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*P*rimary care *A*dherence *T*o *H*eart *F*ailure guidelines *IN D*iagnosis, *E*valuation and *R*outine management (PATHFINDER): a randomised controlled trial protocol

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ABSTRACT

Introduction General practitioners (GPs) routinely provide care for patients with heart failure (HF); however, adherence to management guidelines, including titrating medication to optimal dose, can be challenging in this setting. This study will evaluate the effectiveness of a multifaceted intervention to support adherence to HF management guidelines in primary care.

Methods and analysis We will undertake a multicentre, parallel-group, randomised controlled trial of 200 participants with HF with reduced ejection fraction. Participants will be recruited during a hospital admission due to HF. Following hospital discharge, the intervention group will have follow-up with their GP scheduled at 1 week, 4 weeks and 3 months with the provision of a medication titration plan approved by a specialist HF cardiologist. The control group will receive usual care. The primary endpoint, assessed at 6 months, will be the difference between groups in the proportion of participants being prescribed five guideline-recommended treatments; (1) ACE inhibitor/angiotensin receptor blocker/angiotensin receptor neprilysin inhibitor at least 50% of target dose, (2) beta-blocker at least 50% of target dose, (3) mineralocorticoid receptor antagonist at any dose, (4) anticoagulation for patients diagnosed with atrial fibrillation, (5) referral to cardiac rehabilitation. Secondary outcomes will include functional capacity (6-minute walk test); quality of life (Kansas City Cardiomyopathy Questionnaire); depressive symptoms (Patient Health Questionnaire-2); self-care behaviour (Self-Care of Heart Failure Index). Resource utilisation will also be assessed.

Ethics and dissemination Ethical approval was granted by the South Metropolitan Health Service Ethics Committee (RGS3531), with reciprocal approval at Curtin University (HRE2020-0322). Results will be disseminated via peer-reviewed publications and conferences.

Trial registration number ACTRN12620001069943.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study evaluates the effectiveness of a novel multifaceted intervention (involving pre/post-hospital discharge components) to support heart failure (HF) guideline adherence in primary care.
⇒ The intervention involves a model whereby general practitioners (GPs) are responsible for enacting guideline-advocated care, with prompts and guidance through hospital-based support.
⇒ The model provides an opportunity for experiential learning that can be applied to the management of other patients with HF under the GP's care.
⇒ The intervention is highly translatable to routine practice.
⇒ The study will be conducted in a single-state health jurisdiction and may not translate to other jurisdictions.

INTRODUCTION

Heart failure (HF) is a complex condition affecting over 60 million people worldwide and associated with high mortality and hospitalisation rates,[1 2] placing a heavy burden on patients and healthcare systems.[3] In Australia, the prevalence of HF is estimated to be 1%–2%, resulting in hospitalisation costing approximately $2.7 billion annually.[4] Due to the ageing population, and improved treatment of acute cardiovascular events, the prevalence of HF is expected to increase over the next decade.[2]

Guideline-advocated pharmacotherapy and non-pharmacological treatment, such as cardiac rehabilitation (CR), are core components for the effective treatment of patients with HF with reduced ejection fraction (HFrEF) to improve clinical outcomes, functional capacity and quality of

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life.[5 6] However, despite these established benefits, guideline adherence is often suboptimal.[7–9] This is especially pertinent in primary care.[10] General practitioners (GPs) play an essential role in managing patients with HF[11 12]; patients can be holistically monitored, cared for by the same team members and reviewed regularly.[13] However, despite progress in the adoption of guideline-advocated HF treatment in primary care,[14] barriers remain for the delivery of best-practice management[15] at the patient,[16] provider[17 18] and system level.[19 20] For example, HF medication titration is a well-documented challenge in general practice,[15 21] resulting in HF medications often not being titrated to the target dose.[14 22] Compounding this issue is that access and referral of patients to CR and community-based HF programmes, which support the role of GPs in the management and surveillance of patients with HF, are not ubiquitous.[12 23]

Multifaceted interventions with two or more combined strategies have been found to be more effective than isolated processes for instigating changes in practice among health providers.[24] In outpatient cardiology practice, the Improve the Use of Evidence-Based Heart Failure Therapies in the Outpatient Setting Study, which included clinical decision support tools and chart audits with feedback, and the Get With The Guidelines-Heart Failure (GWTG-HF) Programme, which provided education, webinars and quality improvement conferences to support clinical decision-making, were both associated with increased use of guideline-recommended therapies.[25–27] However, the limited research, which has reported the effectiveness of multifaceted interventions to support guideline-advocated management of HF in primary care, has been less successful. Neither the combined strategies of an educational train-the-trainer course with pharmacotherapy feedback[28] nor guideline summary dissemination, performance audit with feedback, patient-specific chart reminders and patient activation mailings[29] resulted in improvement in the prescription of ACE inhibitors (ACEIs) at any dose. In the Swedish Intervention study, Guideline and NT-pro-BNP analysis in Heart Failure, GPs received an education programme and applied N-terminal pro-B-type natriuretic peptide (NT-pro-BNP)-guided therapy, but there were no statistically significant dose increases of ACEIs/angiotensin receptor blockers (ARBs) or beta-blockers (BBs) between the intervention and control groups at 9-month follow-up.[30]

In Australia, nurse practitioners (NPs) have advanced scope of practice, which includes medication titration and ordering blood tests in response to changing clinical status.[31] Accordingly, they are well credentialed to apply case management for patients with HF. We have recently reported that an NP-led HF clinic can improve self-care behaviour and quality of life, and reduce hospital admissions,[32] highlighting the efficacy of HF models of care involving NPs.

We propose a multifaceted intervention to improve the provision of guideline-advocated management of HFrEF in primary care. The intervention will be facilitated by an NP specialising in HF management, who will provide care support pre-discharge and post-discharge. The study's primary objective is to evaluate the effectiveness of the multifaceted intervention for improving *P*rimary care *A*dherence *T*o *H*eart *F*ailure guidelines *IN D*iagnosis, *E*valuation and *R*outine management (PATHFINDER).

METHOD

Study design

This will be a prospective, multicentre, parallel-group, randomised controlled trial with blinded assessment of study outcomes conducted between February 2021 and September 2022. Two hundred eligible patients will be randomly assigned to either the intervention or a usual care control group at a 1:1 ratio. The intervention group will receive multifaceted support involving prehospital and post-hospital discharge components. Pre-discharge elements of the PATHFINDER intervention will include HF self-management education, the provision of a discharge plan that includes scheduled GP follow-up appointments, CR referral and feedback to the supervising hospital physician. Post-discharge, the intervention will involve letters to participants to remind them to book a GP appointment at 1 week, 4 weeks and 3 months, for review of their HF management. Prior to each appointment, the participant will be provided with an HF medication titration plan, approved by a cardiologist, to take to the appointment, which will include the telephone number of a support line for GPs to contact in the event that they require HF management advice (provided through a specialist HF service). The overall schedule of the trial is outlined in table 1, and the study flow chart is presented in figure 1. Both groups will be followed up for over 6 months.

Recruitment

Patients with HFrEF will be recruited from two tertiary hospitals in Western Australia. A research nurse will identify potential participants from the echocardiogram reporting system and electronic medical records of patients in the cardiology and general medical wards, and a daily list of patients with an admission diagnosis of HF will be generated. The study will also be advertised by posting study flyers in the hospitals' cardiology and general medical wards and the study will be promoted to clinicians at departmental meetings. Patients will be required to provide written informed consent prior to enrolling in the study (online supplemental appendix 1). For patients enrolling in the trial, baseline clinical characteristics and prescribed medication will be documented.

Participants

Inclusion criteria

1. Patients hospitalised with signs and symptoms of HF (dyspnoea at rest or on exertion, plus at least one of the following: raised jugular venous pressure, peripheral

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Table 1 Data collection points

Outcome	Assessment	Baseline	1 week	4 weeks	3 months	6 months
Primary						
Overall guideline adherence	Proportion of patients prescribed five out of five HF quality metrics*					*
Secondary						
Medication adherence	Proportion of eligible patients prescribed ACEIs/ARBs/ARNIs, BBs, MRAs at any dose		*	*	*	*
	Proportion of eligible patients prescribed ACEI/ARB/ARNI, BB or MRA at ≥50% of the target dose or maximum tolerated dose		*	*	*	*
	Proportion of eligible patients prescribed ACEI/ARB/ARNI, BB or MRA at the target dose or maximum tolerated dose					*
	Proportion of eligible patients prescribed an anticoagulant if diagnosed with atrial fibrillation					*
Cardiac rehabilitation	Proportion of patients referred to an exercise training programme or cardiac rehabilitation programme					*
	Proportion of patients attending 16 sessions of cardiac rehabilitation					*
Functional capacity	6-minute walk test distance	*				*
	PROMIS Physical Function Short Form 4a					*
Patients' medication adherence	MMAS-8	*				*
Depressive symptoms	Patient Health Questionnaire-2	*				*
Health status	KCCQ-12	*				*
Self-care	SCHFI V.7.2					*
Healthcare resource utilisation	Visits to physician, hospitalisation, days of admission					*

*Four out of four if five is not indicated. Baseline medications will be documented upon discharge.
ACEI, ACE inhibitor; ARB, angiotensin receptor blocker; ARNI, angiotensin receptor neprilysin inhibitor; BB, beta-blocker; HF, heart failure; KCCQ-12, quality of life measured by the Kansas City Cardiomyopathy Questionnaire-Short Version; MMAS-8, patients' medication adherence measured by the Morisky Medication Adherence Measure Scale-8; MRA, mineralocorticoid receptor antagonist; PROMIS, Patient-Reported Outcomes Measurement Information System; SCHFI V.7.2, self-care behaviour measured by the Self-Care of Heart Failure Index version 7.2.

oedema, third heart sound or pulmonary congestion); or a left ventricular ejection fraction (LVEF) <40%; or an LVEF 41%–49% and fulfilling the diagnostic criteria for HF according to the Australian Clinical Guidelines for the Management of Heart Failure 2018.[5] That is, displaying signs of HF, brain natriuretic peptides >100 ng/L or NT-pro-BNP >300 ng/L or objective evidence of high filling pressure as indicated by at least three of the following echocardiography measures: (1) mitral annular velocity septal e' of less than 7 cm/s or lateral e' of less than 10 cm/s; (2) average mitral valve early wave inflow velocity to mitral annular velocity (E/e') ratio of more than 14; (3) left atrial volume index of more than 34 mL/m^2; (4) tricuspid valve regurgitation velocity of more than 2.8 m/s.

2. Able to nominate a personal GP.
3. >18 years of age.

Exclusion criteria

(1) Patients currently under the management of a specialist HF service; (2) receiving palliative care or with a life expectancy less than 6 months for conditions other than HF; (3) nursing home/assisted living residents; (4) impaired cognitive function; (5) non-English speaking; (6) end-stage renal failure (estimated glomerular filtration rate <15 mL/min/1.73 m^2).

Randomisation and blinding

Randomisation will be performed via a web-based program to generate a block randomisation sequence with a 1:1 allocation ratio. The randomisation list will be generated by an independent researcher not involved in the study. The HF NP will enrol participants and the independent researcher will assign the participants' allocation group to the HF NP by email following consent. Due to the nature of the intervention, it will not be possible to blind either the participants or the practitioner delivering the intervention. The study statistician will be blinded to group allocation when analysing the study outcomes. It is possible that participants being managed by the same GP may be allocated to different arms within the trial, resulting in the potential for contamination; however, we anticipate the likelihood of this is low.

Control group

The control group will receive usual care as provided by their treating cardiologist or general physician while an inpatient, and their GP post-discharge. The *Living Well with Heart Failure, information to help you feel better* (third edition 2020, National Heart Foundation of Australia) will be provided to all control participants prior to hospital discharge.

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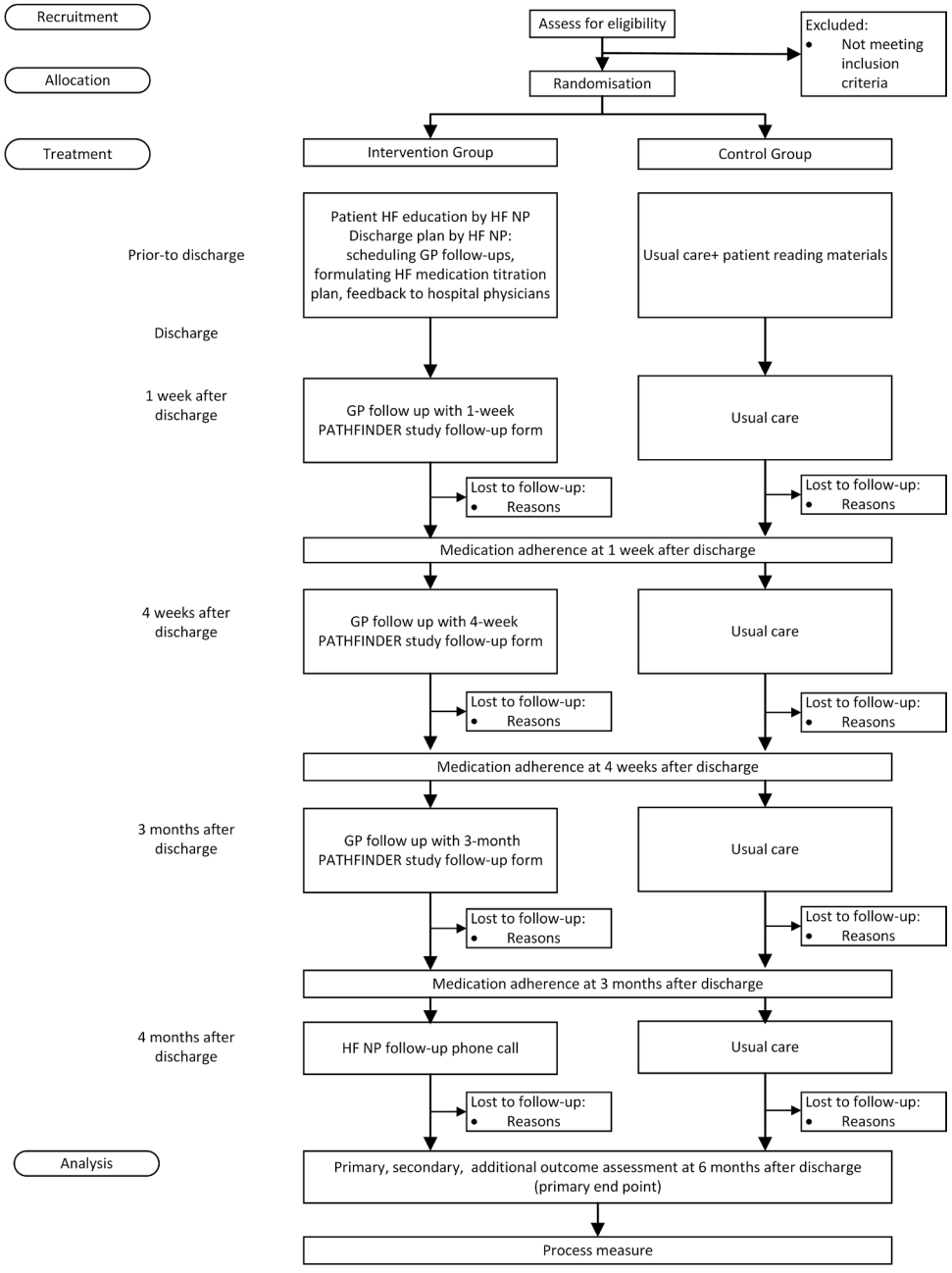

Figure 1 Study flow chart. GP, general practitioner; HF, heart failure; NP, nurse practitioner; PATHFINDER, *P*rimary care *A*dherence *T*o *H*eart *F*ailure guidelines *IN D*iagnosis, *E*valuation and *R*outine management.

Intervention group

In addition to usual care, as outlined for the control group, the intervention group will receive the following components:

Inpatient education

A 30-minute, one-on-one HF education session provided by an HF NP. The education will complement topics in the *Living Well with Heart Failure* and include self-management strategies and information on the value of adherence to HF medications to maintain optimal health.

Post-discharge plan

(1) A PATHFINDER envelope will be provided to participants to take to an appointment with their GP at approximately 1 week, 4 weeks and 3 months after discharge; (2) referral to CR; (3) feedback to the hospital clinical team if the patient is not prescribed an ACEI/ARB/angiotensin receptor neprilysin inhibitor (ARNI), BB or mineralocorticoid receptor antagonist (MRA) despite being eligible, or if there is deviation from the HF medication titration plan (outlined below).

The PATHFINDER envelope will contain a cover letter to the GP detailing the study (online supplemental appendix 2) and the PATHFINDER Study follow-up form. The follow-up form will be individualised to the patient and provide details of dry weight at discharge, current dose and target dose of ACEI/ARB/ARNI, BB and MRA approved by a cardiologist specialising in HF. It will serve

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as both a clinical support and a data collection tool. The form will include the following components: (1) clinical assessment by the GP; (2) HF medication titration plan; (3) details of any further treatment action required; (4) HF medication titration problem-solving guide; (5) HF helpline, which will be available from 08:00 to 16:00 Monday–Friday, for further guidance with medication titration or enacting an action plan for the patient. The HF NP will be the first to respond to calls to the helpline. If the case is out of the HF NP's scope of practice, or clinically complex, it will be escalated to a specialist HF cardiologist to action.

Participants will receive reminders (phone call or text message) to support their adherence to attending the scheduled GP appointments. The HF NP will give the first PATHFINDER envelope directly to the patient during hospitalisation for the 1-week post-discharge GP follow-up and mail the envelopes for the 4-week and 3-month post-discharge GP follow-ups. The HF NP will also phone the patient 4 months after discharge. If the patient is not prescribed 50% of the target dose of HF medications at that point without clinical justification, an additional GP visit will be encouraged. If participants miss a scheduled GP follow-up, they will be encouraged to visit their GP by the HF NP as soon as possible thereafter. Participants who are referred to a specialist HF service following their enrolment in the trial will continue in the trial consistent with intention to treat.

The role of the GP

Participants' GPs will be asked to complete the PATHFINDER Study follow-up forms at the 1-week, 4-week and 3-month appointments. Each follow-up will involve documenting participants' current weight, heart rate, blood pressure and any HF symptoms. The form will also guide GPs in titrating HF medications as recommended by a cardiologist and in accordance with guidelines.[5] At the conclusion of the appointment, the GP will record the current dose or provide justification for not titrating the medication and return the form by fax or email to the HF NP. If the research team does not receive the form despite two reminder calls to the practice, HF medications will be collected by patient report and cross-checked with medical records. Participants in the control group will self-report their medication at the same time points.

Outcomes

Primary outcome

The primary outcome will be the difference between groups in the proportion of patients receiving HF guideline-recommended treatment at 6 months after an index hospital admission for HF based on five quality metrics for HF management:

1. Either prescribed at least 50% of the recommended dose for an ACEI/ARB/ARNI or documentation that such a dose was not tolerated or otherwise inappropriate for eligible patients.[33]
2. Either prescribed at least 50% of the recommended dose for a BB or documentation that such a dose was not tolerated or otherwise inappropriate for eligible patients.[33]
3. Prescribed an MRA at any dose for eligible patients.[5]
4. Prescribed anticoagulation for eligible patients with atrial fibrillation.[5]
5. Referral to an exercise training programme or CR programme.[5]

The criteria for adherence to the HF guideline-recommended treatment will be defined as participants receiving five out of five of the HF quality metrics.[34] Medications and dosage prescribed to participants will be based on documentation on the PATHFINDER Study follow-up form for the experimental group and by patient report in the control group and cross-checked with electronic records or pharmacy medication profiles. Referral to CR programmes will be measured by patient-reported participation and cross-checked with documentation in medical records. If one or more treatments are not indicated, participants will be assessed based on the number of HF quality metrics they are eligible to receive. The recommended dose is based on the target dose of guideline-directed medical therapies in the 2020 American College of Cardiology/American Heart Association clinical performance and quality measures for adults with HF.[33]

Secondary outcomes

The secondary endpoints related to HF guideline-recommended care will include the difference between groups in the proportion of eligible patients receiving the following guideline-advocated treatments:

1. ACEI/ARB/ARNI, BB and MRA at the target dose, or maximum tolerated dose at 6 months.
2. ACEI/ARB/ARNI, BB and MRA at any dose at 6 months.
3. At least 50% of the target dose or maximum tolerated dose of each of ACEI/ARB/ARNI, BB and MRA at 6 months.
4. Anticoagulation if diagnosed with atrial fibrillation at 6 months.
5. Any dose of each of ACEIs/ARBs/ARNIs, BBs and MRAs at 1 week, 4 weeks, 3 months and 6 months.
6. At least 50% of the target dose of each of ACEIs/ARBs/ARNIs, BBs and MRAs at 1 week, 4 weeks, 3 months and 6 months.
7. Referral to an exercise training programme or CR programme by 6 months.
8. Attendance at 16 sessions of an exercise training programme or CR programme at 6 months.

Additional outcomes will be:

1. Functional capacity measured by the 6-minute walk test distance.[35]
2. Patient-Reported Outcomes Measurement Information System Physical Function Short Form 4a.[36]
3. Quality of life measured by the Kansas City Cardiomyopathy Questionnaire-Short Version.[37]

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4. Depression symptoms measured by the Patient Health Questionnaire-2.[38]
5. Self-care behaviour measured by the Self-Care of Heart Failure Index V.7.2.[39]
6. Patients' medication adherence measured by the Morisky Medication Adherence Measure Scale.[40]

The timeline for outcome collection is described in table 1.

Resource use

Healthcare utilisation will include the number of visits to physicians, cardiovascular-related hospitalisation and HF-related hospitalisation, number of cardiovascular-related procedures, days of admission and use of specialised care. Given the feasibility of obtaining health administrative data within the study time frame, we will adapt a validated patient cost questionnaire to obtain self-reported healthcare utilisation data,[41] and this will be cross-checked with medical records. While we recognise the potential for recall bias, there is evidence to suggest that this is a valid method of collecting data on healthcare resource utilisation, especially when administrative data are not easily available.[42]

Safety assessment

An adverse event (AE) will be defined as any undesirable experience resulting in a participant's death, hospitalisation, prolongation of hospitalisation or disability. All AEs will be recorded over the 6-month follow-up period of the study. AEs including symptomatic hypotension, hyperkalaemia and azotaemia will be documented. The research investigators will determine whether there was any AE occurrence by asking the participant and cross-checking with medical records.

Process measures

The Reach, Efficacy, Adoption, Implementation and Maintenance evaluation model[43] will be used to perform a process evaluation. Reach will be assessed using patient-level measures of participation. The recruitment rate, completion rate and reasons for exclusion and dropping out of the study will be determined. Efficacy will be assessed according to the effectiveness of the intervention on influencing GP practice, that is, the Global Adherence Indicator.[44] GPs' satisfaction with the intervention will be measured by a survey administered at the conclusion of the 6-month follow-up period for a participant under their care (online supplemental appendix 3). Adoption will be assessed at the participant and GP level. Participant adoption will be based on the proportion of patients visiting their GP at approximately 1 week, 4 weeks, 3 months post-discharge and the proportion of participants attending at least one session of CR training. Reasons for participants not visiting their GP and not attending CR will be explored. GP adoption will be assessed based on the proportion of GPs completing and returning the follow-up forms at the 1 week, 4 weeks and 3 months time points and the usage of the helpline. Implementation will be assessed based on the extent that the GP delivers the intervention as intended. The proportion of GPs starting, increasing, decreasing, ceasing, and not changing ACEIs/ARBs/ARNIs, BBs, and MRAs will be measured at 1 week, 4 weeks, and 3 months. Reasons for lower dose or medication cessation at 3 months compared with the baseline will be examined. Maintenance will be assessed based on whether the titration of HF medication in primary care, at the levels achieved during the trial, is maintained at 6 months following the conclusion of the trial (table 2). The number of patients with shared GPs will be reported.

Data collection and management

Six-month follow-up assessments will be conducted in person where possible; however, patients who live remotely from the hospital will be assessed via phone and return the questionnaires by mail. A follow-up 6-minute walk test will not be performed in these participants. Participants who withdraw from the intervention protocol will be contacted for the 6-month follow-up assessment for primary, secondary and additional outcomes either in person or via phone (intention to treat). Data will be documented in case report forms and entered into a Research Electronic Data Capture Database. Patient data will be deidentified and saved as a unique trial participant number to assure data confidentiality. Only authorised members of the researcher team will have access to the dataset.

Sample size

A recent Australian audit of HF management observed that 53% of patients were prescribed an ACEI/ARB and BB at ≥50% of the target dose.[45] Furthermore, the prescribing rate of MRAs and anticoagulants with atrial fibrillation was 38% and over 90%, respectively.[45] Data from the GWTG-HF Registry showed that only 12% of patients with HFrEF were referred to CR at discharge, although additional patients may be referred subsequently.[46] It is likely that the proportion of patients treated with ≥50% of the target doses of ACEIs/ARBs together with ≥50% of the target doses of BBs, receiving MRAs and CR referral by 6 months after discharge in combination will be even lower. Based on these assumptions, we estimate that 20% of patients receive five out of five HF guideline-recommended treatments by 6 months after discharge in usual care. We expect to observe an absolute 20% improvement in the intervention group (20% in the usual care group, 40% in the intervention group) 6 months after discharge. With 80% power (type I error=5%, two-sided test), we would require a total sample size of 182, increasing to 220, to account for a potential 20% loss to follow-up.

Statistics

The intention-to-treat principle will be applied, and patients will be analysed according to the group to which they are allocated. Descriptive summaries of patient clinical and selected outcome data will include means

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Table 2 RE-AIM framework of process evaluation

RE-AIM dimension	Definition	Data sources
Reach	The recruitment rate, completion rate and reasons for exclusion and dropping out of the study	Recruitment record; participant's check-in sheet
Efficacy	GAI-3; GP's satisfaction with the intervention arm	Patient-reported medication; case report form; survey
Adoption	The proportion of patients visiting GP at 1 week, 4 weeks, 3 months, reasons for not visiting GP; the proportion of GPs faxing back follow-up form at 1 week, 4 weeks, 3 months; the proportion of patient participating in ≥one session of cardiac rehab; reasons for not attending cardiac rehab; use of the helpline and information requested	PATHFINDER follow-up forms; case report form; field notes; electronic medical records; patient reported
Implementation	The proportion of GP starting, increasing, decreasing, ceasing, and not changing ACEI/ARB/ARNI, BB, or MRA medication at 1 week, 4 weeks, and 3 months; reasons for lower dose or medication cessation at 3 months compared with the baseline	PATHFINDER follow-up forms; case report form; field notes; electronic medical records; patient reported
Maintenance	The proportion of patients prescribed ACEI/ARB/ARNI, BB, or MRA at the same or higher dose, lower dose or ceased at 6 months compared with 3 months; reasons for lower dose and medication cessation	PATHFINDER follow-up forms; case report form; field notes; electronic medical records; patient reported

ACEI, ACE inhibitor; ARB, angiotensin receptor blocker; ARNI, angiotensin receptor neprilysin inhibitor; BB, beta-blocker; GAI-3, Global Adherence Indicator; GP, general practitioner; MRA, mineralocorticoid receptor antagonist; PATHFINDER, *P*rimary care *A*dherence *T*o *H*eart *F*ailure guidelines *IN D*iagnosis, *E*valuation and *R*outine management; RE-AIM, Reach, Efficacy, Adoption, Implementation and Maintenance.

and SDs or medians and IQRs for continuous data and frequency distributions for categorical data. Univariate group comparisons between groups will be performed using t-tests or Mann-Whitney U tests for continuous data and X^2 tests for categorical data. Primary adherence outcomes will be expressed as binary indicator variables. Proportional differences in adherence will be compared between groups at 6 months post-discharge using X^2 tests and modelled using logistic regression models. Models will be adjusted for relevant patient and clinical factors. Results will be summarised as ORs and 95% CIs. Secondary outcomes collected at baseline (during admission) and at 6 months post-discharge will be modelled using generalised linear mixed models, with appropriate link functions depending on data distributions, random subject effects and group–time interaction effects in order to compare differences between groups over time. All models will be adjusted for baseline and relevant patient and clinical factors. Model results will be summarised as estimated marginal mean differences and 95% CIs. Secondary outcome counts of health resource utilisation will be compared between groups using Poisson or negative binomial regression models. Model results will be summarised as estimated marginal mean differences and 95% CIs. Significance levels will be set at alpha=0.05 and Stata V.17.0 will be used for data analysis.

Patient and public involvement

Before designing the intervention, focus groups and interviews with patients with HF, clinicians and administrators in tertiary care and primary care were held to explore barriers and facilitators to post-discharge HF management. Patients were not involved in the recruitment and conduct of the study. The findings of the study will be disseminated to study participants with a narrative summary. The burden of the intervention was not assessed by patients themselves. The research team also consulted the GP liaison officers of the two hospitals involved in the project to discuss the project methodology, including design of the PATHFINDER Study follow-up form.

DISCUSSION AND CONCLUSION

Effective management of HF in primary care practice remains challenging for many clinicians.[47] Despite the availability of evidence-based treatment guidelines, translating these into practice can be complicated by the clinical characteristics of many patients (including hypotension, bradycardia, renal impairment and hyperkalaemia) as well as socioeconomic and behavioural factors relevant to patients.[48–52] Limited access to specialist care,[53] GPs not aware of recent guideline-recommended therapies or contraindications to prescribing medications, nor the importance of achieving the target dose and concerns about adverse effects all contribute to suboptimal HF treatment.[14 52] Moreover, effective systems to support care coordination are often lacking.[15 19] Accordingly, strategies to support general practice in the delivery of evidence-based HF management are required.

Hospital discharge planning plays a vital role in the transition of care from hospital to general practice.[54]

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This includes initiating a medication regimen that can be modified over time.[55 56] Following discharge, a structured medication titration plan can lead to greater responsibility for medication titration by primary care physicians,[57] with point-of-care reminders involving specific guidance having been found to improve medication prescription in accordance with guidelines.[58] However, these studies were limited in their size or trial design, hence the need for a well-conducted randomised controlled trial. Furthermore, providing patients with self-care education during admission can further improve clinical outcomes,[59] and patients who schedule regular follow-up appointments have been found to experience fewer readmissions than those who do not.[59]

The PATHFINDER Study will incorporate these aspects into a multifaceted intervention to support HF management in primary care. A strength of the PATHFINDER intervention will be that it will include components across multiple levels of the health system. The intervention will commence during the inpatient period, involving patient education and medication initiation. An HF NP will subsequently act as a health navigator for the patient, liaising between the patients' GP and a cardiologist. Due to their advanced scope of practice, which includes prescribing and titrating medications, ordering and interpreting pathology and radiology tests and initiating referral to other health professionals,[5 31] NPs are well credentialed to coordinate the management of patients with HF[60] and to support transitional care between the tertiary and primary healthcare sectors.[61 62] The NP will facilitate the follow-up forms and helpline, which will serve as a bridge between the primary and tertiary care sectors, providing clinical decision support and reinforcement of guideline-advocated treatment. Importantly, we anticipate the intervention will help formalise care goals through improved guideline adherence. Improved referral to and uptake of CR will provide stronger multidisciplinary support through ongoing patient education, exercise prescription and clinical surveillance.

There are several limitations to this trial. First, due to the nature of the intervention, it will not be possible to blind either the patient, GP or HF NP to group allocation. Second, because the HF NP will only be employed Monday–Friday, participants admitted to hospital later in the week may be discharged over the weekend before there is an opportunity to review, consent and undertake baseline assessments and self-management education. Third, COVID-19 may impact the opportunity for patients to attend the scheduled GP appointments at the proposed time or face to face, and it is unclear how virtual clinics will impact GPs' willingness to titrate medication. Given that randomisation will occur at the participant level, there is a risk that contamination may occur, whereby the same GP might have a patient enrolled in the intervention and usual care arms of the study, but we anticipate this will occur very rarely.

In conclusion, this study will be a prospective, multicentre, parallel-group, randomised controlled trial with blinded assessment of study outcomes to explore the effectiveness of a multifaceted intervention for guideline implementation in the GP practice. It will determine the feasibility of future large-scale clinical trials aiming to improve primary care physicians' adherence to HF guideline-advocated treatment.

Ethics and dissemination

Ethical approval has been obtained through the South Metropolitan Health Service (RGS3531) with reciprocal approval at Curtin University (HRE2020-0322). Written informed consent will be obtained from all the participants. The project will be conducted in adherence to the Australian National Health and Medical Research Council National Statement for Ethical Research. The current protocol version is V.3.1 dated 4 April 2022. Major modifications during the trial will require a formal amendment to the protocol. Results will be disseminated via peer-reviewed publications and conference presentations.

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