


BMJ Open Protocol of a tailored educational intervention for general practitioners on potentially inappropriate medications among older patients at community healthcare institutions in Beijing, China: a cluster-randomised controlled trial

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To cite: Fu M, Wushouer H, Nie X, *et al.* Protocol of a tailored educational intervention for general practitioners on potentially inappropriate medications among older patients at community healthcare institutions in Beijing, China: a cluster-randomised controlled trial. *BMJ Open* 2021;**11**:e046942. doi:10.1136/bmjopen-2020-046942

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2020-046942>).

Received 16 November 2020
Accepted 06 July 2021



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ABSTRACT

Introduction Prescribing of potentially inappropriate medications (PIMs) has become a prominent issue of public concern among elderly patients. However, no research has involved interventions on PIMs of Chinese elderly patients seeking care at primary healthcare. This study aims to evaluate the effectiveness of a tailored educational intervention programme for general practitioners (GPs), aiming at reducing the occurrence of PIMs in elderly patients.

Methods and analysis This is a parallel group, controlled, cluster-randomised trial, with blinded evaluation of outcomes and data analysis, and un-blinded intervention. Twenty primary community healthcare stations (CHSs) in Dongcheng district in Beijing will be randomised to intervention and control arm with an allocation ratio of 1:1. GPs in CHSs randomised to the intervention arm will receive a two-component intervention: general training of PIMs and distribution of PIMs handbook. GPs in the control arm will assess and manage patients according to the institutions' routine practice. The primary outcome is the change in PIMs patient visit rate.

Ethics and dissemination Ethics committee approval of this study was obtained from Peking University Institution Review Board (IRB00001052-19074). The findings will be published in scientific and conference presentations.

Trial registration number ChiCTR2100047788.

INTRODUCTION

Potentially inappropriate medications (PIMs) is defined as a drug in which the risk of an adverse event outweighs its clinical benefit, particularly when there is a safer or more effective alternative therapy for the same condition.¹ Elderly patients are especially susceptible to PIMs due to pluri-pathology, functional impairment and physiological changes during the ageing process,² which enhance the risk of adverse drug events,³

Strengths and limitations of this study

- This study will provide new evidence of the effectiveness of a tailored educational intervention programme for general practitioners on the occurrence of potentially inappropriate medications prescribing for elderly patients in China, comparing with routine practice.
- The intervention targets one of the most vulnerable populations, if successful, it could be widely disseminated to more primary healthcare institutions across China.
- Limitations of this study are that the sampled institutions may not be fully representative of all community healthcare institutions in China, and the adverse drug reaction or quality of life of the patients were not measured.

functional decline,⁴ prescribing cascade,⁵ medication-related hospital admissions,⁶ mortality,⁷ quality of life decline⁸ and heavy burden.⁹ In 2017, the Rational Drug Use Branch of Chinese Association of Geriatric Research developed the *Criteria of PIM for Elderly patients in China* (the Chinese PIM criteria).¹⁰ Studies have shown that these country-specific criteria have better applicability and a higher detection rate in Chinese institutions, compared with the Beers or Screening Tool of Older People's Prescriptions (STOPP) and Screening Tool to Alert to Right Treatment (START) criteria.¹¹

Prevalence of PIMs can be a useful indicator of prescribing quality in primary healthcare,¹² and it has been relatively well-studied in many countries, with substantial variations of prevalence ranging from 2.9% to 53.7%.^{9 13–20} In China, 52.0% (4.5 billion) of medical visits

occurred in primary healthcare institutions in 2019,²¹ among which elderly patients accounted for the most of the utilisation in community healthcare institutions. Our previous study, evaluating the PIMs utilisation in the community healthcare institutions in Beijing, showed a prevalence of 16.9% in 2018.²²

Early detection of PIMs is of central importance to prevent adverse outcomes and improve geriatric care in elderly patients.²³ Interventions, including medication review,²⁴ pharmaceutical interventions,²⁰ computerised alerts,^{20 25} educational training,²⁶ have been effective measures to improve appropriate drug use in many countries and some also resulted in clinically significant improvements.²⁷ However, little research has involved interventions to reduce the occurrence of PIMs among elderly patients in China. Therefore, we design this study to evaluate the effectiveness of tailored educational intervention programme for general practitioners (GPs) in Chinese primary healthcare institutions, aiming at reducing the occurrence of PIMs in elderly patients. We hypothesise that tailored educational intervention programme targeting at GPs in Chinese primary healthcare will be effective in improving prescribing patterns by reducing the occurrence of PIMs in elderly patients.

METHODS

Trial design

A parallel group, cluster-randomised controlled trial (cRCT) is designed as a pragmatic evaluation of a tailored educational intervention for GPs, targeting at outpatient PIMs, to support a safer prescription practice for the elderly comparing with routine practice (figure 1). The cluster design is an adequate design for evaluating educational outreach and related interventions. Randomisation by institution level minimises the potential contamination of the GPs within the same institution.

Outpatient visit data for all eligible patients of participating GPs in the intervention and control arm will be collected 3 months prior (baseline) and 3 months after (short-term follow-up) and 12 months after (long-term follow-up) the initiation of the trial. Changes in GPs' prescribing patterns for PIMs will be tracked by a set of explicit criteria.

Settings and participants

Inclusion criteria for clusters

The study will comprise 20 public primary community healthcare stations (CHSs) in Dongcheng district in Beijing. Dongcheng, located in the centre of Beijing, has a population of 800 000 and covers an area of 42 km². The public CHSs, all administered by the Dongcheng Health Service Management Center, are equipped with the same hardware and software, and provide homogenised basic outpatient clinical care and public health services to individuals and families in their communities. Each CHS has 4–8 general practitioners and covers 10 000–30 000 citizens. GPs, working in sampled CHSs, who prescribe

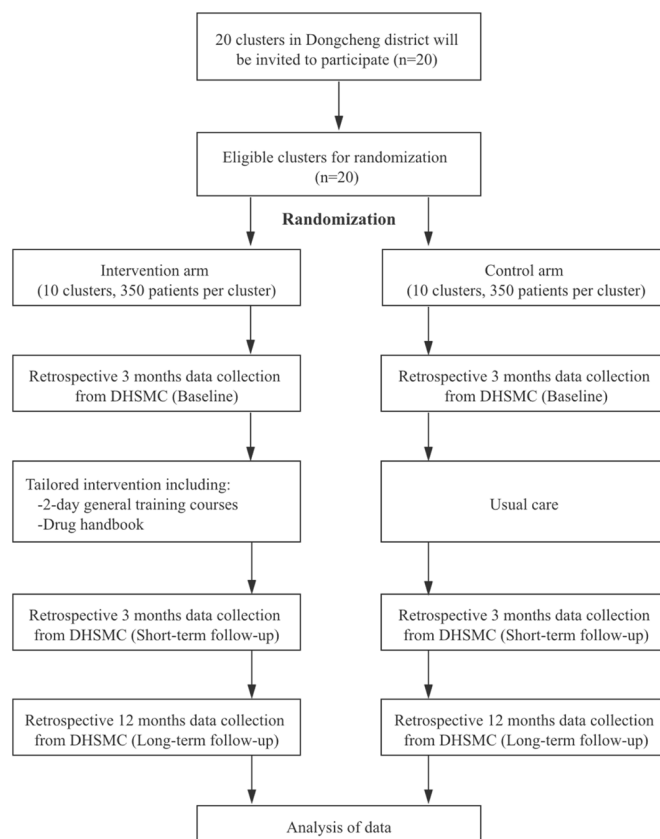


Figure 1 Trial flow chart of the study. DHSMC, Dongcheng Health Service Management Center.

medications for the elderly patients (defined as age ≥ 60 by the Chinese PIM criteria) and have the intention to stay in their CHSs during the follow-up period, and agree to participate in the study will be recruited in the trial after signing informed consent. Detailed consent form is presented in online supplemental eSheet 1.

Inclusion criteria for participants

All outpatient visits for patients aged 60 years and above during the baseline and follow-up data collection period will be eligible for inclusion in our analysis. Since the Chinese PIM criteria only include western medicines, the visits that patients are prescribed with only Traditional Chinese medicines and without at least one western medicine will be excluded.

Interventions

The Chinese PIM criteria (2017) will be used as both an educational tool and an outcome measure in our study. The criteria include 72 risk medications/classes potentially associated with inappropriate use in elderly adults (28 high-risk medications/classes to be avoided, 44 low-risk medications/classes to be used with caution) and 44 medication/class-disease pairs potentially associated with inappropriate use in elderly adults under certain disease conditions.¹⁰ Detailed medication list of the Chinese PIM criteria is presented in online supplemental eTable.

GPs in the CHSs that randomised to the intervention arm will receive a two-component intervention: training session of PIMs and distribution of drug handbook.

Training session of PIMs

GPs will receive a 2-day (8 hours/day), in-person education training session provided by a clinical pharmacy expert panel, led by Professor Yuqin Wang, the chief developer of the Chinese PIM criteria. In the first-day training, experts will present main elements of the educational intervention with special emphasis on definition of PIMs, the specific drugs or drug classes to be avoided or used with caution due to clinically relevant risk or drug-disease interactions based on the Chinese PIM criteria. The second-day training, led by experienced clinical pharmacists and physicians, will cover case analysis and discussion of common PIM prescriptions in sample clusters, in which GPs can have good command of the process of identifying potential harmful prescriptions to the elderly.

Printed drug handbook

A handbook containing information of all the PIMs available at CHSs in Dongcheng district will be designed, printed and distributed to GPs during the general training. Basic pharmacology and pharmacokinetic information, indication, dosage, route of administration, side effects, warnings of potential risk among elderly and suggestions for safer, alternative therapeutic options will be provided for each drug (by generic name) in the handbook.

Usual care for control arm

The control arm will assess and manage patients according to the institutions' homogenised routine outpatient clinical practice. GPs will continue prescribing for elderly patients according to their existing knowledge, and will not have access to the intervention programme during the study period.

Outcomes

The primary outcome is the change in PIMs patient visit rate, with the numerator as the number of visits with at least one PIM and the denominator as the total number of visits. As there might be multiple PIMs occurring in one visit; the secondary outcome is the number of PIMs per 100 visits, with the numerator as the total number of PIMs multiplied by 100 and the denominator as the total number of visits. All outcomes will be calculated at the cluster level.

Sample size

Based on our previous study, the current PIMs prevalence in Dongcheng CHSs is ~20%²² and this is, therefore, assumed for the control arm. Based on a conservative estimate from our review, we expect our intervention to lead to at least an 8% relative reduction in the PIMs prevalence within CHSs. We calculate the intracluster correlation coefficient (ICC) using the prescribing data from the sampled CHSs in 2018, collected during our previous study.²² In order to detect an 8% or greater reduction in

the PIMs prevalence with 90% power at a 5% significance level using two-sided Z-test (unpooled), adjusting for ICC of 0.02, we estimate that we need 10 clusters per arm and a minimum of 350 patient visits per cluster. SAS V.14.2 is applied to calculate the ICC. PASS V.14.0 is applied to calculate the sample size.

Randomisation and blinding

Randomisation of clusters will be done by an independent researcher who will not be involved in the study. The randomisation will be restricted to those allocations resulting in treatment: control arm allocation ratio of 1:1. A random sequence table will be created by a researcher in another department at our institution who is not involved in the study protocol development process. The allocation sequence will be blinded for the investigators. The sequence will be concealed until we complete all the baseline assessments of the GPs. Based on this randomisation, all clusters will be assigned to either the intervention arm or the control arm. Study participating GPs will not be blinded to the intervention, but measures will be taken to ensure a blinded outcome evaluation.

Data collection and management

To evaluate the primary and secondary outcomes, outpatient visits for 350 patients will be randomly selected from each CHS during the 3 months before the implementation of the intervention to provide preintervention data, during the month 1–3 and the month 10–12 after initiation of the trial to provide postintervention data. Deidentified outpatient visits electronic health records of the 20 CHSs will be derived from the General Practitioner Operation System of Dongcheng Health Service Management Center. Information collected will include visit date, patient deidentified ID numbers, patient demographic characteristics, diagnoses and medications. All data will be digitally transferred under password-protection and verified by two investigators.

Statistical methods

Intention-to-treat analyses will be conducted. Initial descriptive analyses will examine the underlying distributions of the primary and secondary outcomes. Then we will construct an analytic model to assess the impact of intervention on PIMs. We will apply generalised linear mixed-effect regression models to evaluate the difference in primary outcome comparing between intervention and control arm, from baseline to month 3 and month 12, respectively. We will also examine the effects of the potential covariates (eg, patient's age, patient's gender, patient's number of diagnosed diseases) on the primary outcome. The level of statistical significance is $p < 0.05$ (two-sided). STATA V.15.0 will be applied to conduct the statistical analysis.

Planned subgroup analyses will be conducted on primary outcome across patients of different ages ((a) age 60–79; (b) age ≥ 80).



Monitoring

The aim of this study is to improve quality for good clinical practice and should therefore not imply risks for the patients involved, and we find it unlikely that the current intervention might worsen the quality of care. A data monitoring committee will not be set up given the lack of any interim analyses and very low risk to participants, but an independent trial steering committee will be set up to supervise the trial, review progress and decide on any changes to the protocol.

Ethics and dissemination

Ethics committee approval of this study was obtained from Peking University Institution Review Board (IRB00001052-19074). Participation and data extraction will be based on written informed consent from all GPs. The consent form will inform GPs about basic information of this study and the practical implications they may have on their practice (online supplemental eSheet). We guarantee the protection of personal information, and the data will be anonymous and used only for academic purposes. We will not obtain informed consent from patients as all the patient visit information we will extract are de-identified data.

The findings will be published in a scientific peer-reviewed journal and conference presentations according to the Consolidated Standards of Reporting Trials guidelines for cRCT. The participants will be informed of conference presentations and publications.

Patient and public involvement

Patients and the public were not involved in the development of the research questionnaire, outcome measures, design, recruitment and implementation of the study. The results will be disseminated through scientific journals.

DISCUSSION

Educational intervention according to well-established principles for good clinical practice towards GPs has the potential to reduce PIMs prescribing and utilisation.²⁷ Nevertheless, evidence of its effectiveness on the GPs' prescribing behaviour in China is lacking. This study will be the first to involve an intervention programme, aiming at reducing the occurrence of PIMs among elderly patients, towards GPs in Chinese primary healthcare institutions. As the study intervention targets one of the most vulnerable populations, if successful, it can have an impact on the health of elderly patient and the superior intervention could be widely disseminated to more primary healthcare institutions across China.

Limitations of this study should be noted. First, Dongcheng is a unique district in the centre of Beijing with higher economic status and better medical resources. Thus, the study settings are not fully representative of all community healthcare institutions in China. Second, as 20 participating institutions are not randomly selected from all the community healthcare institutions in Dongcheng

district, there is a possibility of selection bias. Third, due to the limitations of the data access, the adverse drug reaction or quality of life of the patients were not measured.

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Acknowledgements The authors acknowledge the contributions made by Professor Yangfeng Wu in designing this study. The authors acknowledge the contributions made by Professor Yuqin Wang, Professor Lan Zhang and Professor Chen Liu from Xuanwu Hospital, Professor Xin Xu from Peking University First Hospital, Professor Jingxuan Guo and Dr Yingying Yan from Peking University Third Hospital in designing and implementing the intervention. We sincerely appreciated to Dongcheng Health Service Management Centre (DHSMC) for providing great support for this study.

Contributors XG is the principal investigator of this study and refined the protocol. MF and HW wrote the manuscript and contributed to the design of the study. MF, XZ and XN will recruit the patients and conduct the trial. MF and FW will collect the data. LS will supervise the trial. NL, the medical statistician for the study, will contribute to the statistical design and analysis of data. All authors have revised the protocol critically for important intellectual content and approved the final manuscript.

Funding This work is supported by China Medical Board (CMB), grant number: 19-342.

Disclaimer The funding sources had no role in the design of this study and will not have any role during its execution, analyses, data interpretation or decision to submit results.

Competing interests None declared.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

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