Study Design, Implementation and Case Analysis of Randomized Controlled Trials in Community-based Primary Care Settings

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Abstract

As an important method for high-quality medical research, randomized controlled trials (RCTs), when conducted in a standardized manner in primary community settings, can significantly facilitate the generation and validation of medical evidence, the optimization of guidelines, and the translation, dissemination, and application of clinical practice. However, the design and implementation of community-based RCTs in primary care and general practice often face numerous challenges, including contextual constraints, methodological limitations, and insufficient resources. This article reviews and discusses the key design considerations, implementation methods, critical steps, precautions, and limitations of RCTs in primary community settings. By integrating relevant domestic and international research cases and implementation processes, it analyzes design details and advantages, providing useful references for researchers in primary care and general practice to scientifically conduct RCTs.

Full Text

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【Abstract】 Randomized controlled trials (RCTs), as an important method for high-quality medical research at present, when conducted in standardized ways in primary community settings, can significantly contribute to the generation, validation, guideline optimization, clinical practice translation, and widespread application of medical evidence. However, when designing and implementing community RCTs in the fields of primary care and general practice, researchers

often face many challenges, including conditional constraints, methodological limitations, and insufficient resources. This article reviews and discusses the design essentials, implementation methods, key steps, precautions, and limitations of RCTs in primary community settings; and, by combining relevant domestic and international research cases and implementation processes, analyzes design details and advantages, thereby providing useful references for researchers in primary care and general practice to carry out RCTs scientifically.

【Keywords】 randomized controlled trial; research design; primary health care; general practice; case analysis

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【Abstract】 As the "gold standard" of medical research evidence, randomized controlled trials (RCTs) can significantly enhance the external validity and practical transformability of medical evidence when conducted in primary care community settings. However, the design and implementation of community-based RCTs in the fields of primary care and general practice often face practical constraints, methodological limitations, and insufficient resources. This article aims to introduce and discuss the core design principles, implementation strategies, and key procedures of community RCTs, as well as their precautions and

limitations. By integrating domestic and international case studies, the authors analyze the technical details and essential requirements of these

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trials, providing a valuable reference for conducting robust randomized controlled research in primary care and general practice.

【Key words】 Randomized controlled trial; Research design; Primary health care; General practice; Case analysis

Randomized controlled trials (RCTs) are research methods that randomly allocate subjects to an intervention group and a control group and compare the effects of interventions under strictly controlled conditions for bias. Their core features include randomization, blinding, control settings, and standardized outcome assessment, among others

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. As a high-level evidence design method in medical research, the value of evidence from RCTs lies in the following: by eliminating confounding factors and selection bias, they can clarify the causal relationship between interventions and outcomes and provide high-level evidence; their rigorous design ensures the reproducibility and reliability of results, and they are often used to verify drug efficacy, formulate clinical guidelines, and guide public health strategies and policy optimization, playing an irreplaceable role especially in the evaluation of new therapies or complex interventions

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RCTs targeting specific patients are mostly carried out in relatively large tertiary hospitals, specialized medical centers, or clinical research institutions. Research

results obtained from such institutions, and the resulting conclusions and protocols, are often difficult to verify or disseminate among community populations. Therefore, some peers advocate conducting RCT studies in grassroots communities, hoping to improve the external validity and practical translational value of scientific evidence, ensure that research findings better meet real-world needs at the primary level, and enhance the generalizability of evidence

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; they also hope that such studies can optimize the cost-effectiveness of primary medical resources and screen out low-cost, highly feasible intervention models suitable for community dissemination. Community-oriented RCTs are also an important tool for promoting health equity and precise policymaking. By focusing on disadvantaged groups, studies can verify universal health interventions and reduce health disparities. Their conclusions provide scientific evidence for governments to formulate primary health policies, help build an "integration of medicine and prevention" network for chronic disease prevention and control, and, through the integration of multiple resources, strengthen community health resilience, improve residents' health literacy, and provide practical pathways to address the increasingly severe challenges of population aging and chronic diseases.

However, implementing interventions and observing effects in real-world complex scenarios is particularly important for a practical discipline such as general practice. In the primary-care setting of communities, RCTs in a strictly scientific sense often face multiple challenges involving subjective and objective environments, methodological deliverability, and legal and ethical issues

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For example, standardized RCTs require setting inclusion and exclusion criteria for "trial subjects," but the remaining pure sample is distorted; those excluded in large numbers are the patients commonly seen in daily clinical practice, which may lead to differences between the study sample and the target application population and reduce the external validity of study conclusions

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. How to implement randomization, blinding, control settings, and outcome evaluation of RCTs in primary-care and community settings is a dilemma and difficulty faced by many researchers. This article, combining relevant literature and analysis of classic cases, introduces and discusses methods for designing and conducting RCTs in primary-care and community settings.

1 Introduction to the Methodology of Community RCTs

The implementation of community RCTs covers the entire process from design preparation to results reporting; their scientific rigor and standardization are

the keys to research success. At present, the recognized 2025 version of the Consolidated Standards of Reporting Trials (CONSORT) is used to guide study implementation

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. This guideline provides a checklist of reporting items and a research flow diagram.

1.1 Identify the Research Question and Formulate the Research Protocol

1.1.1 Select the Research Question Identifying the research question is the first step in conducting community RCTs and is also the basis for ensuring that the research protocol is scientifically feasible. At the methodological level, to identify a research question suitable for community RCTs, the PICOS (population—study subjects, intervention—intervention measures, comparison—control regimen, outcome—outcome indicators, study design—research design) principle

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can be used to transform broad goals into a specific, verifiable scientific question. At the same time, it can be combined with the Consensus Reporting Items for Studies in Primary Care (CRISP)

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to closely integrate the specific research question with the community context (Table 1).

1.1.2 Sample Size Estimation Sample size estimation is a fundamental and critically important design component. Its purpose is to determine the minimum number of subjects required for the study, thereby ensuring that the study results have sufficient statistical power and reliability

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. Before estimation, the research protocol must clearly define a series of key design elements, including the type of hypothesis test, the research design structure adopted, group settings, primary outcome indicators, and the planned statistical analysis method.

Because interventions in community RCTs are often allocated by cluster with the community as the unit—that is, cluster randomized controlled trials (cluster RCTs)—individual observation results within the same community often have similarity, known as the intra-cluster correlation coefficient (ICC). If this correlation is ignored, the actual required sample size will be greatly underestimated, thereby placing the study at risk of insufficient statistical power and potentially failing to detect a truly existing intervention effect.

Therefore, it is particularly important to correct the sample size according to the estimated value of the ICC. Researchers should give priority to obtaining the ICC value by conducting a pilot trial. A pilot trial can not only verify the feasibility of the intervention in the community environment, but also provide intra-cluster correlation data that best fit the real research setting, thereby ensuring the accuracy of the final sample size calculation. In comparison, ICC values from previous research reports are prone to bias due to differences in environment, community culture, or disease spectrum. If there is neither high-quality literature for reference nor a reliable ICC estimate obtainable through a pilot trial, researchers should adopt more conservative parameter settings when calculating the sample size (such as appropriately increasing the pre-estimated ICC value to enlarge the sample-size allowance), and should describe this in the study limitations section. Professional statistical software (such as PASS, Stata, etc.) should be used to calculate the sample size required to achieve the preset power.

In the design of single-center RCTs, the calculation of sample size mainly depends on the expected effect size and the degree of data dispersion. To evaluate community hypertension

Table 1 Elaboration of PICOS elements integrated with the CRISP checklist

Element	Elaboration	Supplementary elaboration of meaning after integration with CRISP
P (population, study participants/population, study subjects)	The inclusion and exclusion criteria for the study participants/population must be clearly defined	Details of the characteristics of participants and populations should be described in detail to facilitate comparison with other primary care patient populations, and people-centered language should be used to refer to participants with complex health needs. The selection of study subjects should not exclude patients with comorbidities merely in pursuit of sample purity; except for ethical taboos, complex patients with multiple chronic diseases should be excluded as little as possible, so that the study results can better reflect the characteristics of real community populations.

Element	Elaboration	Supplementary elaboration of meaning after integration with CRISP
I (intervention, intervention measures)	The intervention measures must be described in detail, including their content, theoretical basis, implementation methods, frequency, intensity, and expected duration	The intervention should be a trial measure constructed on the basis of theory or evidence, with a clear definition and standardized process, and should be reproducible and evaluable, rather than a natural extension of routine work. The intervention and the details of its implementation should be described in detail, and the competencies and qualifications of members of the medical care team should be specified so that readers can assess the applicability of the intervention in their own setting. It should also describe whether primary care stakeholders (such as patients, clinical medical staff, and community residents) participated and how they participated in the research process; such co-design helps to propose more operationally feasible interventions.

Element	Elaboration	Supplementary elaboration of meaning after integration with CRISP
C (comparison, control measure, usually routine care, alternative intervention, or other forms of blank control, attention control, etc.)	Control measure; usually routine care, alternative intervention, or other forms of blank control, attention control, etc.	In order to create a reasonable comparison without harming patients, the background of the health-care system and the specific reasons for conducting the study must be described in detail, ensuring that the measures received by the control group are fully defined within the specific primary care context.
O (outcome, outcome indicators)	Outcome indicators; objective, reliable outcome indicators highly relevant to the research question should be selected. The protocol should clearly distinguish the primary outcome indicators used to test the main hypothesis from the secondary outcome indicators that provide supplementary information or evaluate safety and secondary effects.	The reported study outcomes should be relevant to primary care and should be interpretable clinically by primary care service providers and patients. The measurement tools used should have been validated in primary care populations or settings, and the significance of these tools for patients and their medical care should be described.
S (Study design, study design)	Study design; may be combined with other research approaches, such as "real-world studies," "stepped-wedge design," "adaptive design," etc.	It is necessary to determine that the selected study design is appropriate for the research question in primary medical care and health care.

Taking the effect of systolic blood pressure (SBP) management in patients with hypertension as an example, assume that the intervention group is expected to have a mean SBP reduction of 15 mmHg (1 mmHg = 0.133 kPa), while the control group has a reduction of 10 mmHg, and that the standard deviation (SD) of both groups is 12 mmHg. Under the assumptions of a significance level of $\alpha = 0.05$ (two-sided) and a test power of $1-\beta = 0.80$, the calculation formula is:

$$n = \left[2\left(Z_{\alpha/2} + Z_{\beta}\right)^2 \cdot \sigma^2\right] / \delta^2.$$

Here, $Z_{\alpha/2} = 1.96$, $Z_{\beta} = 0.84$, $\sigma = 12$ (standard deviation), and $\delta = 15-10 = 5$ (mean difference). Substituting the parameters gives:

$$n = \left[2(1.96 + 0.84)^2 \cdot 12^2\right] / 5^2 \approx 90.3.$$

Thus, approximately 91 participants are needed in each group. This means that, without considering dropout, if the trial is divided into an intervention group and a control group, for a total of 2 groups, a single-center study must recruit at least 182 participants in total in order to detect the expected clinical difference statistically.

If the above study is a cluster RCT conducted jointly by 5–6 centers, the design effect (DE) must be introduced on the basis of the above individual randomization calculation to correct the sample size. Because patients within the same community are affected by the same family physician team or environment, intra-cluster correlation exists among samples and is measured by the ICC. Suppose each center recruits an average of 30 participants ($m = 30$) and the estimated ICC is 0.05; then the formula for calculating DE is:

$$DE = 1 + (m-1) \cdot ICC, \quad N_{cluster} = n_{individual} \cdot DE.$$

That is,

$$E = 1 + (30-1) \cdot 0.05 = 1 + 1.45 = 2.45.$$

At this point, the sample size required for each group in a multicenter study should be the single-center calculation result multiplied by DE, namely:

$$N_{cluster} = n_{individual} \cdot DE, \quad N_{per\_group} = 91 \cdot 245 \approx 222.95 \text{ persons}.$$

Therefore, to offset the loss of statistical power caused by cluster assignment, 223 participants need to be enrolled in each group. If the trial is divided into an

intervention group and a control group, for a total of 2 groups, the total sample size required is approximately 446.

It should be emphasized that, because community populations are highly mobile and because interventions are sometimes non-mandatory, dropout rates are usually relatively high. Therefore, on the basis of the initial sample-size calculation results, it is recommended that an additional 10%–20% sample size be reserved. This design is not only to meet statistical sample-size requirements, but also to prevent insufficient trial power caused by uncontrollable loss to follow-up, thereby ensuring the rigor of the study and the authenticity of its results.

1.1.3 Randomization and allocation concealment

Randomization is a core feature of RCTs. Its purpose is to randomly assign every individual participant or entire cluster unit participating in the study to each trial group and the control group. The main goal of randomization is to balance confounding factors between the trial group and the control group, ensure comparability between the two groups in baseline characteristics, and thereby allow differences in between-group outcomes to be attributed to differences in intervention effects. It is recommended that, in primary care settings, cluster randomization using streets (communities) and/or townships (villages) as units should be prioritized, and balance between groups at the overall level should be ensured through block randomization or multistage sampling.

Allocation concealment refers to the process by which, before study subjects are formally enrolled in the trial and assigned to a specific group, the researchers responsible for recruiting participants cannot predict or influence which group the next participant will be assigned to. Effective allocation concealment can prevent selection bias [13]. Correct randomization depends on appropriate allocation concealment [14]; allocation concealment can effectively improve selection bias and make various factors comparable between groups. Commonly used allocation concealment methods [14] are shown in Table 2.

When community interventions with clear potential health benefits are involved, researchers should pay attention to ethical issues and fully fulfill informed consent. Before randomization and grouping, researchers should inform participants of the nature of each group' s intervention plan and the potential differences in health benefits. At the same time, researchers need to actively identify the risk that the control group may face a lack of medical care, and consider incorporating it into the study protocol.

···in the design. It is recommended that the design of the intervention pathway be optimized to ensure that all participants can obtain corresponding health care and service utilization during the study process.

1.1.4 Blinding Blinding refers to a trial method in which, throughout the entire trial process, participants, researchers, and evaluators remain unaware of

the treatment allocation of the study participants. Its core function is to effectively avoid implementation bias and measurement bias that may arise during the trial process

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. The type of blinding is determined according to the scope of the blinding target, and can be divided into single-blind, double-blind, triple-blind, and even quadruple-blind

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. In single blinding, participants are usually unaware of allocation information, mainly to eliminate participants'psychological cues and tendencies; double blinding additionally requires that the intervention implementers also be unaware of allocation, thereby avoiding the influence of the implementers' subjective bias during treatment on the quality of the intervention; triple blinding further requires that data collection and statistical analysis personnel remain blind to group codes before the analysis is completed, so as to ensure the objectivity and fairness of statistical results; quadruple blinding requires that study monitors or outcome interpreters likewise remain blind when evaluating trial safety or drawing final conclusions.

Blinding should be implemented throughout the entire clinical trial to ensure the objectivity of study results. For community RCTs, blinding of simple, concise, and easily implemented interventions is relatively feasible. However, in community RCTs, because interventions are often non-pharmacological, complex, or behavioral interventions, their nature makes complete double blinding or triple blinding difficult to achieve. For example, in community physician interventions that provide health education or implement specific management models, it is easy for physicians to know which group their service recipients belong to and to understand the intervention plan, and participants can usually also perceive the intervention content they receive. It should be noted that, when designing blinding in a community context, the focus is on participants being unaware of their allocation, so as to minimize psychological expectation bias and related behavioral changes caused by knowledge of allocation.

For such non-pharmacological interventions, if it is difficult to blind all participants, researchers should ensure the quality of blinding implementation as much as possible by strengthening quality control, standardized training, using objective measurement tools, and adopting centralized evaluation. If it is difficult to blind all participants, researchers must at least ensure that personnel evaluating outcome indicators remain blinded, to prevent subjective expectations from affecting the assessment of standardized outcomes, thereby maximizing the rigor and reliability of the results.

1.1.5 Selection and Measurement of Outcome Indicators According to importance, study outcome indicators are divided into "primary outcome indicators" and "secondary outcome indicators" ; according to the nature of the

research question, they are divided into "effectiveness indicators" and "safety indicators"

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. Primary outcome indicators are the most central indicators in the study design and the most critical for evaluating intervention results, referring to clinical events that have the greatest and most direct impact on study participants and that participants care about most or most wish to avoid. Secondary outcome indicators supplement the primary outcome indicators and are used to further evaluate the auxiliary effects of the intervention measures. Effectiveness outcome indicators evaluate the impact of the intervention on the disease itself. Safety outcome indicators evaluate adverse reactions experienced by participants during the study as a result of the intervention measures. The study should include measurement of safety outcome indicators that can identify adverse reactions caused by the intervention, such as defining serious complications as serious adverse events and reporting them immediately.

In community RCTs, it is recommended to preferentially select routine indicators that are inherent in the public health system or easy for family physicians to collect, so as to avoid loss to follow-up due to overly complicated examinations. In terms of indicator measurement, objective, reliable, and scientific measurement methods should be selected as much as possible to improve the feasibility of conducting community RCTs in resource-constrained areas. For patient-reported outcomes, they must be verified by experts and possess clear, concise, and operable characteristics. The number of outcome indicators should follow the principle of "few but essential" ; too many indicators will increase researchers' burden and the difficulty of data collection. It is recommended to set 1–2 primary outcome indicators and to control secondary outcome indicators at 3–5.

1.2 Study Registration and Informed Consent

Researchers should select a registration platform recognized by the International Committee of Medical Journal Editors (ICMJE) for registration

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. In China, widely used platforms include the U.S. ClinicalTrials.gov (https://www.clinicaltrials.gov/) and the Chinese Clinical Trial Registry (http://www.chictr.org.cn/index.aspx). In addition, clinical trial protocols may also be published in officially issued journals, but the prerequisite before publication is that the trial must have a valid registration number. The research team must register the trial protocol to meet ethical and academic publication requirements. It is recommended that, before conducting community RCTs, researchers prepare all materials required by the clinical research ethics committee, communicate extensively with ethics experts, and revise and improve materials according to ethical requirements. If cluster RCTs are conducted, informed consent must be obtained separately for each individual

within each cluster. Researchers need to communicate early with community administrators and residents, gain their support and trust, and attend to the balance between collective community interests and individual rights and interests.

Table 2 Common allocation concealment methods

Allocation concealment method	Implementation details	Advantages	Limitations
Sequentially numbered, opaque, sealed envelopes	Place the allocation cards in envelopes with sequential numbers. The envelopes must be opaque and sealed, and are opened in sequence only after enrollment registration	Extremely low cost; does not require electronic equipment; suitable for community settings with limited resources	Extremely susceptible to intervention. Researchers may predict the next patient' s allocation by transillumination with strong light, searching in sequence, or opening privately in advance
Sequentially numbered containers	Place the intervention drug or tool in containers that are identical in appearance and have only sequential numbers, and distribute them in enrollment order	Concealment is synchronized with the intervention; simple to operate; suitable for drug trials	Containers are bulky, and logistics and storage costs are high; if the numbered label is damaged, concealment immediately fails
Scratch-card method	Similar to a lottery ticket: the allocation information is covered under a coating, and after enrollment the coating is scratched off to obtain the allocation result	Compared with envelopes, physical destructiveness is more obvious, and it is relatively difficult to conduct without leaving traces	Poor coating quality may lead to see-through; production costs are high in large-sample studies; and it cannot prevent researchers from scratching it open privately

Allocation concealment method	Implementation details	Advantages	Limitations
Internet-center random allocation	Through a controlled third-party webpage or system, after researchers enter the patient' s basic information, the system immediately displays the allocation result	Optimal solution 15. It achieves true physical isolation, is unpredictable and unalterable, and can record operation logs in real time to ensure audit tracing	Requires network support; system development or account purchase may incur certain costs; has certain requirements for informatization at the primary-care level

1.3 Implementation of the Study Protocol and Data Management

During the implementation of community RCTs, it is recommended that the research team provide detailed and uniform training for all research personnel to ensure that participants have a consistent understanding of details such as the study objectives, inclusion and exclusion criteria, randomization procedures, and implementation of intervention measures. In particular, for core intervention measures, standardization and adherence in their implementation must be ensured. Standardized data management is a core component in ensuring the authenticity of study results during protocol implementation. This includes establishing data collection and management systems before the trial begins, and designing clear case report forms and databases. Throughout data management, information security strategies should be strictly implemented. By desensitizing participants' personally sensitive information, establishing dedicated databases with access-permission controls, and using encrypted transmission technologies, the security and privacy of research data during storage and interaction can be ensured. The entire implementation process requires the establishment of continuous quality control and on-site monitoring mechanisms. Researchers should regularly conduct on-site monitoring at community health service centers to check the signing of informed consent forms, compliance with enrollment criteria, adherence to the randomization process, and whether interventions are strictly implemented according to the protocol. For interventions that may cause adverse reactions, an immediate reporting mechanism must be established; in particular, serious adverse events must be reported immediately to the ethics committee and sponsor in accordance with regulations.

1.4 Analysis of Study Results

Analysis of study results should be based on the intention-to-treat (ITT) principle, so as to minimize, to the greatest extent possible, bias caused by participant dropout. In actual research, participants may drop out because of adverse events, poor adherence, or loss to follow-up. ITT emphasizes that all participants who have been randomized, regardless of whether they comply with or receive the intended treatment, should be included in the analysis according to their initial assigned groups[^20]. If dropout cases are excluded and only participants who completed the study are analyzed, the analytical results may be biased and no longer reflect the outcome of choosing one treatment approach rather than another[^20]. Common statistical analysis sets include the full analysis set, per-protocol set, and safety analysis set. The full analysis set is the primary analysis set for efficacy evaluation and is a set formed after minimal exclusion of all randomized participants; the per-protocol set consists of participants who completed the trial strictly according to the protocol; and the safety analysis set includes all participants who received at least one treatment and is used for safety evaluation. When evaluating the efficacy of a confirmatory trial, it is advisable to use both the full analysis set and the per-protocol set for statistical analysis of the primary variables; before statistical analysis, the analysis set to which each participant belongs should be determined during blinded review, and the reasons for exclusion should be recorded.

1.5 Writing the Results Report

It is recommended that study results be reported with reference to the CONSORT 2025[^7] standards, and that the results be fed back to the community to promote the translation of evidence into practice. Throughout the process, special attention should be paid to community participation, cultural adaptability, and resource integration, so as to improve the acceptability, adherence, and sustainability of the study, thereby providing high-quality, generalizable scientific evidence for community health.

2 Case Analysis of Community RCTs in China

In view of the low control rate of hypertension in rural China and the shortage of medical resources, Peking University, China Medical University, Tulane University, and other institutions collaborated to carry out the China Rural Hypertension Control Project (CRHCP), aiming to verify the effectiveness of a management model led by rural doctors that integrates standardized treatment protocols and multiple intervention measures in improving blood pressure control among rural residents[^21].

First, identify the research question. The choice of research question should have a relatively high degree of population representativeness and clinical urgency.

The CRHCP study accurately captured the core weak links in rural health services, namely the large rural population of older adults with lower educa-

tional attainment and poor blood pressure control. It therefore has relatively high reference value for other primary-level regions. The intervention measures consisted of multifaceted interventions led by rural doctors, including initiating and titrating medications according to standardized protocols, providing health education, guiding home blood pressure monitoring, and establishing performance-based incentive mechanisms for rural doctors; the control group received enhanced usual care, namely one blood pressure follow-up visit every 6 months.

The intervention measures not only included standardized treatment protocols, health education, and blood pressure monitoring, but also closely followed rural clinical practice, making them relatively easy to implement in rural areas. In addition, a performance incentive mechanism was introduced, solving the problem of motivation in primary-level research. From an ethical perspective, the control group' s receipt of "enhanced usual care" ensured basic medical rights and interests, while the success of the intervention group verified the feasibility of empowering rural doctors to manage complex chronic diseases in low-resource areas.

The study selected as its primary outcome the proportion of patients with blood pressure <130/80 mmHg. The number of outcome indicators was not complicated; the definition was clear and explicit, ambiguity was unlikely, data were easy to collect, and the study was easy to carry out at the primary level. The study design adopted an open-label, cluster RCT, which was more suitable for rural China and reduced intervention contamination. The specific PICOS elements are shown in Table 3.

Second, estimate the sample size. Because this study relied on a well-established large-scale cohort and the number of clusters and participants in the CRHCP trial was fixed, the sample size had already been determined. Therefore, the study calculated statistical power. During the calculation, the ICC was considered to be 0.001, the incidence reference came from previous studies in Chinese populations, the effect size was derived from the results of four meta-analyses, and the calculation software was PASS 2008.

Third, randomization and allocation concealment. The study adopted a cluster-randomized and stratified design, using "village" as the randomization unit. After stratification by province, county, and township, villages were randomly assigned at a 1:1 ratio. A total of 326 villages and 33 995 hypertensive patients aged ( )40 years were enrolled. This method not only conformed to the natural medical-care ecology in which rural doctors manage villagers, but also effectively prevented contamination caused by communication among participants within the same village. In addition, through stratified random allocation at the provincial, county, and township levels, baseline differences in economic level and medical resources among different regions were balanced to the greatest extent possible.

Fourth, blinding. This study used an open-label design, and both participants

and rural doctors knew their group assignments. Under circumstances in which blinding was difficult to implement, researchers measured blood pressure automatically and uploaded data in real time, thereby excluding subjective bias from manual readings. The study strictly implemented blinding in outcome adjudication and statistical analysis: outcomes were adjudicated by a third-party committee that was unaware of group information, so as to prevent subjective expectations from affecting the evaluation of standardized outcomes, thereby ensuring the rigor and reliability of the results to the greatest extent possible.

Table 3 PICOS elements of a community-based RCT in China

Element	China Rural Hypertension Control Project (CRHCP)
P (population, study participants)	Residents in 326 villages in China who were aged ( )40 years and whose blood pressure control did not meet targets (high-risk population with ( )140/90 mmHg or ( )130/80 mmHg)
I (intervention, intervention measures)	A diversified intervention led by village doctors, including: initiation and titration of medications according to standardized protocols, home blood pressure monitoring guidance, lifestyle-change guidance, and adherence guidance for medication use
C (comparison, control regimen)	Enhanced usual care: participants underwent one blood-pressure follow-up monitoring visit every 6 months
O (outcome, outcome indicators)	Primary outcome: proportion of patients whose blood pressure was controlled at <130/80 mmHg at 18 months
S (Study design, study design)	Open-label, cluster RCTs

Note: 1 mmHg = 0.133 kPa.

The fifth step was selection and measurement of outcome indicators. The primary outcome of the study was the proportion of patients whose blood pressure was controlled at <130/80 mmHg after 18 months. Secondary outcomes were the mean changes in systolic and diastolic blood pressure from baseline to 18 months, the proportion of participants with blood pressure below 140/90 mmHg, and the proportion of participants adhering to medication. Study outcomes were measured using automated blood-pressure monitors and data were uploaded in

real time. The results were relatively objective and reliable, and could be obtained even in communities with comparatively poor conditions. The researchers who collected data underwent training and assessment. At each follow-up visit, according to the standard protocol, participants were asked to rest quietly for 5 minutes, after which blood pressure was measured three times in the seated position. The data-collection process was rigorous, with quality control throughout.

The sixth step was study registration and informed consent. Before project initiation, the study had been registered at ClinicalTrials.gov (identifier: NCT03527719). During implementation, all participants signed written informed consent before enrollment. Considering that some older participants in rural areas might have difficulty understanding the study, before signing, the researchers provided detailed oral explanations of the intervention process and follow-up obligations, ensuring the adequacy and compliance of the informed-consent process.

The seventh step was implementation of the study protocol and data management. The study adopted a standardized electronic medical-record management system; blood-pressure measurement data for all participants were collected by automated devices and synchronized in real time. During the 18-month follow-up period, loss-to-follow-up rates in both groups were controlled at a relatively low level, ensuring data completeness.

The eighth step was analysis of study results. Statistical analysis followed the ITT principle. There were 1,953 participants lost to follow-up in the intervention group and 2,064 participants lost to follow-up in the control group. These lost-to-follow-up participants were ultimately included in the ITT analysis according to their initial allocation, and a generalized linear mixed model was used to handle the clustering effect brought about by the cluster-randomized design. The results showed that after 18 months, the target-achievement rate in the intervention group was 57.0%, higher than the 19.9% in the control group ($P < 0.001$); the net between-group difference in SBP reached -14.5 mmHg ($95\%CI = -15.7 \sim -13.3$ mmHg, $P < 0.001$).

The ninth step was writing the study report. This study was written strictly in accordance with CONSORT.

As a large-scale cluster RCT conducted in a low-resource setting, the CRHCP study provided a highly valuable model for research in general practice and primary care. This study not only achieved breakthroughs in clinical research output, but also suggested that in remote areas lacking specialist physicians, through standardized clinical pathways, systematic training and supervision, and reasonable performance incentives, village doctors can likewise manage complex chronic diseases safely and with high quality.

3 Discussion

RCTs conducted in the fields of primary care and general practice show distinct characteristics of "contextualization"and "pragmatism."Their research questions usually arise from the real health needs of community residents; intervention measures emphasize feasibility and scalability; and their content often involves multidimensional integrated interventions such as lifestyle management, health-behavior promotion, and chronic-disease prevention and control. In study design, sampling methods tend to use cluster randomization in order to adapt to community organizational structures and avoid contamination. In terms of outcome indicators, in addition to traditional clinical outcomes, patient-reported outcomes, implementation-process indicators, and health-economic evaluation indicators are often included, so as to comprehensively reflect the overall value of the intervention. In addition, community RCTs attach importance to the participation of community health-service institutions and emphasize verification of the effectiveness and sustainability of interventions under real-world conditions.

In recent years, the number of RCT papers in China' s primary care and general practice fields has steadily increased, and research quality has gradually improved. These studies generally focus on localization and adaptation of interventions and capacity building for primary-care personnel. However, several problems and challenges remain: first, methodological rigor needs to be strengthened, and some studies have insufficient reporting on randomization concealment, implementation of blinding, and sample-size estimation; second, there is insufficient innovation in study design, with most studies being parallel-control RCTs and relatively few applications of methods such as adaptive designs and stepped-wedge designs; third, outcome indicators are biased toward clinical biomarkers, with insufficient comprehensive evaluation of functional status, quality of life, health economics, and other aspects; fourth, the scientific research capacity of primary medical staff varies greatly, and they often face practical constraints such as insufficient research training, limited time and energy, and inadequate team support; fifth, mechanisms for translating research findings into policy and practice are not smooth, and the efficiency of evidence use needs to be improved.

Conducting RCTs in primary-care and community settings faces challenges. On the one hand, some previous studies had problems such as unclear design descriptions and lack of rigor in logic; on the other hand, the objective conditions of real communities make implementation of RCTs uniquely difficult. In complex community scenarios, during the implementation of behavioral interventions and other intervention measures, traditional blinding and placebo designs are almost impossible to fully implement; at such times, forcing designs that plainly do not fit clinical reality may also trigger ethical controversy. In addition, proximity between communities may easily lead to contamination. Faced with these real-world constraints, researchers should not blindly apply the standards of classic RCTs, but should instead adopt flexible alternative approaches according to the characteristics of community population mobility and management.

When individual randomization is prone to contamination, cluster randomization may be selected, such as randomization at the village level, or geographic buffer zones may be established between groups. When blinding is difficult to implement, evaluator blinding may be used.

International case analysis:

To address the challenges of high diabetes intervention costs and shortages of professional personnel in low-resource settings, India' s diabetes prevention project (Scale-up of the Kerala Diabetes Prevention Program, K-DPP) evaluated a low-cost lifestyle intervention model led by non-professional peer mentors[ˆ22]. The study used a cluster RCT design, with 60 electoral wards as randomization units (1:1 allocation), and enrolled 1,007 individuals at high risk for diabetes who had been screened by risk scoring and had normal glucose tolerance.

To prevent contamination between groups, the study established a spatial interval of at least 2 km between electoral wards as a geographic buffer zone. In selecting intervention measures, the study chose a lower-cost intervention program that was responsive to local practical difficulties and more suitable for implementation in low-resource areas, and that also has high reference value for other low-resource settings. In the intervention group, trained peer mentors carried out 12 months of group meetings and community support activities, aiming to promote physical activity and healthy diet; the control group received only a health education booklet.

For sample-size calculation, the study referred to a specialized study in the Indian population that set an annual incidence rate of 18.3% for the control group; the data source was relatively accurate. An ICC of 0.02 was prespecified, and power calculations were performed on the basis of a Poisson distribution, in order to fit the statistical characteristics of incidence data. The study also considered a 10% loss-to-follow-up rate to ensure the accuracy of the sample size. The primary outcome indicator was the cumulative incidence of diabetes at 24 months of follow-up.

Although blinding of participants could not be implemented because of the nature of the intervention, field measurement personnel, laboratory technicians, and the principal investigators were all blinded, thereby reducing bias. Statistical analysis followed the ITT principle, and generalized estimating equations were used to adjust for cluster effects. The 24-month follow-up results showed that the incidence in the intervention group (14.9%) was slightly lower than that in the control group (17.1%), but the difference was not statistically significant ($P = 0.36$); however, the intervention group showed significant improvements in secondary indicators such as diabetes risk score, fruit and vegetable intake, and physical quality-of-life score ($P < 0.05$).

The K-DPP study demonstrated the feasibility of managing high-risk populations for chronic disease through a non-professional peer-support model in low-resource settings. This case suggests that community mobilization and peer

empowerment can effectively improve multiple cardiovascular risk factors, providing important reference for global chronic disease prevention and control, and emphasizing that intervention measures must take into account both cost-effectiveness and cultural adaptability.

or introduce independent third-party adjudication to reduce bias. When background differences in primary care across regions are large and it is difficult to directly refer to findings from studies in other regions, pilot trials, co-design, or multiple rounds of expert consultation may be used to involve grassroots medical staff and other stakeholders at an early stage, so as to ensure that the study design is both scientifically structured and truly implementable in busy primary-care work. The value of community RCTs lies in how, through these design strategies and under the premise of respecting real-world environments, evidence with policy-translation potential can be explored.

RCT research in the international field of general practice and family medicine began relatively early and has formed a relatively mature methodological system and research model. Its characteristics include: attention to the systematic nature and continuity of research questions; emphasis on the cyclical construction and theoretical support of intervention measures; extensive use of mixed methods to evaluate effects and implementation processes; attention to patient and community participation in study design; and a high degree of transparency in publication and increasingly common data sharing. In comparison, domestic clinical trial research has progressed rapidly with support from national and local projects[^23], especially in large-scale community chronic disease intervention trials, where certain resources and implementation conditions are already in place. However, there remains room for improvement in the use of theoretical frameworks, patient participation, long-term follow-up evaluation, and reporting of results. In the future, methodological training should be further strengthened, methodological innovation encouraged, integration of real-world evidence with RCTs promoted, collaborative research networks built, and sound platforms for dissemination and translation of results established.

This article focuses on introducing how to conduct RCTs in community settings, but RCTs are not applicable to the evaluation of all intervention effects for community patients, populations, or the public. In practice, RCTs face many real-world constraints, and in some situations strict randomized allocation or implementation of blinding may be ethically infeasible. Therefore, researchers in community health service institutions, when gold-standard evidence from RCTs cannot be obtained, should carefully select appropriate methodological tools according to the research purpose, resource conditions, and ethical considerations, and consider alternative approaches such as quasi-experimental designs, pragmatic clinical trials, or natural controlled studies.

Owing to space limitations, this article cannot discuss in depth more details and precautions related to conducting community RCTs. Interested readers may further consult *Clinical Epidemiology*[^1], the CONSORT statement[^7-8], the Wuhan University course *Evidence-Based Medicine* on China University

MOOC[^24], *Fundamentals of Clinical Trials*[^25], *The PRECIS-2 Tool: Designing Trials That are Fit for Purpose* published by Loudon et al.[^26], and *A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance* published by Skivington et al.[^27], among others, to further explore implementation details and key points of community RCTs in practice. In the future, China' s primary health care and general practice fields should continue to adhere to needs orientation, quality as the core, innovation as the driving force, and translation as the goal, and should conduct more rigorous, pragmatic, and impactful community RCTs, so as to provide solid evidence for improving residents' health, optimizing the service system, and contributing to the construction of a Healthy China.

4 Summary

Community RCTs are a high-quality research design type carried out from the perspectives of primary care and general practice. They are an important means of evaluating the effectiveness of intervention measures applied at the grassroots level under specific circumstances. They have unique advantages in external validity and practical translation, and can provide evidence support for general practice clinical practice and primary health-policy formulation. By combining specific cases, the authors demonstrate the design of community RCTs.

provided useful methodological guidance for standardized conduct of experimental studies by researchers in primary care and general medicine.

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