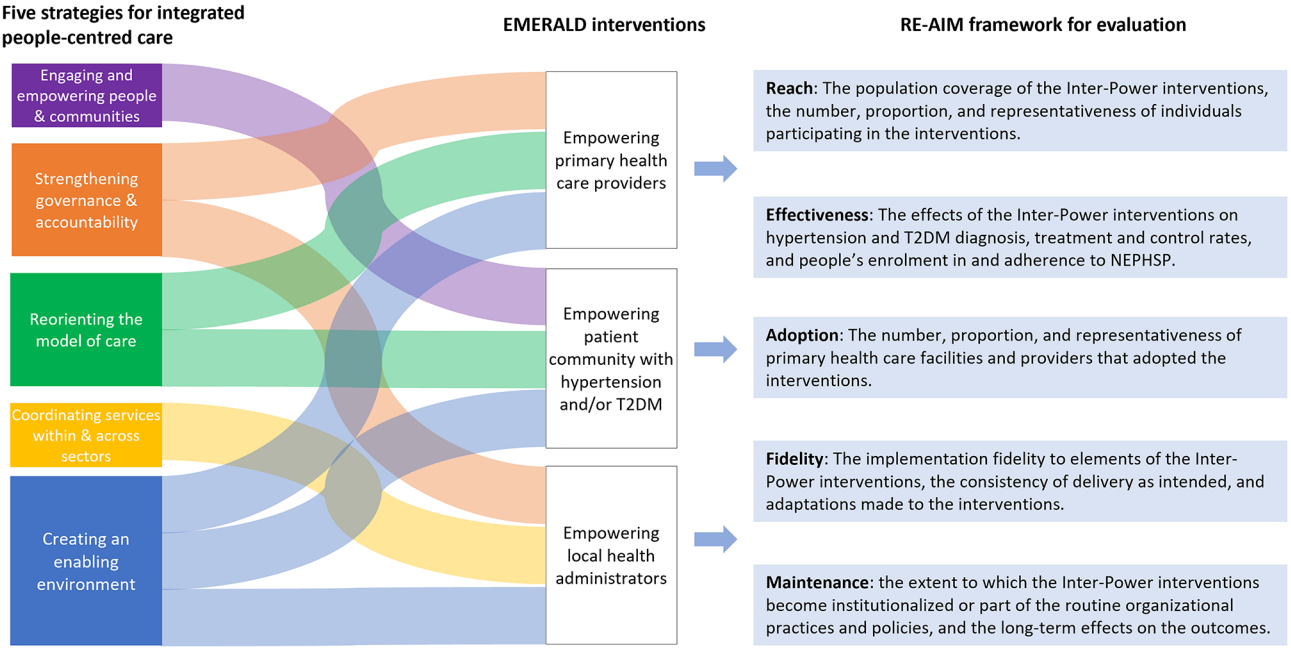

Fig. 2 Theoretical frameworks and the EMERALD Interventions

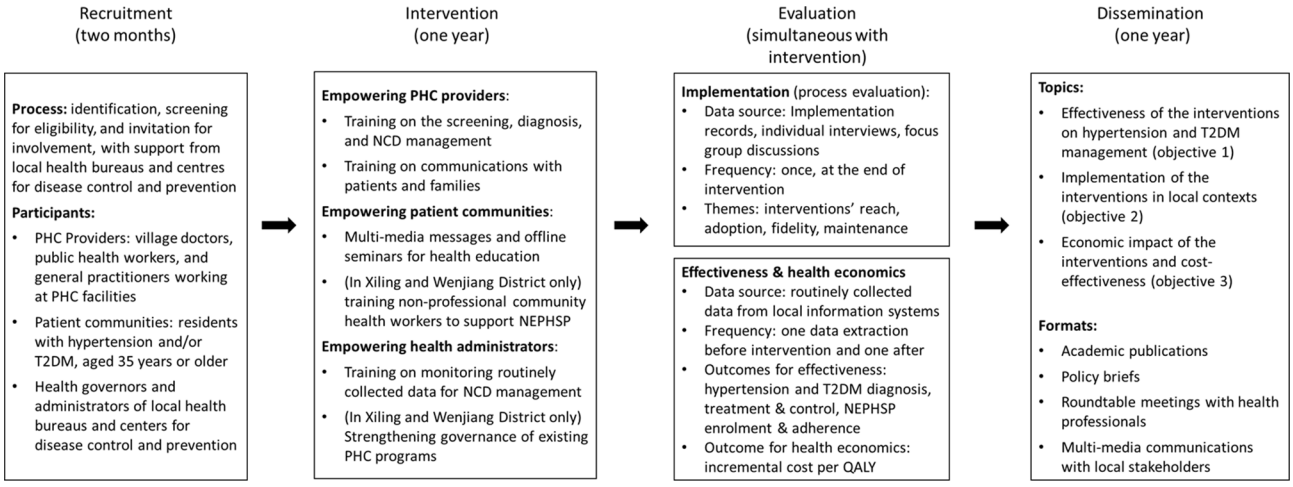

Fig. 3 Study process flowchart including recruitment, intervention, evaluation, and dissemination

self-management, promoting healthy lifestyle on physical activity, diet, drinking and smoking, improving medication adherence, and raising awareness for and promoting services of the NEPHSP. Contents of the messages and seminars will be created by the research team with support from health education experts, and will be distributed and promoted by local CDCs. Moreover, in Xiling District and Wenjiang District, an additional region-specific intervention component will be introduced to empower patient communities. This involves training non-professional community health workers to assist existing PHC providers for the NEPHSP in basic capacities, including reminding and mobilizing residents to attend quarterly follow-ups and annual health checks, and delivering medications to those in need.

Third, we aim to empower local health administrators on health governance. This includes training for local health administrators of all study sites on PHC data monitoring. Our previous study has demonstrated the feasibility of using linked health data across various local information systems to provide insights about hypertension and T2DM management in local populations [6]. In this study, local health administrators will be trained to utilise and monitor the local routinely collected health data to assess PHC performances in hypertension and T2DM management, and to supervise the accuracy and quality of data input into the information systems. Moreover, in Xiling District and Wenjiang District, several locally initiated PHC programs will be integrated as region-specific interventions. Specifically, in Xiling District, an ongoing establishment of "community clinics" in residential communities was initiated by the municipal government, which will be governed by community health centres (a traditional urban PHC facility) to increase the coverage and quality of PHC services. In Wenjiang District, an important local PHC initiative was the creation of a "provincial public health committee". This initiative aims to enhance collaborations across government sectors, specifically the Provincial Health Commission and the Department of Civil Affairs, with the goal of strengthening the provision and adoption of the NEPHSP. Regular engagement meetings will be held in these study sites, where researchers will support local health administrators in the governance of these local PHC programs.

Eligibility criteria for participants

We are using the classification of health facilities by China's National Health Commission's health statistics yearbook to identify eligible PHC facilities that provide services for the NEPHSP [20]. Such PHC facilities include community health centres, community health stations, township hospitals, and village clinics, overseen by the local CDCs [3].

Corresponding to the three intervention components, three participant groups are involved in the interventions (Fig. 3): (1) PHC providers, including village doctors, public health workers, and general practitioners working at PHC facilities; (2) local residents aged 35 years or older, diagnosed with hypertension and/or T2DM; and (3) health administrators at the city and district levels, including those at the city and district health bureaus, city and district CDCs, and district hospitals.

Residents will be excluded if they have (1) serious audio-visual disability; (2) severe impairment leading to loss of most self-care capacity in daily function; or (3) terminal illness or life-threatening diseases. PHC providers and health administrators will be excluded if they are (1) on annual or maternity leave; or (2) new to the related position and have worked for less than three months in the role.

Trial outcomes

Effectiveness outcomes

The primary effectiveness outcomes are the treatment rates for hypertension and T2DM, separately, defined as the proportion of people receiving recommended treatments for hypertension/T2DM among those that are diagnosed and enrolled in the NEPHSP. Guideline-recommended medicines for hypertension and T2DM and insulin for T2DM will be included as recommended treatments.

Secondary effectiveness outcomes include:

1. Diagnosis rates for hypertension and T2DM, separately, and diagnosis rate for the two diseases combined, defined as the proportion of people with a recorded diagnosis in local routinely collected data among the estimated total numbers of people living with hypertension/T2DM;
2. Control rates of hypertension and T2DM, separately, and control rate for the two diseases combined, defined as the proportion of people achieving the control targets according to the NEPHSP among those receiving treatments [3]. For hypertension, the target is having blood pressure lower than 140/90 mmHg for people aged 35–64 years, and 150/90 mmHg for those aged 65 years or older; for T2DM, the target is having fasting plasma glucose lower than 7.0mmol/L; [3]
3. Enrolment rates in the NEPHSP for hypertension and T2DM separately, and enrolment rates for the two diseases combined, defined as the proportion of people enrolled in the NEPHSP among those with a recorded diagnosis of hypertension/T2DM in routinely collected data; and.
4. Adherence rates to the NEPHSP for hypertension and T2DM separately, and enrolment rates for the two diseases combined, defined as the proportion of people adhering to the routine care of the NEPHSP among those enrolled, which include quarterly follow-up visits and an annual health check [3].

Implementation outcomes

A mixed-methods process evaluation based on both qualitative and quantitative information will be conducted to examine the implementation of the interventions, guided by the RE-AIM framework (Fig. 2) [17].

1. "Reach" will include numbers, proportions, and representativeness (e.g., diversity in locations, demographics, and socioeconomics) of residents and communities reached by the multi-media messages and offline health education seminars.
2. "Adoption" includes numbers, proportions, and representativeness of PHC facilities adopting the provider training modules, and numbers, proportions, and representativeness of PHC providers receiving and completing the training sessions.
3. "Fidelity" includes the consistency of delivery as intended, and adaptations made to the interventions.
4. "Maintenance" refers to the extent to which the EMERALD interventions become institutionalised or part of the routine organisational practices and policies, and the long-term effects on the outcomes. Both fidelity and maintenance will be determined mainly through qualitative interviews with local health administrators.

Data collection

Effectiveness evaluation and health economic modelling

To determine the effectiveness of the interventions and to construct health economic models (Fig. 3), we will analyse routinely collected data from local health systems, which include all eligible electronic records of those aged 35 or above and with hypertension and/or T2DM. Linked data sources include: (1) regional health insurance data from the local healthcare security administration; (2) NEPHSP archive and service records from local PHC facilities; (3) electronic health records from local hospitals; and (4) death surveillance data from local CDCs. We have previously demonstrated the feasibility of collecting, linking and analysing these data sources [6].

Data extraction will be performed twice on the routinely collected datasets (Table 1). The first data extraction will be performed before the interventions commence, and the second data extraction at the end of the one-year intervention. A total of 24 data points will be generated for the interrupted time series (i.e., 12 data points before the intervention and 12 after), with a one-month gap between two consecutive data points. Data to be extracted from the routinely collected data include residents' demographic and socio-economic information, disease diagnosis, medication use, blood pressure and blood glucose readings, enrolment status of the NEPHSP, and service records in the NEPHSP. For the health economic models, we will further extract data on the cost of the inpatient services, outpatient services, clinical visit records, mortality information, and program implementation data, to support the economic evaluation.

Data will be extracted and monitored by a local data manager/technician nominated by the head of the local healthcare security administration, PHC facility and centres of disease control of each study site, independent from the research team. With assistance from the research team, the local data technician will perform the

Table 1 Summary of data collection process

What data	From where	When to collect
Effectiveness of interventions, based on local routinely collected data		
• Health insurance data	• Local healthcare security administration	• Twice in total: once before intervention, and once 12 months post-intervention
• NEPHSP archive and service records	• Local PHC facilities	
• Electronic health records	• Local hospitals	
• Death surveillance data	• Local CDCs	
Mixed-methods evaluation on implementation		
• Quantitative data on communities and residents reached by health education	• Local CDCs	• 12 months post-intervention
• Quantitative data on residents attending offline health education seminars	• Local CDCs	• 12 months post-intervention
• Quantitative data on PHC facilities adopting provider training modules	• Local CDCs	• 12 months post-intervention
• Quantitative data on PHC providers receiving and completing training sessions	• Local CDCs	• 12 months post-intervention
• Qualitative interviews with patient community members	• Local PHC facilities	• 12 months post-intervention
• Qualitative interviews with PHC providers	• Local PHC facilities	• 12 months post-intervention
• Qualitative interviews with local health administrators	• Local CDCs	• 12 months post-intervention
• Qualitative interviews with policy makers	• National and provincial health commission, national and provincial CDCs	• 12 months post-intervention

extractions, and will conduct individual linking based on the national IDs of participant data from the different sources of routinely collected data. Participant identifiable information, including the national IDs, will not be accessible to the research team.

Mixed-methods evaluation on implementation

During project implementation, the local CDCs will record quantitative data related to the implementation of interventions (Table 1), including information on communities and residents reached by the health education messages and seminars, PHC facilities adopting the provider training modules, and PHC providers receiving and completing the training sessions.

At the end of the one-year interventions, we will conduct semi-structured interviews to further identify factors influencing the intervention implementation with a diverse sample of PHC providers, patient community members, and local health administrators (Fig. 3). PHC providers will be identified and contacted by collaborators from the local CDCs. Patient community members with hypertension and/or T2DM will then be identified and invited by providers of the involved PHC facilities. Based on the eligibility criteria, policy makers, health administrators will be purposively identified from the investigators' existing contact network. In addition, we will also seek insights from policy makers, health administrators representing national and provincial health commission, national and provincial CDC officials. Snowball sampling will be also used to identify additional potential participants.

Focus group discussions will be the primary mode of data collection for PHC provider and patient interviews, because this allows for participant interactions amongst each other, stimulating interactive discussion on major themes, and can increase contributions from people who may otherwise remain silent. We will involve 3–5 individuals in each focus group discussion. For policy makers and health administrators, on the other hand, we will conduct individual interviews to gain better understandings of managerial reflections and concerns. The focus group discussions and individual interviews will be conducted face-to-face.

One senior study investigator will facilitate each interview. Trained researchers will take notes about the overall interview process including the nonverbal expression of the interviewees during the interviews. The interview guides were developed based on the RE-AIM domains (Appendix 3 - interview guide for policy makers, health administrators, and PHC providers, and Appendix 4 – interview guide for people with hypertension and/or T2DM). Interviews will be audio-recorded and transcribed verbatim. Participant identifiable information will not be collected and audio-recorded during the interview.

Data analysis

Effectiveness of interventions

At each data time point, we will conduct descriptive analyses to determine the diagnosis, treatment, and control rates for hypertension and T2DM, separately, and the enrolment and adherence rates for the NEPHPSP. After that, we will generate scatter plots of the time series to identify the underlying trend, seasonal patterns and outliers. Within the scatter plot, we will plot the "expected" line of trend on the time series based on the previous year without intervention, to indicate normal fluctuations due to non-intervention factors such as seasonality. We will conduct the interrupted time series analysis using Prais-Winsten generalised least-squares regression with robust

standard errors, to account for first-order autocorrelation [21]. The regression model will be conducted separately by each study site, and then the results will be pooled together through meta-analysis using study site as a random effect.

Health economic evaluation

A modelled cost effectiveness analysis will be conducted to evaluate the economic merits of scaling up the interventions. The economic evaluation will be conducted from a health system's perspective. We will include the cost of the inpatient services, outpatient services, medication use, pathology tests, and intervention implementation for the analysis. We will use changes in blood pressure and HbA1c measurements from the trial to model the potential health benefits and cost-effectiveness over a 10-year period. The risk of atherosclerotic cardiovascular disease (ASCVD) over 10 years and quality-adjusted life years (QALYs) will be used as effectiveness measures in the economic evaluation. We will utilise the 10-year ASCVD risk prediction equation [22], to evaluate the difference in ASCVD over 10 years period between the intervention group and a hypothetical population without intervention. The incremental cost of reducing 1% in 10-years risk of ASCVD and of one QALY gained will be calculated to determine the cost-effectiveness of intervention. We will use 128,000 RMB (US$17,782) per QALY as the cost effectiveness threshold [23].

Mixed-methods evaluation on implementation

For quantitative data associated with intervention implementation, we will conduct descriptive analysis on the implementation outcomes, which will be summarised as mean ± SD or median (inter-quartile range) for continuous variables and frequency (n and %) for categorical variables.

For qualitative analysis, a combination of inductive and deductive approaches and thematic content analysis will be used. First, the deductive approach will involve reviewing the transcripts verbatim and assigning codes around the five major RE-AIM domains (i.e., reach, effectiveness, adoption, fidelity, and maintenance). The inductive approach will identify and generate granular codes under each domain to determine participant perceptions of factors that influenced the implementation of the interventions. At least two coders will conduct the qualitative analysis independently. The research team will discuss the coding discrepancies and resolve by consensus to optimise inter-coder reliability.

Sample size considerations

Our previous research based on routinely collected data in the same study sites (except for Wenjiang District, which was changed from Wenchuan County in the same province) estimated that the numbers of people with hypertension were 111,902 in Xiling District, 127,726 in Acheng District, and 68,404 in Jiao District, and the numbers for T2DM were 38,504 in Xiling District, 43,949 in Acheng District, and 23,537 in Jiao District [6]. These estimations were calculated by multiplying the numbers of residents aged 35 years or older in each study site (Fig. 1) with nationally representative large-scale epidemiological data on the prevalence of hypertension and T2DM, separately [24, 25]. Following the same methods, there are estimated to be 181,125 people with hypertension and 62,322 with T2DM in Wenjiang District. Based on these estimates, the overall diagnosis, enrolment, treatment, and control rates across four study sites in the previous research were 46.0%, 65.4%, 70.8%, and 80.9%, respectively, for hypertension, and 45.6%, 66.1%, 82.2%, and 73.9%, respectively, for T2DM. In this interrupted time series study, to allow for statistically significant results including a 5% effect size in treatment rates (primary effectiveness outcome), the power calculations suggest that a total of 24 data points will suffice for over 80% power.

For qualitative data collection, we expect to recruit a total of 8–16 policy makers, 8–16 health administrators from city/district health bureaus, 8–16 health administrators from district hospitals, 12–20 PHC providers, and 24–40 residents with hypertension and/or diabetes, across all study sites (Table 2). However, the actual numbers will be finalised when thematic saturation is reached.

Discussion

This study protocol describes a quasi-experimental study with an interrupted time series design, to evaluate the effectiveness, implementation, and health economic impact of the EMERALD intervention package in hypertension and T2DM management in PHC in China. Guided by the five strategies for integrated people-centred care [16], the intervention package consists of empowerment of PHC providers through workforce strengthening, empowerment of patient communities through health education and training community health workers, and empowerment of health administrators through health data monitoring and governance of local PHC programs. Findings from this study are expected to generate insights on strategies to strengthen the management of hypertension and T2DM in PHC in China.

The effectiveness of many components of the EMERALD interventions has been documented in the literature, including PHC provider training in China [10, 11], and beyond [26–28]. Similarly, a systematic review showed that health education improves disease self-management and lifestyle changes for people with T2DM [29]. Another review suggested that integrating digital health technologies and organizing group-based

Table 2 Sample size for qualitative interviews in four study sites

Types of participants	Wenjiang District	Xiling District	Acheng District	Jiao District	Total
Policy maker in national health commission	NA	NA	NA	NA	1
Policy maker in Chinese center for disease control	NA	NA	NA	NA	1
Policy maker in provincial health commission	1	1	1	1	3*
Policy maker in provincial centres for disease control	1	1	1	1	3*
Administrator from city health bureau	1–2	1–2	1–2	1–2	4–8
Administrator from district health bureau	1–2	1–2	1–2	1–2	4–8
Administrator from district hospitals	1–2	1–2	1–2	1–2	4–8
PHC provider focus group**	1	1	1	1	4
Patient focus group discussion**	1	1	1	1	4

* Acheng District and Jiao District are both in Heilongjiang Province. Therefore, the total numbers of policy makers in provincial health commission across four sites are three instead of four. Same for policy maker in provincial centres for disease control

** Each focus group will have 3–5 participants for PHC providers and patients, separately

activities were effective implementation strategies for enhancing health literacy among the elderly [30]. A distinct characteristic of the EMERALD interventions is the integration with the existing PHC system. By leveraging the existing efforts of the local governments, including health data monitoring and the locally initiated PHC programs, this study could provide further evidence on contextually calibrated strategies to strengthen local health governance and to improve the management of hypertension and T2DM.

Study strengths include a pragmatic yet rigorous quasi-experimental design to examine both the effectiveness and the implementation process of the interventions in real-world settings – a feature that few existing trials on related topics in China possess. The mixed-methods evaluation on the implementation process will complement and help explain the effectiveness outcomes and shed important insights into the complex interaction between the intervention components and the local health systems in which they are delivered. Second, the EMERALD interventions are highly aligned with the NEPHSP in PHC workforce strengthening, patient community engagement, and health governance strengthening [1], which could facilitate translation to other settings in China. Third, the selection of four diverse study sites from three provinces increases the generalizability of the research findings and provides insights into effectiveness and implementation outcomes in different health system contexts. Fourth, the use of local routinely collected health data in effectiveness outcome assessment is less costly than traditional methods based on primary data collection, and it enables the assessment of long-term health and economic impacts.

Study limitations include the following. First, the EMERALD intervention is multi-faceted involving PHC providers, patient community, and local health administrators, so it may be challenging to attribute the effectiveness (or non-effectiveness) to specific elements of the intervention package. Nevertheless, the mixed-methods process evaluation will provide in-depth insights for the implementation of each component from multiple stakeholder perspectives. Second, the secondary use of routinely collected health data for outcome assessment is subject to data quality issues including the reporting bias of performance driven PHC provider incentives, which is an issue reported in previous studies [4, 5, 31]. However, a recent study we conducted examining the robustness of these data sources indicate they are suitable for assessing the effectiveness outcomes of interest in this study [6]. Third, the reliance on a quasi-experimental study design without randomisation is subject to potential confounders, such as unexpected influences from other concurrent issues (e.g., new policies, programs, or other interventional studies) during the research period. This limitation will be mitigated through our close communications and engagement with local stakeholders to understand relevant confounding factors.

In summary, by determining the effectiveness, implementation, and health economic impact of the EMERALD intervention, this study has the potential to provide evidence on effective and scalable strategies to empower the PHC providers and patient communities and to strengthen local health governance for hypertension and T2DM management in China.

Abbreviations

ASCVD	Atherosclerotic cardiovascular disease
CDCs	Centres for disease control and prevention
cRCT	Cluster-randomised controlled trial
EMERALD	Empower primary health care stakeholders
NCD	Non-communicable disease
NEPHSP	National essential public health service package
PHC	Primary health care
QALYs	Quality-adjusted life years
T2DM	Type-2 diabetes mellitus

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12889-024-20027-5.

Supplementary Material 1

Acknowledgements
Not applicable.

Author contributions
MT, DP, LM, and SX led the conception of this study. WJ, YW, CH, MB, and FL provided critical suggestions for the protocol of this study. YM, TL, XZ, and JW provided central coordination and led the stakeholder engagement for the project. JY, HH, NP, RJ, and QW led the localisation of study protocol in different study sites. QL contributed to the statistical analysis plan and sample size calculations. TL and LS contributed to the economic modelling component. SX led the ethics application and drafted the manuscript, MT, DP, LM, PY, BL, ZC, and XD made critical suggestions and edits to the draft. All co-authors approved the submission of this paper.

Funding
The study is supported by National Health and Medical Research Council (NHMRC) Global Alliance for Chronic Disease funding (APP1169757). The funder has no role in the study conceptualization, design, data collection, analysis, decision to publish, or preparation of the manuscript.

Data availability
No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate
The study has been reviewed and approved by the Ethics Committee of University of New South Wales, Australia (project ID: iRECS 4500) and Chinese Centre for Disease Control and Prevention (project ID: 202325). Any notable amendments to the protocol will be reviewed and approved by the ethics committees. Consent will be obtained from all participants before participation (Appendix 5). Given the quantitative data analysis will be based on routinely collected data and there will be no direct data collection from participants, approval has been obtained for the waiver of individual consent.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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Received: 22 May 2024 / Accepted: 9 September 2024
Published online: 19 September 2024

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