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Impact of a clinical pharmacist on optimising the quality use of medicines according to the acute coronary syndrome (ACS) secondary prevention guidelines and medication adherence following discharge in patients with ACS in Sri Lanka: a prospective non-randomised controlled trial study protocol

Nanayakkara Muhandiramalaya Yasakalum Bagyawantha ,[1,2] Ian D Coombes ,[3,4] Indika Gawarammana,[2,5] Mohamed Fahim[2,6]

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For numbered affiliations see end of article.

Correspondence to
Nanayakkara Muhandiramalaya Yasakalum Bagyawantha; bagyawanthanmy@gmail.com

ABSTRACT

Objectives Ensuring quality use of medicines (QUM) through clinical pharmacy services can improve therapeutic outcomes of patients diagnosed with acute coronary syndrome (ACS). The major objective of this study is to demonstrate the added value of a clinical pharmacist to the medical and nursing team providing care to patients with ACS on the continuation of quality use of the patients' medicine after discharge.

Study design This protocol outlines a prospective, non-blinded, non-randomised, controlled interventional study.

Study setting The study will be conducted at the professorial medical wards of a tertiary care teaching hospital in Sri Lanka.

Participants Sample size will be 746 patients in both control and intervention arms. Patients diagnosed with ACS who are 18 years old or above and expected to visit the hospital for their routine clinic follow-ups after discharge will be recruited and randomised 1:1 to either the intervention group or the control group. Patients who are diagnosed and suffering from psychological disorders will be excluded from this study.

Interventions The planned interventions that will be delivered at discharge include review and optimisation of medications, assessing patient adherence and providing discharge medication counselling. Data will be collected at recruitment, 1 month, 3 months and 6 months' time intervals in both groups. Improvement of patients' medication adherence, reduction of hospital readmissions, reduction of drug-related problems, the attitude of doctors and nurses towards clinical pharmacy services and the cost-effectiveness of the clinical pharmacy services will be the major outcomes of this study.

Ethics and dissemination Ethical approval for this study has been obtained from the ethics review committee, Faculty of Medicine, University of Peradeniya (2019/EC/26) and the trial is registered at the Sri Lanka Clinical Trials Registry. The results of this study will be disseminated via conference proceedings, journal publications and thesis presentations.

Trial registration number SLCTR/2019/039.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The study design ensures pseudo-randomisation between wards and delivery of planned interventions to the recruited patients.
⇒ The questionnaires and tools used in this study are pretested and validated resulting in reliable findings.
⇒ The researcher has obtained specialised training in the delivery of clinical pharmacy services in addition to their academic qualifications.
⇒ Patients requiring percutaneous coronary intervention and coronary artery bypass grafting have to be transferred to another hospital which will mean loss of patients as they may go to other hospitals for their secondary prevention treatments.
⇒ There is potential contamination of control patients receiving some parts of the interventions as the study is conducted without blinding of staff in the same wards and blinding of an education study is not possible under these settings.

INTRODUCTION

Cardiovascular diseases (CVDs) such as heart failure (HF), ischaemic heart diseases

including acute coronary syndrome (ACS) and myocardial infarction (MI) are the leading causes of deaths globally.[1] ACS is the most common cause of mortality in western countries and the mortality rate is increasing in the Asian Pacific region, secondary to increasing population in the urban areas, industrialisation and the changing lifestyle of people.[2] In Sri Lanka, ACS is a considerable healthcare burden and ischaemic heart disease has been the leading cause of hospital deaths in Sri Lanka since 2010.[3] In addition, managing ACS and other CVD conditions are suboptimal in Sri Lanka and other developing countries compared with developed countries.[4] Lack of percutaneous coronary intervention (PCI) facilities and less training of first contact doctors, underuse of beta blockers and poor record keeping on readmissions after discharge have contributed to suboptimal CVD management.[5]

Patients who are diagnosed with ACS receive a range of medicines; a study conducted at the Teaching Hospital at Peradeniya in Sri Lanka has revealed that majority of the patients with ACS have received aspirin, clopidogrel, statins, ACE inhibitors and beta blockers following thrombolytic therapy.[5] Also, a significant proportion of patients with ACS had comorbidities such as hypertension, diabetic mellitus and dyslipidaemia. Multiple disease conditions have led to complex therapeutic regimens in these patients with treatment options having potentially dangerous drug-related problems (DRPs) and adverse effects like gastrointestinal bleeding from dual antiplatelet therapy, chronic kidney disease from ACE inhibitor (ACEi)/angiotensin receptor blocker (ARB) and hypotension from vasodilators and beta-blockers.[6]

Quality use of medicines (QUM) is an important component of improving therapeutic management of acute and chronic diseases such as ACS/heart failure. A key objective of QUM is to reduce avoidable DRPs in health systems and improve the safe and effective continuation of medicines. People who live in developing countries are at higher risk of such medication errors than developed countries.[7] Clinical pharmacists when integrated into and accepted by the ward-based medical and nursing teams can enhance QUM by supporting the identification as well as resolution of DRPs and optimisation of patients prescribed and administered therapy. The clinical pharmacist can also assist in collaborating with provision of medication information to patients in collaborations with doctors during the inward stay as well as at discharge.[8] The addition of a clinical pharmacist to the healthcare team can result in improved care to the patient while there is no evidence of harm to the patients by the addition of a clinical pharmacist.[9] Also, a clinical pharmacist added to the healthcare team managing patients with ACS improves the patient adherence and clinical outcomes ensuring QUM.[10]

The use of a patient held medication action plan is a patient centred document containing a list of actions for the patient to use in tracking progress of medication self-management and it can be a part of an evidence-based medication management programme. Clinical pharmacists can actively participate in developing medication-related action plans during patient discharge medication counselling.[11]

The Pharmaceutical Care Network Europe (PCNE) has defined DRPs as 'an event or circumstance involving drug therapy that actually or potentially interferes with desired health outcomes'.[12] DRPs are a considerable public health issue in most of the healthcare systems. Even though the use of drugs is an important factor in disease management, getting the optimum therapeutic outcomes with minimum unwanted effects is challenging in the clinical practice because of DRPs. Identifying and solving DRPs is one of the core activities of clinical pharmacy practice.

Justification for the study

On discharge from hospitals, patients often vary from the planned medication regimens intended by their prescribing physicians. Underlying factors for this important issue are either intentional (patient-centred, eg, poor adherence) or unintentional. Unintentional factors may include system-centred issues such as poor communication of medication plans to patient or caregiver and their ongoing healthcare team after discharge.[13] These miscommunications result in decreased potential benefit from secondary prevention medication for the patients with ACS. This problem should be addressed critically as it can result in adverse health outcomes, including reinfarction, development of heart failure, angina or even death and also increased healthcare cost of readmissions.[14]

After discharge from hospital patients routinely take one or two antiplatelet agents; an ACEi or ARB, a statin, a beta blocker plus other medication for associated medical history. The incident of medicine-related harm, associated with these cardiovascular medicines is not insignificant.[15]

It is evident that addition of a clinical pharmacist to perform clinical pharmacy services is expected to contribute in a positive manner to improve the QUM and also enhance the patient-centred therapeutic outcomes in patients with cardiovascular and other chronic conditions. There are some published studies on non-communicable diseases in Sri Lankan healthcare setting which evaluated the feasibility, importance and acceptance of a clinical pharmacist inside the wards and demonstrated positive impacts such as significant reduction in unplanned readmissions and more appropriate medications and less DRP.[16]

All discharged patients with ACS from the government hospitals of Sri Lanka receive their medication free of charge. Because all patients from government hospitals receive their medications free of charge and return to the hospital for ongoing supply; this is an excellent opportunity to ensure initiation of the correct medication supply; counselling and ability for a pharmacist to have a conversation with patients about their medicines; ability to correct misunderstanding or ill-informed beliefs in order

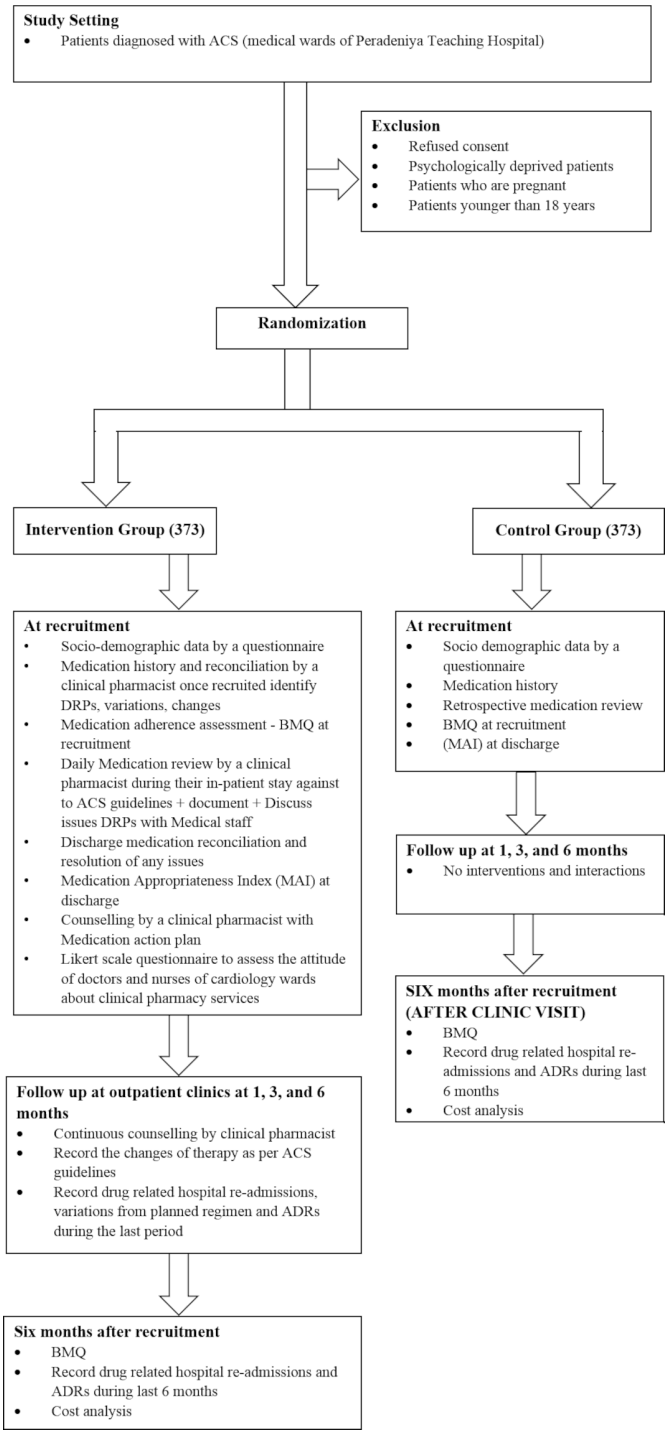

Figure 1 Flow chart of the study procedure.

for patients to achieve maximal health benefits and minimise their risk of medicine-related harm. In addition, poor patient adherence is a healthcare burden not only related to its therapeutic implications but also regarding the waste of public resources with a depleted healthcare budget in developing countries. Therefore, it is essential to improve the patient adherence to the planned medication regimen at discharge[17]

Even though there are studies conducted in Sri Lanka which reveal epidemiological information of ACS, there were no published studies about the added role of a clinical pharmacist to the healthcare team managing patients with ACS particularly at discharge. This has created a gap in knowledge which needs to be filled to address the important policy decisions in future about implementing clinical pharmacy services in Sri Lanka. Therefore, this study is designed to address this requirement of ensuring the continuation of quality use of medicines for patients on discharge from hospitals with ACS by implementing clinical pharmacy services in cardiac and medical wards.

Study hypothesis and principal objectives

We hypothesised that the addition of a clinical pharmacist to the healthcare team providing care to patients with ACS will be accepted by the healthcare team and enhance the continuation of quality use of medicines, patient's medication knowledge/understanding and medication adherence after discharge from hospital.

Primary objective of this study is to demonstrate the added value of a clinical pharmacist to the medical and nursing team providing care to patients diagnosed with ACS on the medication adherence and continuation of quality use medicine after discharge from hospital. In order to demonstrate this broader primary objective, we plan to evaluate the impact of a clinical pharmacist on improving medication adherence, detecting and avoiding DRPs and reducing unplanned hospital readmissions under secondary objectives. Also, the other secondary objectives include assessment of cost-effectiveness of planned clinical pharmacy interventions and evaluation of the perception of the doctors and nurses attached to medical wards towards the clinical pharmacy services.

METHODS AND ANALYSIS

This protocol was developed in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement[18] (see online supplemental material 1 SPIRIT checklist).

Study design

The study will be conducted as a prospective, non-blinded, non-randomised, controlled interventional study. Participants will be randomised 1:1 to either the intervention group (intervention and standard care) or the control group (standard care).

There is no established ward-based clinical pharmacist at the study setting and the hospital pharmacists are largely engaged in medication procurement, storage and dispensing. Hence, the expansion of the pharmacist's role to a more patient facing, clinical setting can be considered as a novel concept in Sri Lanka. Therefore, the qualified graduate pharmacist who will be the principal investigator of this study, has undergone a 6-week ward-based intensive clinical pharmacy training at three hospitals in Brisbane and Mackay, Australia, before the study commencement. The training was conducted by Australian clinical pharmacy educators who have visited

Table 1 Outcome measures

Outcome measures	Baseline	1 month	3 months	6 months
Medication adherence assessment	✓			✓
Drug-related problems	✓*			
Medication appropriateness	✓			
Medication-related hospital readmission		✓	✓	✓
Cost-effectiveness of clinical pharmacy services				✓
Perception of healthcare team towards clinical pharmacy services				✓

*Initial medication review and during discharge.
m, months.

Sri Lankan hospital wards on several occasions for Bachelor of Pharmacy undergraduate teaching and training at University of Peradeniya as part of the CASPPER (Collaboration of Australian and Sri Lankans for Pharmacy Practice Education and Research) collaborative.[19] The training programme was evaluated using the Clinical Competency Assessment Tool for Australian Pharmacists (clinCAT) and the medication-related consultation framework (MRCFr). Furthermore, the clinical pharmacist will participate in Skype case-based conference tutorials every second week with senior clinical pharmacists from Australia and UK throughout the study.

Study setting

Trial will be conducted at the University medical wards of Teaching Hospital, Peradeniya, Sri Lanka; a large 1000-bed tertiary care teaching hospital with approximately 600 admissions with ACS annually. Patients who are diagnosed with ACS from the medical wards will be randomly selected for this study adhering to the inclusion criteria.

Inclusion criteria

Patients who are diagnosed with non-ST elevated myocardial infarction (NSTEMI), ST elevated myocardial infarction (STEMI) and unstable angina (UA), who are 18 years old or above will be included in this study. Patients who will be included are expected to visit the hospital for their routine clinic follow-ups after discharge.

Exclusion criteria

Patients who are currently diagnosed (based on medical records and patient history) with and undergoing treatments for psychological disorders, patients who are pregnant and patients who are below 18 years will be excluded from the study.

Patient and public involvement

Patients and the public were not involved in the development of the research question or outcome measures. The initial patient involvement in this study will be at their recruitment and participants will be given contact details of the researcher to request the results of the study.

Recruitment

All the admissions which are diagnosed as ACS (NSTEMI, STEMI and UA) will be initially considered for the study. Their diagnosis will be confirmed by the written diagnosis of the bed head ticket (patient notes). Next, the researcher will approach the eligible participants and seek their willingness to participate in the study.

Randomisation

Eligible consenting patients will be recruited and divided into control and intervention groups by a simple dividing method. The medical wards at Teaching Hospital Peradeniya consists of four sections, namely A, B, C and D with different medical and nursing teams. Consecutive patients recruited from A and B sections during the first 2 months will be added to the control group and the patients recruited from C and D sections during that period will be added to the intervention group. The sections will be swapped between control and intervention during every 2 months' time of the study to maintain the uniformity. ACS admissions to these sections are not in equal proportion resulting in some sections having more patients with ACS whereas some having less patients with ACS. Therefore, patients will be divided into two groups every 2 months to obtain a uniform sample in both control and intervention groups. The treating team will be explained of the sampling method well in advance to avoid any confusions at each time of crossover.

Since blinding of a patient is not practical for this study due to interaction between the patients in the same wards, consecutive individual patient randomisation within each unit may lead to contamination of the education intervention and hence the above randomisation approach will be used. However, data analysis will be blinded.

Sample size

Sample size will be approximately 746 patients. Several studies have shown that approximately 45% of the patients are adherent to ACS medications post-discharge at 1–2 years follow-up.[7] In this study it is anticipated a 30% increase (58%) in knowledge/adherence after introducing the clinical pharmacy intervention. Therefore,

Table 2 Schedule of enrolment, interventions and assessments

Time point		–T3: selecting patients	–T2: recruitment	–T1: before discharge in ward	T0: date of discharge	T1: 1 month post discharge	T2: 3 months post discharge	T3: 6 months post discharge
Procedure	**Details**			**Baseline Intervention**		**Follow-up and intervention**	**Follow-up and intervention**	**Follow-up and evaluation**
Enrolment:								
Eligibility screen	Check diagnosis for NSTEMI, STEMI, UA and ACS	X						
Randomisation			X					
Informed consent			X					
Intervention:								
Patient medication history	Patient interview			X				
Medication adherence assessment	Using BMQ			X				X
Medication review	Medication reconciliation			X				
Identifying DRPs and resolving				X				
Optimising the discharge medication list					X			
Discharge medication counselling	Counselling with written information				X			
Recording hospital readmissions	During follow-up					X	X	X
Identifying and assessing the changes to planned medication regimen	During follow-up					X	X	X
Resolving any DRPs and counselling about the changes to the plan	During follow-up					X	X	X
Assessments:								
BMQ			X					X
MAI					X	X	X	X
DRPs					X	X	X	X
ADRs					X	X	X	X

Continued

Table 2 Continued

Time point		–T3: selecting patients	–T2: recruitment	–T1: before discharge in ward	T0: date of discharge	T1: 1 month post discharge	T2: 3 months post discharge	T3: 6 months post discharge
Procedure	**Details**	**Baseline Intervention**				**Follow-up and intervention**	**Follow-up and intervention**	**Follow-up and evaluation**
Record hospital readmissions			X*			X	X	X
Record to changes to planned medication regimen						X	X	X

*At recruitment and during follow-up
ACS, acute coronary syndrome; ADRs, adverse drug reactions; BMQ, Brief Medication Questionnaire; DRPs, drug-related problems; MAI, Medication Appropriateness Index; NSTEMI, non-ST elevated myocardial infarction; STEMI, ST elevated myocardial infarction; UA, unstable angina.

the calculated sample size is 324 patients in each arm with the level of significance of 0.05 and statistical power of 90%. The researchers have factored in a 15% dropout and hence sample size is re-calculated as 373 patients in each arm.

Procedure

Patients who fulfil the inclusion criteria will be recruited and divided into control and intervention groups by a simple dividing method by the intervention pharmacist. Informed written consent (see online supplementary material 2, Sample consent form) will be obtained from the participants in order to collect data at the time of recruitment and respective follow-ups by the intervention clinical pharmacist. Socio-demographic data and patient knowledge about prescribed medication will be collected in both groups using an interviewer administered structured questionnaire at baseline. The patients in the control group will receive standard care while the patients in the intervention group will receive standard care together with additional clinical pharmacy interventions. Standard care comprises of the general ACS management without clinical pharmacist being involved in the medication management process. Standard care is provided by the healthcare team in the wards following 'STEMI Management Guidelines' Sri Lanka (Sri Lanka Heart Association and Sri Lanka STEMI forum, 2014) developed by the Sri Lanka Medical Association.[20]

Interventions

Patients in the intervention group will have their medications reviewed by a qualified trained clinical pharmacist and reconciled against their medication on admissions and compared with the ACS treatment guidelines. 'STEMI Management Guidelines' Sri Lanka[20] and electronic Therapeutic Guidelines (eTG) Australia[21] will be used as reference for the medication review by clinical pharmacist. Any opportunities for optimisation of medications will be discussed with the in-patient medical team. The clinical pharmacist will work collaboratively with the medical and nursing teams and patients to ensure that the patients are discharged on the appropriate medications as per the guidelines. All members of the ongoing team (patient, caregiver, primary care physician and pharmacist) will be aware of this patient management plan.

Medicine appropriateness evaluation

A systematic medication review will be conducted on the discharge medications of the intervention patients in order to identify DRPs and the identified DRPs will be classified according to the system created by the PCNE.[22] The appropriateness of the discharge medication list for control and intervention group patients will be assessed using the Medication Appropriateness Index (MAI) which is a validated tool for such purposes at the time of discharge.[23] In addition, the patients in the intervention group will receive discharge medication counselling together with a patient medication action plan developed

by the clinical pharmacist as a part of the clinical pharmacy services. Both these interventions will be targeted to increase the patient's knowledge about medication, lifestyle modifications and medication adherence. Further interventions such as continuous counselling on newly added medicine, checking DRPs and drug interactions with newly added medicine and provision of non-pharmacological advice will be carried out over a period of 6 months by the clinical pharmacist. Both DRPs and MAI entries will be cross-checked by selected Australian clinical pharmacy educators for the authenticity and for the purpose of quality assurance.

The intervention group patients will be followed up by a telephone interview as well as by directly meeting them in the relevant clinic dates by the clinical pharmacist and research assistant at 1 month, 3 months and at the end at 6 months in order to identify and record any unplanned variations from planned medications, any drug-related hospital readmissions, adverse drug reactions (ADRs) (which are managed by clinic, other doctors and which are not managed, see online supplemental material 3, ADR form) and or number of deaths, which had occurred over the previous month. Also, the planned and deliberate changes according to the ACS treatment guidelines will be identified and the pharmacist will check the patient's adherence to those changes as well. A pretested questionnaire will be used to document readmission information. Summary of the study procedure is explained in figure 1.

Adherence assessment

Brief Medication Questionnaire (BMQ) will be used after obtaining the required permission from the original developers of the tool for the assessment of patients' beliefs about medication and likely adherence at baseline and after the follow-up period.[24] The difference between the mean BMQ scores at baseline and after 6 months will be compared with to evaluate the medication adherence improvement.

Hospital readmissions assessment

The data related to drug-related readmissions will be collected at 1 month, 3 months and 6 months of intervention in the intervention group while the similar data will be collected in the control group after 6 months. Readmissions related to medicines commenced after the patients' discharge will be excluded from the data collection.

Economic evaluation

A simple cost benefit comparison will be carried out to assess the financial impact of adding a clinical pharmacist to the ACS treating team. Costs of the planned clinical pharmacy intervention will be calculated considering pharmacist salary and benefits together with patient monitoring costs (costs of implementing the programme). Benefits of the clinical pharmacy programme will be calculated considering costs saved by hospitalisations avoided, deaths avoided, preventing DRPs, preventing unnecessary usage of medicine and by avoiding additional tests and investigations. A pretested set of questions will be used during the patient follow-ups to record additional costs associated with hospital readmissions and standard rates of costs will be considered to quantify the average per day cost for a hospital admission. The importance of the clinical pharmacy programme will be evaluated by comparing the benefits of the programme against the cost incurred.[25]

Assessing the attitudes of medical and nursing teams towards clinical pharmacy services

A pretested, self-administered questionnaire which has been validated and used successfully in previous similar studies in Sri Lanka will be used to evaluate the attitude of medical and nursing teams towards clinical pharmacy services. The views of the doctors and nurses regarding the benefit of having a clinical pharmacist in the team and the acceptance of the input of a clinical pharmacist is assessed, mainly by this questionnaire. The value of a clinical pharmacist in tailoring the drug therapy to individual patients and improving patient adherence will also be evaluated by this questionnaire.[16 26]

Outcomes

Outcomes (table 1) of this study includes:

- Identifying and resolving DRPs between both groups.
- Improving the patients' medication adherence based on change in BMQ scores.
- Reduction in the medication-related hospital readmissions.
- Assessing the cost-effectiveness of planned clinical pharmacy interventions and estimation of cost saving
- Assessing the perception of medical and nursing team towards clinical pharmacy services

Data collection and cleaning

The schedule of the different data collection points and timings is explained in table 1. All the entered data will be subjected to data audit before they are being analysed. Data cleaning will be performed for all the entered data to ensure the accuracy, relevance, timeliness, reliability and validity of the collected data. Entered data will be cross-checked with the original source of the data in order to achieve this.

Data audit

As a part of the data audit, the identified DRPs and their classification according to the PCNE categorisation will also be double-checked for the authenticity by an independent experienced and practicing clinical pharmacist in Australia. At least 10% of the collected data will be subjected to audit by the independent trained clinical pharmacists in order to improve the authenticity of the collected data.

Data sharing

No additional data available

Statistical analysis

Data will be entered into a Microsoft Excel 2019 database and then on to SPSS V.21 for analysis. Data cleaning will

be carried out by the investigator to assure the quality of entered data to identify any true outliers. Descriptive statistics will be presented as means SD or median with IQR and frequencies where appropriate. Differences between groups will be identified using the $\chi 2$ test for categorical data, independent sample t-test (reporting mean and SD) for parametric continuous data or Mann-Whitney U test when parametric assumption cannot be considered. Correlation between variables will be tested using Spearman's correlation. Independent comparison of more than two groups will be carried out using analysis of variance or Kruskal-Wallis test where appropriate. Paired analysis will be compared within the group where necessary. P values less than 0.05 ($p<0.05$) will be considered to be statistically significant. The summary of enrolment, interventions and assessments in this study is shown in table 2.

ETHICS AND DISSEMINATION

Ethical approval has been obtained from the ethics review committee, Faculty of Medicine, University of Peradeniya (2019/EC/26). All the participants will be clearly informed about the intended study outcomes and the study procedure. Verbal and written informed consent will be obtained from all the participants. This will be a completely voluntary study which allows the participants to leave the study at any given instant and the refusal to participate in the study will not affect the standard care provided to the patients at the respective hospitals. The collected data will be stored in a confidential, password-protected database and those data will only be used for the purposes of this study. The study is registered with Sri Lanka Clinical Trial Registry. All the identified ADRs during the study period will be recorded according to the ADR reporting form. Study findings will be disseminated by publications in peer-reviewed journals and presentations at relevant scientific proceedings. We only anticipate minor amendments to protocol based on the initial operational assessment of the study. However, such changes will be communicated to the institutional review boards/research ethics committees. We do not anticipate any major modification which warrant change in trial design. Version 3 approved on June 16 2020 by the ethics review committee, Faculty of Medicine, University of Peradeniya, is the current approved version of this study.

Author affiliations
[1]Department of Pharmacy, Faculty of Allied Health Sciences, University of Peradeniya, Peradeniya, Central, Sri Lanka
[2]South Asian Clinical Toxicology Research Collaboration (SACTRC), Faculty of Medicine, University of Peradeniya, Peradeniya, Sri Lanka
[3]School of Pharmacy, The University of Queensland, Saint Lucia, Queensland, Australia
[4]Collaboration of Australians and Sri Lankans for Pharmacy Practice, Education and Research (CASPPER), Brisbane, Queensland, Australia
[5]Department of Medicine, Faculty of Medicine, University of Peradeniya, Peradeniya, Central, Sri Lanka
[6]School of Pharmacy, University of Sydney, Sydney, New South Wales, Australia

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

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ORCID iDs
Nanayakkara Muhandiramalaya Yasakalum Bagyawantha http://orcid.org/0000-0002-8692-3927
Ian D Coombes http://orcid.org/0000-0002-1009-6136

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