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Impact of primary care and public health integration of chronic conditions in China: a protocol for a prospective multicentre cohort study

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ABSTRACT

Introduction The prevalence of chronic conditions is increasing. Given that the majority of chronic patients are managed by primary healthcare providers, there is a need to integrate primary care with public health to address the prevailing situation and enhance patient outcomes. The purpose of this study is to establish, implement and evaluate an integrated primary care and public health model in China for patients with chronic conditions.

Methods This prospective, multicentre and observational study will be conducted at 12 township hospitals on patients (n=7200) diagnosed with chronic conditions (hypertensive, diabetic or stroke). Participants were divided into two groups: pilot areas and mainstream areas follow-up groups. The primary outcome will be the difference in the proportion of controlled chronic conditions among the two groups. Secondary outcomes will be the differences in mean change in diastolic and systolic blood pressures, fasting glucose, total cholesterol and triglyceride, death from any cause and participant-reported physical and psychological health status.

Ethics and dissemination Ethics approval was obtained from the Ethics Committee of Tongji Medical College, Huazhong University of Science and Technology. We plan to publish the results of this study in a peer-reviewed journal article.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Data on both physiological assessments and psychometric properties are collected in our study.
⇒ Face-to-face household surveys are employed to ensure the quality of data.
⇒ The study will last for 18 months and participation of several health workers will be required.
⇒ The generalisability of the sample may be limited to similar groups with chronic conditions in China.

INTRODUCTION

Accompanied by changes in lifestyle and age structure,[1] chronic conditions, including hypertension, diabetes and triggered cardiovascular diseases, have become a significant threat to population health and emerged as the leading causes of death.[2–4] For the majority of patients, the condition remains indolent, and burdensome surveillance is required following initial diagnosis and treatment. However, the proportions of chronic patients who were optimally controlled remain alarmingly low.[5]

Integrated primary healthcare provided by a primary care team, consisting of multilevel, multicomponent strategies, is of pivotal importance for the prognosis and control of chronic conditions.[6] Several approaches have been proven to hold immense potential to recognise conditions,[7] improve clinical outcomes[8] and enhance the quality of life[9] of individuals with chronic conditions, including team-based care,[10] continuing medical training,[11] management information system,[12] lifestyle intervention[13] and patient engagement.[14]

In China, primary care and public health integrated service is piloted, and Qianjiang is one of the National Demonstration Areas for comprehensive prevention and control of chronic conditions. Patients with chronic conditions received treatment for their existing medical conditions from the primary care team. The primary care team comprised one general practitioner, one preventive medicine physician, one nurse, one village doctor and other health workers in primary healthcare organisations. In addition, medical specialists, such as respiratory physicians, ophthalmologists, obstetricians and gynaecologists, or traditional Chinese herbal medicine doctors are also involved, thus integrating primary and specialty care services. The quality and quantity of medical and prevention integrated service is one of the metrics for incentive supplements to the primary care team.[15] The care plan is developed collaboratively by primary care team,

and a shared electronic care record is accessible by the patient, members of their primary care team and medical system across city, county or township hospitals.

Nevertheless, multiple barriers, such as disseverance between primary care and public health and low health literacy, to control chronic conditions among healthcare systems, primary healthcare providers and patients could contribute to the evidence-to-practice gap.[16] The effectiveness of a primary care team-led approach to chronic condition control has not been carefully evaluated in cohort studies. Practical lessons and policy recommendations summarised in this study will provide references to chronic condition prevention and control practices in China and other low- and middle-income countries. Consequently, we aim to describe the detailed methods and data sources for establishing a chronic patients-based cohort study in a central area of China in this protocol to assess the effect of primary care and public health integration on the health of patients with chronic conditions in the pilot areas compared with the mainstream areas.

METHODS AND ANALYSIS

Design

This is a prospective, observational cohort study. The subjects of the study were chronic patients with hypertension, diabetes or stroke who had been under management since March 2023 in 12 hospital sites in Qianjiang City.

Setting

Qianjiang City of Hubei, China, is the geographical setting of this study, with a total of 856 000 people inhabiting an area of 2004 km². The study is being conducted at six townships piloting primary care and public health integration and six townships with mainstream care for chronic conditions. The region was selected because of its outstanding primary care team-based primary care units and integrated health information system, which enables us to use comprehensive data for clinical and epidemiological research.

In townships piloting primary care and public health integration, a primary care team, comprising one general practitioner, one preventive medicine physician, one nurse, one village doctor and medical specialists, will provide every patient with (1) medical service, including medical treatment, clinical care, transfer treatment and return visit. (2) health education and medication counselling for their conditions, such as hypertension, diabetes and stroke. Health education and health promotion will focus on proactive self-management,[17] such as healthy food and physical activity,[18] disease prevention and screening, and medication adherence. (3) In addition, primary care team fosters the establishment of self-managed groups in patients, where participants are encouraged to gain and share knowledge or healthcare experience of ongoing health conditions and how to practice self-management for chronic condition healing and resilience.

In townships with mainstream care, usual practices will continue without any of the above-mentioned interventions. Usual practices will include other government-initiated chronic condition management programmes, including medical treatment and lifestyle education.

Time

The programme was initiated in January 2023. Enrolment, including the baseline survey, began in August 2023 and completed in September 2023. Participants would then be followed up for a period of up to 18 months and advised to complete four time-point measurements: at baseline, 6 months, 12 months and 18 months. Follow-up visits consist of a general questionnaire and clinical data to assess changes in health conditions.

Participants

We are planning a cohort study containing a total of 7200 participants from 12 township hospitals: 3600 in the pilot areas and 3600 in the mainstream areas follow-up groups. Directors of all 12 eligible township hospitals agreed to adopt and be enrolled in the trial. The 12 township hospitals are then matched in pairs according to regional economic level, hospital size and patient characteristics. A sample of 600 patients with chronic conditions (240 hypertensive patients, 240 diabetic patients and 120 stroke patients) is shortlisted from the patients in each township hospital district. Patients will be eligible to participate if they meet all the following inclusion criteria: (1) male or female >18 years old; (2) permanent residents of Qianjiang; (3) had a chronic health condition (hypertension, diabetes or stroke) that was diagnosed at least 6 months earlier and (4) can complete the investigation independently or with the help of investigators. Patients will not be eligible to participate if any of the following exclusion criteria are present: (1) unconsciousness or mental disorders and (2) communication challenges or inability to understand the questionnaire.

Training

A study sample of 12 townships in Qianjiang, Hubei Province, was divided into pilot areas and mainstream areas groups based on whether their townships have implemented the intervention of primary care and public health integration policy. All community healthcare providers participating in this cohort study will receive systematic training before the first recruitment of patients. Only qualified providers will participate in this study. Once agreed, a signed informed consent form will be submitted.

Before actual operation, follow-up time, the content of the questionnaire, methodology (process) and quality control requirements, and evaluation indicators will be provided through centralised training. Investigators will be familiar with questionnaire composition and questionnaire techniques, will develop interviewing skills and

will understand fieldwork protocols and their respective responsibilities. The training includes conducting field interviews and rehearsals and is supervised by auditors. We select only those who pass the assessment and perform well in the rehearsal.

Data sources

For each participant, we will conduct a household survey on a half-yearly basis according to their baseline home address by trained programme investigators. Telephone interviews will be conducted for participants who cannot be contacted face to face. Subjects will be deemed lost to follow-up if they cannot be contacted by telephone or household survey, and their medical or death records are inaccessible. The expected proportion of participants lost to follow-up is <10%. We will recruit new participants in their community to replace the lost participants, matching by age and sex.

We will draw on two sources of data: a questionnaire survey and a health information system. A self-report questionnaire is administered for each data collection time point: when the patient is admitted to the cohort and 6, 12 and 18 months after being discharged. The questionnaire includes five sections: general demographic characteristics (including sex, ethnic group, education, occupation and income), lifestyle behaviours (including drinking, smoking, drug compliance and physical exercise), physical conditions (including quality of life using the EuroQoL Group's 5 Dimension scale),[19] functional activities using Functional Activities Questionnaire[20] and psychological conditions (including depression using Center for Epidemiologic Studies Depression Scale,[21] cognitive functions using Ascertain Dementia-8[22] and proactive health consciousness).

Furthermore, individual participants' clinical data, including health check information, condition management and death certificates, would be collected from the health information system in Qianjiang, which integrates information on public health surveillance and the health information system in hospitals. In both arms, patients receive follow-up evaluations from their primary care team at least semiannually. Blood pressure and serum markers, including fasting glucose, total cholesterol, triglyceride, low-density lipoprotein cholesterol and high-density lipoprotein cholesterol, will be executed by the primary care team during every half-yearly follow-up survey and accessed in health information systems.

Outcomes

The primary outcome would be measured by the proportion of hypertension control in participants with hypertension (patients with a systolic blood pressure of less than 140 mmHg and a diastolic blood pressure of less than 90 mm Hg at 18 months), the proportion of diabetes control in diabetic participants (patients with fasting glucose <7 mmol/L or 126 mg/dL) and number of stroke events in stroke participants at the final follow-up visit.

Secondary outcomes include a mean change in diastolic and systolic blood pressures (mm Hg), fasting glucose, total cholesterol and triglyceride between baseline and 18 months recorded by health information systems in Qianjiang and death from any cause, participant-reported physical health status according to the mean score of quality of life and functional activity, and participant-reported psychological health status according to the mean score of depression, cognitive function and proactive health consciousness. Other prespecified secondary outcomes are self-management behaviours, including items such as diet, smoking, alcohol, exercise and medication adherence.

Statistical methods

All outcomes will be described at baseline and each follow-up. Normally distributed continuous variables will be described by the mean and SD, and skewed distributed continuous variables will be summarised by the median and IQR. Participants who are lost to follow-up are included in the final analysis, with mean imputation used for missing data. The differences in the proportion of participants with controlled blood pressure, fasting glucose and the number of stroke events between pilot areas groups and mainstream areas groups are tested using a generalised linear mixed-effects model, with two-sided tests at the 5% significance level. The crude and adjusted treatment effects for all secondary or other outcomes are also estimated using various mixed-effects models. In these models, participants, townships and time are assumed to be random effects, and the intervention is assumed to be a fixed effect. Statistical analysis will be performed using the Stata statistical software, V.16.0.

Quality assurance

The following strategies will be adopted to ensure homogeneity between the exposed and non-exposed groups. First, the sample participants will be chosen based on similar population characteristics, socioeconomic status and accessibility of medical resources to minimise pre-existing differences. Second, the baseline characteristics of the patients in the two groups, including age, gender and severity of the chronic conditions, will be recorded and compared in detail. Moreover, in data analysis, methods such as stratified analysis or covariate adjustment will be used for processing.

Quality control measures will be employed in each follow-up, including quality control sessions at the time of training and a self-checklist on completion. The questionnaires and follow-up surveys are administered and completed by trained investigators with at least a master's or bachelor's degree and primary care team. Additionally, the data managers rigorously summarise and evaluate the data, review inconsistencies with questionnaires in the process, raise questions and urge the investigators and the survey team to make corrections promptly.

Patient and public involvement

Patients or the public were not involved in the design of our study.

DISCUSSION

To the best of our knowledge, this is the first large-scale, multicentre primary care and public health integration cohort in China that focuses on integrated primary care teams. Unlike previous studies that focused only on the beneficial role of specific measures or workers[23 24] in chronic disease management, we explored the role of integrated care teams led by general practitioners in managing people with chronic conditions at the grassroots level through a combination of medical and preventive forms.

In recent years, the focus on primary care and public health integrated service for individuals with specific chronic illnesses has expanded in both the clinical setting and the field of research.[24 25] Nevertheless, with constrained economic and healthcare resources, low- and middle-income countries face an even more formidable challenge as the awareness of integrated care and self-management is lacking, and the number of trained primary healthcare professionals is limited. The study is established to use longitudinal measurements to integrate innovative primary care and public health into primary care among residents of Qianjiang, China. We will also provide evidence for the implementation of integrated service in real-world circumstances. We expect that these data will support a wide range of public health research.

A primary strength of the study is the breadth and diversity of the physiological assessments and psychometric properties that data held within it, allowing analyses into a range of health research questions to be conducted. Half-yearly follow-ups are designed to assess health management in the participating population. Second, the cohort study is innovative because hypertension, diabetes and stroke are treated and managed together. Meanwhile, it integrates multifaceted medical and prevention strategies led by the primary care team rather than tests the effect of every single component of the multifaceted interventions on chronic condition control. Finally, performed by an experienced research group, the study combines expertise from health areas to contribute to Chinese evidence-based health and medical policies. Specifically, our research will generate robust evidence for the integration of public health and medicine in the field of chronic noncommunicable diseases.

The study has several limitations. First, its short duration may not allow sufficient assessment of the long-term effect on chronic condition control. Second, although the study has a relatively large number of participants, it is a regional study located in a central area of China. The study population is, therefore, not nationally representative.

Ethics and dissemination

The study was reviewed and approved by the Ethics Committee of Tongji Medical College, Huazhong University of Science and Technology (2022IECA251). The study followed the requirements of the Strengthening the Reporting of Observational Studies in Epidemiology study.[26] Written informed consent will be obtained by the research assistant from each participant who agrees to participate in the survey in a private setting before enrolment during the fieldwork. Case report forms will be used to determine whether participants meet eligibility criteria. For illiterate adults, thumbprints will be obtained from patients, or legally authorised signatures from legal representatives.

We plan to publish the results of this study in a peer-reviewed journal article. We will report between-group differences for all outcomes. The results of the study will also be disseminated through presentations at national and international conferences. In addition, the evaluation of the cohort study will be presented to policymakers in the healthcare sector to provide a theoretical basis for planning future norms for integrating primary care and public health services based on chronic condition populations.

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Contributors HQ conceived of the prototype of the intervention, the study design and analytical methods. HQ, Y-ZH, EY, Y-LW, C-yW, HD and JS contributed to the design of questionnaire and the quality control of field. ST contributed to development of the sampling and the security of study site. HQ and ST organise and coordinate the process of data collection. ST is responsible for the overall content as guarantor. All authors read and approved the final manuscript.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, conduct, reporting or dissemination plans of this research.

Patient consent for publication Not applicable.

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Note from the Editors: Instructions for reviewers of study protocols

Since launching in 2011, BMJ Open has published study protocols for planned or ongoing research studies. If data collection is complete, we will not consider the manuscript.

Publishing study protocols enables researchers and funding bodies to stay up to date in their fields by providing exposure to research activity that may not otherwise be widely publicised. This can help prevent unnecessary duplication of work and will hopefully enable collaboration. Publishing protocols in full also makes available more information than is currently required by trial registries and increases transparency, making it easier for others (editors, reviewers and readers) to see and understand any deviations from the protocol that occur during the conduct of the study.

The scientific integrity and the credibility of the study data depend substantially on the study design and methodology, which is why the study protocol requires a thorough peer-review.

BMJ Open will consider for publication protocols for any study design, including observational studies and systematic reviews.

Some things to keep in mind when reviewing the study protocol:

- Protocol papers should report planned or ongoing studies. The dates of the study should be included in the manuscript.
- Unfortunately we are unable to customize the reviewer report form for study protocols. As such, some of the items (i.e., those pertaining to results) on the form should be scores as Not Applicable (N/A).
- While some baseline data can be presented, there should be no results or conclusions present in the study protocol.
- For studies that are ongoing, it is generally the case that very few changes can be made to the methodology. As such, requests for revisions are generally clarifications for the rationale or details relating to the methods. If there is a major flaw in the study that would prevent a sound interpretation of the data, we would expect the study protocol to be rejected.