BMJ Open

Study protocol for the evaluation of pharmacist-participated medication reconciliation at county hospitals in China: a multicentre, open-label, assessor-blinded, non-randomised, controlled study

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To cite: Yu A, Wei G, Chen F, *et al*. Study protocol for the evaluation of pharmacist-participated medication reconciliation at county hospitals in China: a multicentre, open-label, assessor-blinded, non-randomised, controlled study. *BMJ Open* 2022;**12**:e053741. doi:10.1136/bmjopen-2021-053741

► 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-2021-053741).

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Received 22 May 2021
Accepted 03 February 2022

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ABSTRACT

Introduction Pharmacist-participated medication reconciliation proved an effective strategy to decrease the risk of medication discrepancy-related errors. However, it is still under pilot in China and its effectiveness in the Chinese healthcare system remains unclear. This study aims to conduct a pharmacist-participated medication reconciliation intervention for elderly patients in county hospitals in China and to evaluate its effect.

Methods and analysis This is a multicentre, prospective, open-label, assessor-blinded, cluster, non-randomised, controlled study for elderly patients. The study will be conducted in seven county hospitals, and the clusters will be hospital wards. In each hospital, two internal medicine wards will be randomly allocated into either intervention group or control group. Patients in the intervention group will receive pharmacist-participated medication reconciliation, and those in the control group will receive standard care. The primary outcome is the incidence of medication discrepancy, and the secondary outcomes are patients' medication adherence, healthcare utilisation and medical costs within 30 days after discharge.

Ethics and dissemination Ethics committee approval of this study was obtained from Peking University Institution Review Board (IRB00001052-21016). We have also obtained ethical approvals from all the participating centres. The findings will be published in scientific and conference presentations.

Trail registration number ChiCTR2100045668.

Strengths and limitation of this study

- This study will provide new evidence of the effectiveness of a tailored medication reconciliation programme for the incidence of medication discrepancy at county hospital in China.
- This is the first study in China that will evaluate the effect of a pharmacist-participated reconciliation programme at county-level hospitals.
- A multicentre, prospective, open-label, assessor-blinded, cluster, non-randomised, controlled study is designed as a pragmatic evaluation of a tailored medication reconciliation programme to decrease medication discrepancies for the elderly compared with routine practice.
- The limitation is that the study is implemented in seven county hospitals in Ganzhou city, which may limit its generalisability to other areas or to other medical settings like primary care facilities.

INTRODUCTION

Medication discrepancies often occur at transitions of care, when patients' medication information may not be communicated accurately to patients and/or across health facilities.[1–3] A systematic review reported that the average number of discrepancies at discharge per patient varied from 1.2 to 5.3 across countries.[4] Studies showed that medication discrepancies could occupy more medical resource utilisation and preventable adverse drug events, especially in the elderly population.[5–8] Elderly patients often have high rates of comorbidity and polypharmacy and are more sensitive to adverse drug events due to changes in pharmacokinetics and pharmacodynamics.[9 10] Thus, measures that involve medication review to reduce medication discrepancies in elderly patients are needed to ensure the effectiveness and safety of their medications.[1 3]

Medication reconciliation is identified as a major intervention to reduce medication discrepancies.[1 11 12] The WHO defines medication reconciliation as a formal process in which healthcare professionals partner with

patients to ensure that accurate and complete medication information are communicated at transitions of care.[13] Medication reconciliation is defined by National Institute for Health and Care Excellence as the process of identifying an accurate list of a person's current medicines and comparing them with the current list in use, recognising any discrepancies and documenting any changes, thereby resulting in a complete list of medicines to be accurately communicated to patients across healthcare facilities.[14] After it was first adopted as a National Patient Safety Goal by the Joint Commission in 2005,[15] several international health organisations, including the WHO and the Institute for Healthcare Improvement,[16 17] took medication reconciliation as an imperative procedure to identify and correct medication discrepancies. After being implemented in routine clinical practice across countries,[18–21] pharmacist-participated medication reconciliation proved an effective strategy to decrease the risk of medication discrepancy-related errors, hospital readmission, emergency department visits and medical costs, and to improve patients' medication adherence.[22–24] On the contrary, some studies showed limited benefit or even negative effect of medication reconciliation.[25 26] However, medication reconciliation is under pilot in China and its effectiveness in the Chinese healthcare system remains unclear.

County-level hospitals offer treatments and technical guidance in rural areas of China, serving more than 70% of rural residents across the nation.[27 28] Promoting quality of treatments at county-level hospitals is among the core objectives of the Chinese public hospital reform.[29] Thus, we aim to conduct a pharmacist-participated medication reconciliation intervention for elderly patients in county-level hospitals in China and to evaluate the effect of this programme.

METHODS AND ANALYSIS

Study design

This is a multicentre, prospective, open-label, assessor-blinded, cluster, non-randomised, controlled study (figure 1). The study will be conducted in county-level hospitals and the clusters will be hospital wards. To eliminate the contamination of the control group, detailed information on the intervention was only provided to the intervention group. In each hospital, two internal medicine wards will be randomly allocated to either intervention group or control group. Patients in these wards who satisfy the inclusion criteria and provide consent for participation will be included in the study (see online supplemental file 1 for consent form). Patients in the intervention group will receive pharmacist-participated medication reconciliation, and those in the control group will receive standard care. We then will evaluate the effect of medication reconciliation on the incidence of medication discrepancy, medication adherence, healthcare utilisation and medical costs of the patients. Study

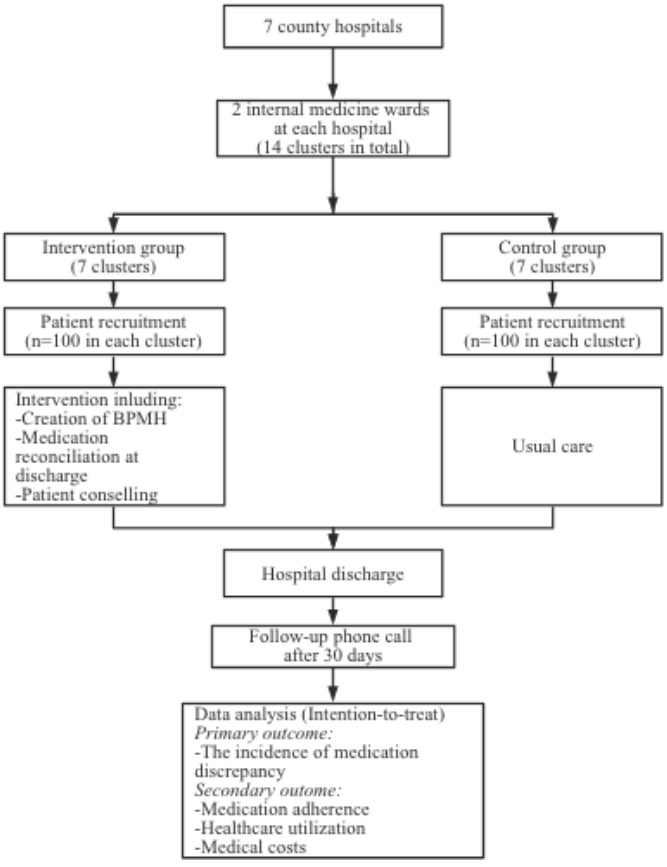

Figure 1 Flow chart summarising the study procedure. BPMH, best possible medication history.

enrolment will start from 1 December 2021, and the study is expected to complete within 3 months.

Study settings

Ganzhou city is the largest city in Jiangxi province, located in the middle of China, and has a residential population of 9.8 million. We included 7 of 18 county-level hospitals in Ganzhou based on willingness to participate. In each hospital, two internal medicine wards admitting the most elderly patients were selected.

Participants

Patients who are treated in and discharged from the sample wards during our study period will be eligible for inclusion if they are (1) 60 years or older at admission; (2) have at least one of the following diagnoses: hypertension, hyperlipidaemia, diabetes, coronary artery disease, pulmonary heart disease, atrial fibrillation, hearth failure, asthma, chronic obstructive pulmonary disease and (3) prescribed with ≥3 medications at discharge. Patients who (1) have tumour, transplantation, chemotherapy or other severe complications; (2) unable to understand Chinese or (3) unwilling to receive medication reconciliation will be excluded from the study.

Preliminary work

To understand the extent of medication discrepancies and discharge medication regimen common for elderly

patients at the seven sample hospitals, we conducted a retrospective study in priori. We collected demographic characteristics, diagnoses and discharge medication regimen for 100 elderly patients from each hospital. Our clinical pharmacy experts, led by the chief pharmacist from the Peking University First Hospital, developed standards for and established type of medication discrepancy. The types of medication discrepancy are (1) medication duplication, (2) medication omission, (3) medication interaction, (4) medication addition, (5) inappropriate/unclear usage and (6) others.

Then, based on the results of retrospective study, we will hold a 2-day training session for pharmacists serving the intervention group at sample county-level hospitals. The session will focus on basic knowledge of medication regimen of chronic disease, the criterion for medication discrepancy as well as the tailored, standardised operating procedure of conducting medication reconciliation.

Interventions

Patients in the intervention group will receive pharmacist-participated medication reconciliation. Trained pharmacists will conduct medication reconciliation for patients following the three steps listed below:

Step 1: generate the best possible medication history (BPMH)

The first step of the intervention is to generate a patient's BPMH by pharmacists during patient rounds. The BPMH outlines medications that the patient actually takes before admission, including the name, dosage form, dose and admission route of each medication. This step will ensure that the subsequent recommendations to simplify and optimise the medication regimen are based on full and accurate information of the patient's medication regimen. We will interview the patient's family members if the enrolled patient is unable to participate in the interview.

Step 2: conduct medication reconciliation at discharge

The second step of the intervention is to conduct a pharmacist-participated medication reconciliation at discharge. Pharmacists will identify medication discrepancies between patient's in-hospital medication records and discharge list. Discrepancies will be discussed with physicians and resolved by consensus. The pharmacists will then form a best possible medication discharge list (BPMDL). Information about medications at discharge (eg, rationale for changed medications and monitoring needs for newly initiated or stopped medications) will be summarised in the BPMDL and provided to the patient with the consent from the physician.

Step 3: provide counselling for patients

The third step is to provide patient counselling. Patients will receive tailored counselling conducted by pharmacists with the patients' BPMDL. The therapeutic goals and rationale for medication optimisation proposal will be explained and discussed in detail with each patient, as well as the benefits and potential harms of their medication treatment. Pharmacists will also provide diet and lifestyle recommendations for the patients.

Usual care for control arm

Patients assigned to the control group will receive standard clinical treatment provided by physicians and nurses. Patients will receive a standardised discharge summary from their physicians, listing their medical diagnoses and medications to take after discharge. Patients will also receive counselling for discharge summary from the medical team. Pharmacists will not be involved in the treatment of patients in the control group.

Outcomes

Primary outcome

The primary outcome is the incidence of medication discrepancy in intervention and control groups. This outcome will be evaluated by clinical pharmacy experts from our affiliated tertiary hospitals (blinded) based on patients' medical records during hospitalisation, and on the BPMDLs (intervention group) or discharge summaries (control group).

Secondary outcome

Secondary outcomes are patients' medication adherence, healthcare utilisation and medical costs within 30 days after discharge. These outcomes will be assessed by follow-up survey via calls. The care team members, blind for the allocation, will call each participant on the 30th day after discharge to elicit relevant information using a predefined set of questions (see online supplemental appendix 2 for follow-up questionnaire). Patients' medication adherence will be measured by the Adherence to Refills and Medications Scale (ARMS).[30] ARMS is a 12-item structured, self-report adherence measurement scale. Each item is set with responses of 'none', 'some', 'most', or 'all', of the time, and is given a value from 1 to 4. Adherence scores range from 12 (optimal adherence) to 48 (complete lack of adherence). Healthcare utilisation is defined as a binary outcome (yes/no) indicating whether patients had any readmissions or emergency department visits because of the same morbidity within 30 days after discharge. Medical costs are direct medical costs within 30 days after discharge. To control for participation bias introduced by patients' self-reported medication costs, we will also review the electronic medical records for patients' medical costs.

Sample size

Based on our previous study, we expect the incidence of medication discrepancy in the control arm would be approximately 60%.[31] Given a significance level of 5% and an 80% power, 387 patients are needed to detect a difference of at least 10% between the two groups. Considering a 10% loss to follow-up and a design effect of 2, we aim to include 1400 patients (700 in the intervention group and 700 in the control group) in this study.

Blinding

Due to the nature of medication reconciliation, neither patients nor their caregivers can be blinded to the intervention. However, all investigators, outcome assessors, experts from tertiary hospitals and statisticians will be blind to the allocation to minimise potential bias.

Data collection and management

Clinical data will be extracted from the electronic medical records at the sample hospitals, including patients' date of admission and discharge, de-identified ID number, demographic characteristics, diagnoses, medication information, healthcare utilisation and medical costs within 30 days after discharge. Information of patients' medication adherence within 30 days after discharge will be collected via telephone survey with self-reported questionnaires as well as healthcare utilisation and medical costs.

Patients' identifiable information will not be available to research team members. Access to the patient's medication utilisation data will be limited to investigators. The data will be stored using codes assigned by the investigators and be kept on password-protected computers.

Statistical analysis

We will use Stata 15.0 software for data analysis. Intention-to-treat analysis will be conducted. The baseline characteristics of the study population will be summarised using descriptive analyses. The intervention group will be compared against the control group for all primary and secondary outcomes. We will use two-sample t-test for continuous variables and the Chi-square test for categorical variables. Logistic regression or Poisson regression models will be performed to evaluate the effect of pharmacist-participated medication reconciliation. All reported p values will be two-sided and tests will be performed with a 5% level of significance.

Patient and public involvement

Patients were not directly involved in developing research questions, study design, intervention designs, outcome measures, recruitment and conducting of the study. At the end of this study, the patients will be informed of any conference presentations and publications by phone or message.

DISCUSSION

Medication reconciliation is critical for promoting medication and patient safety, especially at transitions of care.[32] This study will be the first study to assess the impact of a pharmacist-participated medication reconciliation intervention on the incidence medication discrepancy at county-level hospitals in China. It will inform policy design by providing solid evidence of the effect of medication reconciliation on improving the quality of medication use and patients' medication adherence. We hope that results from this study will help improve performance of pharmacists at county-level hospitals where medical treatments and resources are limited. If our study elicits positive results, medication reconciliation could be disseminated to more healthcare institutions across China.

This study has a few limitations. First, this study will be implemented at 7 of 18 county-level hospitals in Ganzhou city, which may not be representative of Chinese county hospitals. Besides, it may cause bias since hospital enrolment was based on the willingness to participate. Second, collecting medication adherence by patients' self-report measurement scale may introduce biases. Third, although we have taken measures to avoid contamination, there might still be unpredictable leakage between colleagues at the same hospital. Fourth, although we extracted relevant data from both follow-up surveys and electronic medical records at hospitals, it might not reflect true medical costs spent by each patient.

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Acknowledgements We would like to thank the Longnan No. 1 People's Hospital, Ningdu People's Hospital, Ruijin People's Hospital, Shangyou People's Hospital, Xinfeng People's Hospital, Xingguo People's Hospital and Yudu People's Hospital for their support and cooperation.

Contributors XG is the principal investigator of this study and obtained grant funding. AY, MF GWa and GWe participated in the design of the study protocol; they drafted the protocol and wrote the protocol manuscript. XG and HW refined the study protocol. GWe, FC, ZW and XL assisted in the development and implementation of the study. LS will supervise the study. All authors critically reviewed and approved the final manuscript.

Funding This study was supported by the China Medical Board (CMB) Fund Programme 'Evaluation of Pharmacists-Participated Medication Reconciliation in County Hospital in China' (grant number: 19–342).

Competing interests None declared.

Patient consent for publication Consent obtained directly from patient(s).

Provenance and peer review Not commissioned; externally peer reviewed.

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