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Primary care-based integrated disease management for heart failure: a study protocol for a cluster randomised controlled trial

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ABSTRACT

Introduction Heart failure (HF) is a common chronic disease that increases in prevalence with age. It is associated with high hospitalisation rates, poor quality of life and high mortality. Management is complex with most interactions occurring in primary care. Disease management programmes implemented during or after an HF hospitalisation have been shown to reduce hospitalisation and mortality rates. Evidence for integrated disease management (IDM) serving the primary care HF population has been investigated but is less conclusive. The aim of this study is to evaluate the efficacy of IDM, focused on, optimising medication, self-management and structured follow-up, in a high-risk primary care HF population.

Methods and analysis 100 family physician clusters will be recruited in this Canadian primary care multicentre cluster randomised controlled trial. Physicians will be randomised to IDM or to care as usual. The IDM programme under evaluation will include case management, medication management, education, and skills training delivered collaboratively by the family physician and a trained HF educator. The primary outcome will measure the combined rate (events/patient-years) of all-cause hospitalisations, emergency department visits and mortality over a 12-month follow-up. Secondary outcomes include other health service utilisation, quality of life, knowledge assessments and acute HF episodes. Two to three HF patients will be recruited per physician cluster to give a total sample size of 280. The study has 90% power to detect a 35% reduction in the primary outcome. The difference in primary outcome between IDM and usual care will be modelled using a negative binomial regression model adjusted for baseline, clustering and for individuals experiencing multiple events.

Ethics and dissemination The study has obtained approval from the Research Ethics Board at the University of Western Ontario, London, Canada (ID 114089). Findings will be disseminated through local reports, presentations and peer-reviewed publications.

Trial registration number NCT04066907.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Embedding community-initiated integrated disease management in primary care practices across Ontario, Canada will improve access to integrated disease management and provide an upstream approach to heart failure (HF) management.
⇒ The proposed intervention uses a portable agnostic electronic point of service tool with embedded national and international HF management guidelines to guide the patient encounter in support of standardised programme delivery across sites and programme fidelity on future programme spread and scale.
⇒ This study selects for high-risk individuals with recent urgent health services use who we hypothesise will benefit most from integrated disease management, therefore, maximal impacts of the programme can be identified.
⇒ Selecting a composite primary outcome including, all-cause emergency department visits, hospitalisations and mortality will maximise study power and minimise measurement bias.
⇒ Whereas the generalisability of integrated disease management can be limited, we have mitigated this limitation by defining the intervention, aligning programme standards with international HF guidelines, and supporting future spread and scale nationally or internationally by employing a portable agnostic electronic point of service system tool.

INTRODUCTION

Over 70% of global mortality is attributable to non-communicable diseases, including 17.9 million deaths from cardiovascular disease anually.[1 2] Heart failure (HF), a common consequence of cardiovascular disease, is a complex and progressive clinical syndrome.[3] People with HF often experience poor exercise tolerance and a reduction in quality of life (QoL) and survival, with 40% dying within 4 years of diagnosis.[3–5] In developed countries, HF is a leading cause of hospitalisation and other health service utilisation (HSU) with substantial and increasing financial implications. Annual costs for Canadians

admitted to hospital due to an HF diagnosis are projected to increase to US$720 million by 2030.[6]

Advances in medical treatment promise to increase HF survival and improve QoL, however, access to guideline based best practices remains limited.[4 5 7] One explanatory factor contributing to this limited access is that most healthcare interactions occur in primary care with HF treatment managed predominantly by the patient's family physician. However, HF management is complex, involving medical, psychosocial and behavioural factors.[5 8] HF populations tend to be older, symptomatic and often lack social and financial support.[9 10] Approximately, 65% of people over 65 years have more than one chronic condition and individuals with HF have a substantially higher number of comorbidities and associated polypharmacy than comparable individuals without HF.[5 11] Adherence to medication is low, between 50% and 60%, and prescribed doses are often suboptimal, consequentially worsening symptoms, increasing the risk of hospitalisation and other HSU, and impairing QoL.[9 12–14] Given these complexities, an enhanced primary care management strategy is required that can meet guideline best practices, substantiating a move towards an integrated disease management (IDM) approach.

IDM has been defined as a systematic delivery of care, integrated through interdisciplinarity using education and self-management strategies to promote guideline concordant best practice.[15] HF-IDM programmes include education, regular follow-up monitoring, pharmacological optimisation and development of management strategies that connect across levels of care.[4 8 10 14 16 17] HF disease management interventions that include varying components of IDM have been most extensively evaluated when initiated during or immediately post an HF-related hospital admission. Meta-analyses have shown that post-acute, hospital associated, specialist-led, HF management programmes are effective at reducing all cause and HF-related, mortality and hospitalisation rates.[4 8 18 19]

This reactive approach to care is limited, in that hospitalisation is a prerequisite to initiate IDM programme services. A further limitation is that not all patients with HF who may benefit from IDM are able to access specialist care. Of over 200 000 patients admitted to hospital with HF, in Canada, only 17% had a cardiologist as the primary physician responsible for care.[20] There are over 700 000 individuals with HF in Canada, who are being cared for in health systems with intensified demands on primary care, arguably too many individuals for physician-based management alone.[21] The evaluation of proactive programmes in primary care that improve access to IDM care is a priority.

More recently, randomised controlled trials (RCTs) investigating a proactive upstream approach to HF-IDM initiated in primary care have not confirmed a reduction of HSU, although, some studies have observed an improved QoL.[22–26] A large, comprehensive RCT in Israel, enrolled 1360 patients and captured 3421 patient years of follow-up, comparing HF-IDM initiated in primary care to usual care.[27] Despite this large sample size, the investigators did not find a difference in the composite endpoint of time to first HF hospitalisation or all-cause mortality. The secondary outcome analysis, however, demonstrated a notable difference in HF hospitalisations in a subset of participants (38%) who had recently (within 2 months) been discharged from the hospital (HR 0.74 95% CI 0.58 to 0.94).[27] Agvall *et al* (2013) conducted a smaller trial involving 160 patients recruited from primary care demonstrated a positive impact of HF-IDM, measured by a broad composite outcome of HSU, QoL and physiological markers.[28]

Whereas there is strong evidence that IDM is effective as a transitional post-hospitalisation management strategy; it appears these findings are not yet generalisable to the primary care setting, this study aims to evaluate the effectiveness of an IDM programme initiated in a Canadian primary care HF population. We hypothesise that this HF-specific IDM will be superior to usual physician-based care measured by a rate reduction in the composite measure of all-cause hospitalisations, emergency department (ED) visits and mortality events per patient year of follow-up.

METHODS

Study design

A 1-year multicentre cluster randomised trial will compare the efficacy of the Best Care IDM programme to usual care in a primary care HF population. The study cohort will be identified from patients attending one of ten family health teams (FHTs) or family health organisations (FHOs) in Southwestern Ontario. Presently, HF in this population is managed by family physicians with access to a cardiologist or internist on a referral basis. A cluster is defined as a primary care physician's practice, patients rostered under their care. Thus, a family physician will only be responsible for HF management of participants in either the control group or the intervention arm, but not both. Clustering by organisation or by site required a sample size that was outside of available study resources. Stratified randomisation of family physician clusters will be performed by FHT/FHO, giving greater balance between arms and reduced between cluster variability.

Patient and public involvement

A focus group was held to elicit a patient perspective on the proposed IDM programme, questionnaires and other outcome measurements, and time commitments. All attendees (n=5) were either diagnosed with HF (n=4) or a caregiver to someone diagnosed with HF (n=1). Response to the programme and the time commitment proposed was positive. There was strong group consensus that one of the largest barriers within the current health system was the coordination and communication between and within different levels of care. Case management, a key component of IDM, is designed to address this patient and care-giver concern.

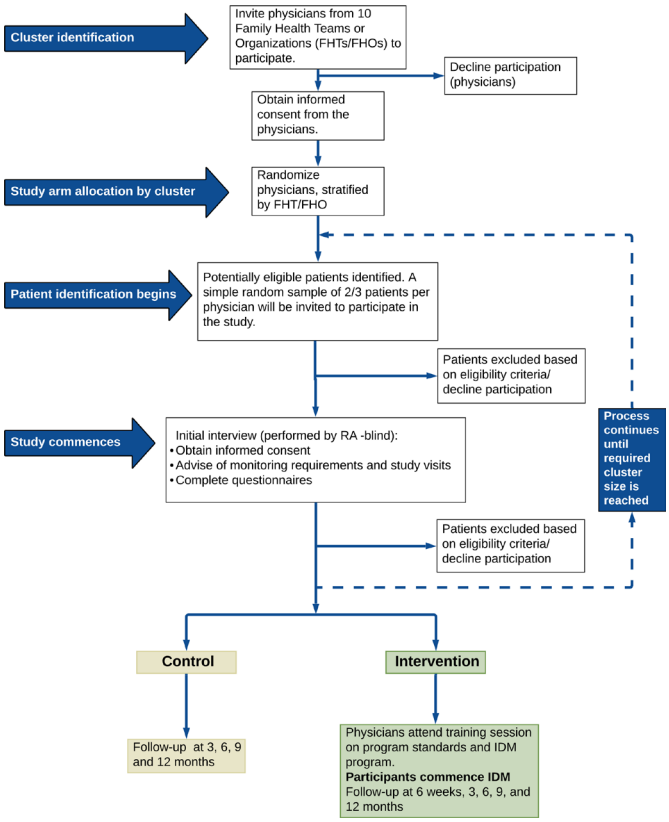

Figure 1 Study flow for cluster and patient recruitment, and cluster randomisation. FHO, Family Health organisation; FHT, Family Health Team; IDM, Integrated Disease Management; RA, research assitant.

Recruitment and randomisation

Family physicians from the participating FHT/FHOs will be invited to participate, and informed consent will be obtained. In Ontario, primary care clinics receive automated electronic hospital discharge summaries On receipt, these records are matched to the patient's primary care electronic medical record (EMR). Primary care providers will perform standardised searches of the primary care EMR to identify patients of participating physicians with an HF or cardiovascular-related hospital admission or ED visit in the prior 2 years. The search strategy has been developed with assistance from the Quality Improvement Decision Support Specialists in primary care using diagnostic and billing codes, and discharge summaries. Patients identified through this search will be assessed for trial eligibility from their medical records and invited to participate in the study. Once all participating physicians from a FHT/FHO have been consented, random assignment of group will be computer generated using Stata V.16.1 by the study team epidemiologist. FHT/FHO strata will be balanced by number of patients identified per physician with an arm allocation ratio of 1:1. Patients can continue to enter the study over the study period until the desired cluster size is reached (figure 1).

Eligible patients who wish to participate in the study will receive a study document package that includes a consent form and study questionnaires. Following the receipt of this package an initial telephone contact will be made to discuss study details, obtain informed consent, and complete questionnaires. Telephone visits will be performed by a single research assistant (RA) blinded to group allocation of the patient. Questionnaires will be completed by the consented participants in paper format. At this stage, participants will also be unaware of their group allocation (designated through the random assignment of their family physician). Participants may be excluded or decline participation during the initial interview; therefore, this process may need to be repeated until the predetermined cluster size is reached. Following this visit, participants assigned to the intervention arm will enter the IDM programme. Any patient undergoing cardiologist management or treatment will continue as scheduled. See online supplemental file 1 for the patient informed consent document.

Eligibility criteria

Inclusion

Patients ≥18 years, New York Heart Association (NYHA) classification of stage II, III or IV, with a clinical diagnosis of HF and a supporting diagnostic echocardiogram (HF with a preserved (>45%) or reduced (≤45%) ejection fraction), and an HF or cardiovascular-related hospitalisation and/or ED visit in the 24 months prior to recruitment will be eligible for inclusion in this study.

Exclusion

People with haemodynamic instability, awaiting cardiac surgery, an expected survival of <1 year due to terminal illness, a lack of English language skills, a reduced cognitive function that affects the ability to complete the questionnaires, enrolment in other cardiac trials, formalised HF education (eg, Telehomecare) in the 6 months prior to enrolment, scheduled for cardiac rehabilitation, and severely impaired renal function requiring dialysis will be excluded.

Intervention

The Best Care Heart Failure clinical programme supports primary care to deliver high-impact, evidence-based best practices in HF with the goal to improve health outcomes. By using team-care, led by a triad of HF educator (HFE), the patient and their primary care practitioner, the programme focuses on the delivery of case management, medication management, skills training and education (table 1). HFEs are regulated healthcare professionals (respiratory therapists or nurses) with educator certification (Canadian Certified Respiratory Educator through Canadian Network for Respiratory Care) who have successfully completed 5 days of internal HF training and at least 4 weeks of mentored practice (with an experienced HFE and cardiologist support). Family physicians randomised to intervention will attend a 2-hour training session by a cardiologist covering programme standards and details of IDM.

Table 1 The components of integrated disease management for heart failure

Components of integrated disease management	Team member
Case management	
Detailed history of HF; NYHA stage	Physician/HFE
Detailed history of other comorbidities	Physician/HFE
Immunisation	Physician/HFE
Standardised implementation of programme guidelines using an electronic POSS	Physician/HFE
Action plan development	Physician/ HFE
Communication of management to cardiologist	Physician/HFE
Referral to cardiologist as required	Physician
Advanced care/end-of-life planning	Physician/HFE
Medication management	
Medication review	Physician/HFE
Medication optimisation (titrated to optimal level)	Physician/HFE
Educational topics	
Understanding the meaning of an HF diagnosis	HFE
Basic HF pathophysiology	HFE
Pharmacotherapy in HF	HFE
Nutrition counselling	HFE
Fluid restriction	HFE
Exercise	HFE
Weight management	HFE
Smoking cessation counselling	HFE
Skills training	
Action plan for use during acute episode; management with diuretics	HFE
Acute episode diary	HFE
Weight diary	HFE
Symptom monitoring	HFE
Medication adherence	HFE

HF, heart failure; HFE, heart failure educator; NYHA, New York Heart Association; POSS, point of service system.

At the first IDM appointment the HFE will meet with participants at their primary care provider clinic to obtain a detailed history of their HF, baseline clinical and demographic information and provide education, self-care management strategies (medication adherence, symptoms monitoring, dietary adherence, fluid restriction, exercise, weight management, smoking cessation), an immunisation review, and a medication review. If medication is not optimal (as per current guidelines), up-titration of the appropriate medications will be commenced, with frequent follow-up to monitor changes. It is anticipated that all medications will be optimised for all participants (as tolerated) within 6 months. A self-management action plan will be developed with the HFE and family physician to enable the patient to monitor and manage their HF. Cardiologist and specialised care will continue as usual with open communication channels between the specialist and IDM team. Referrals to social worker, dietitian or other specialists will be made where appropriate.

A key component of IDM is a portable agnostic electronic point of service system (POSS). This tool has been collaboratively developed and is evidence-based, compliant with international guidelines and programme standards. This POSS provides a framework for the IDM supporting highly standardised and guideline adherent care for all patients through clinical decision support. The POSS will be used by the HFE during every patient encounter prompting the delivery of current evidence-based practice and pharmacotherapy, recording their delivery and standardising the interventions across sites and between HFEs. It can be easily adapted to accommodate evolving best practices, new medications or alternate performance measures. At the end of each patient encounter the HFE completes a structured medical report and plan of care that is uploaded into the patient's primary care EMR. See online supplemental file 2 for details on the Best Care HF programme background, development, POSS and programme fidelity measures.

Control

Subjects will receive HF care as usually provided by their family physician, as advised, or as needed. Care may be in conjunction with a cardiologist and referrals to specialists and other healthcare professionals will be made when deemed appropriate by the family physician. All contact between the study team and the control participants will be by telephone.

See figure 2 for full details of the study timeline and study-related appointments with approximate time commitments for both the intervention and the control groups.

Baseline data

Baseline data will be collected by the HFE, at the initial IDM visit for the intervention group and by telephone appointment for the control group (figure 2). Demographic and clinical characteristics collected include age, sex, occupation, race, smoking history, HF medical history (including HF classification by ejection fraction: reduced vs preserved), comorbidities, body mass index, prior year HSU for HF (visits to, family doctor, walk-in clinic, urgent care, ED and any hospital admissions), prior year ED visits and hospitalisations for any reason and current medications. Comorbidity data collected will be used to calculate a Charlson Comorbidity Index for each patient. The Charlson Comorbidity Index is a validated prognostic index that quantifies the impact of comorbidities in terms of survival.[29]

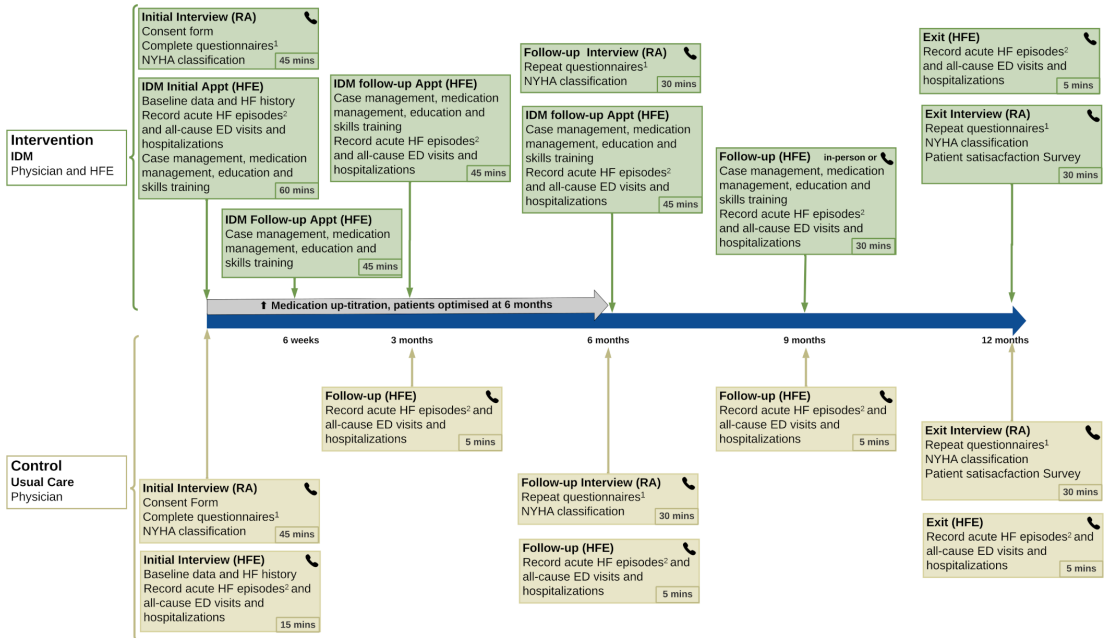

Figure 2 Appointment timeline for intervention and control patient participants. ✆ Appointment conducted by telephone (all other appointments are to be conducted in-person at the patient's primary care provider clinic); [1]Refer to table 2 for list of questionnaires; [2]Acute HF episode is defined as a worsening of symptoms of HF leading to increase in medication (activation of action plan), an unscheduled physician visit, walk-in clinic, urgent care facility, emergency department or hospitalisation; ⬆ Medication will be reviewed and optimized as per guidelines and/or as tolerated (frequent follow-up may be required during this period); ☆All data will be collected by telephone for the control group to minimise contact due to the COVID-19 pandemic. However, all data collected by telephone for the control group and in person for the intervention group will be checked using the patient's primary care electronic medical records. ED, emergency department; HFE, heart failure educator; HF, heart failure; IDM, Integrated Disease Management; NYHA, New York Heart Association; RA, research assistant.

Primary outcome

The primary outcome is a composite of the total number of all-cause, hospitalisations, ED visits and mortality events per patient-year of follow-up. The ED visits are visits that do not lead to hospitalisation. Including all-cause events in the primary outcome will maximise event rate and differential between groups, and eliminate errors associated with ambiguous categorisation of events thereby ensuring all true HF events are captured. By including mortality as an event, we will capture a difference between hospitalisations that end in mortality (two events) and those where the patient recovers and returns home (one event). In addition, mortality events that may not have any preceding ED visit or hospitalisation will be recorded. These outcome data will be self-reported by the patient and validated by the HFE through chart abstraction for both the intervention and the control group. Mortality, hospitalisation and ED visit data will be further validated by linkage to administrative data through the ICES (formerly known as the Institute for Clinical Evaluative Sciences). An ICES data analyst, blinded to group allocation, will use the International Classification of Disease, 10th Revision codes and Ontario Health Insurance Plan billing codes to identify the reason for hospitalisation or ED events. Canada has a universal healthcare system administered provincially. In Ontario, all health services use is captured in a provincial administrative database that is available though the ICES. This outcome data can be collected, with participant consent, even if a patient withdraws from the study.

Secondary outcomes

See table 2 for details of the questionnaires, tools and data collected for each group.

Health Service Utilisation: HF-related hospitalisations, HF-related ED visits, unscheduled physician visits, urgent care facility visits and a decomposition of the primary outcome. These will be self-reported by the participant and validated through chart abstraction and ICES data.

Acute HF Episodes (follows the definition of acute HF30): An acute HF episode will be recorded if the participant experiences any of the following:

- Worsening signs or symptoms of HF leading to an unscheduled physician visit and/or urgent care facility.
- Worsening signs or symptoms of HF leading to a visit to an ED visit.
- Worsening signs or symptoms of HF leading to hospitalisation.
- Worsening signs or symptoms of HF leading to the activation of an action plan

QoL questionnaires: The Kansas City Cardiomyopathy Questionnaire (KCCQ) is a reliable and validated questionnaire for HF that has shown to be sensitive to change, consisting of 23 disease-specific items quantifying physical limitation, symptom burden, symptom frequency,

Table 2 Questionnaires, forms and data collected for control and intervention groups

	Intervention group						Control group				
	Appointment intervals (months)						Appointment intervals (months)				
	Initial	1.5	3	6	9	12	Initial	3	6	9	12
Questionnaires/forms/data											
Consent	X						X				
KCCQ	X			X		X	X		X		X
SF12	X			X		X	X		X		X
EQ-5D-5L	X			X		X	X		X		X
Mediterranean diet	X			X		X	X		X		X
AHFKQ	X			X		X	X		X		X
NYHA classification	X	X	X	X	X	X	X		X		X
Symptom profile	X	X	X	X	X	X	X		X		X
Medication use	X	X	X	X	X	X	X		X		X
Health service utilisation*	X	X	X	X	X	X	X	X	X	X	X
Acute heart failure episodes	X	X	X	X	X	X	X	X	X	X	X
Patient satisfaction survey						X					

*Unscheduled physician visit, walk-in clinic, urgent care facility, emergency department, hospitalisation.
AHFKQ, Atlanta Heart Failure Knowledge Questionnaire; EQ-5D-5L, European Quality of Life 5-Dimensional 5-Level questionnaire; KCCQ, Kansas City Cardiomyopathy Questionnaire; NYHA, New York Health Association; SF12, Short Form 12 item health survey.

symptom stability, QoL, social limitations and self-efficacy. The KCCQ is scored from 0 to 100 where higher scores indicate better health and a change of 5 points is clinically relevant.[7 31 32]

The 12 item Short Form Health survey (SF-12) is a generic health questionnaire with a physical component summary score and a mental component summary score. Both summary components score from 0 to 100 where 100 corresponds to best health.[33 34]

The European Quality of Life-5 Dimensions-5 Levels (EQ-5D-5L) is a generic health questionnaire for clinical and economic appraisal. It measures five levels of severity, scored 1–5, in five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression where 1 represents best health and 5 the worst. Collectively the EQ-5D-5L is scored from 0 to 1 where a score of 1 corresponds to best health. In addition, respondents rate their overall present health using the EuroQol-visual analogue scale (EQ-VAS) from 0 to 100 with 100 representing the best possible health.[35]

Knowledge questionnaires: The Atlanta Heart Failure Knowledge Questionnaire (AHFKQ) consists of 30 questions and was developed to ascertain knowledge about HF, treatment and self-care.[36]

The Mediterranean Diet is a 14-item questionnaire to assess adhesion to a Mediterranean diet, proven to be beneficial to people with HF.[37]

NYHA: The NYHA is a classification system for the extent of HF. It classifies patients in one of four categories based on limitations during physical activity due to symptoms of HF.[3] There is increasing risk of hospitalisation and mortality with NYHA class.[38] A decrease in category ≥1 at 12 months will be considered clinically significant. The NYHA assessment will be undertaken for all patients by the RA (blinded to group allocation).

Patient Satisfaction Survey: This is a short 11-item locally produced questionnaire that gives the opportunity for participants to evaluate the programme (see online supplemental file 3).

Sample size

Participants recruited will have experienced either a cardiovascular-related hospitalisation or ED visit in the 2 years prior to recruitment. We hypothesise that the greatest impacts from the intervention will be demonstrated in this cohort, therefore, maximising any observed between group differences. Assessing a retrospective 1-year history was considered but was increased to 2 years due to concerns over attaining the required sample size.

We found only one primary care study that combined and analysed ED visits and hospitalisations (as a secondary outcome).[28] Patients receiving intervention experienced 38% fewer events (38 events (n=79)) than patients receiving usual care (62 events (n=81)).[28] Based on this study, and other studies that measured HF hospitalisation events, the sample size has been calculated to detect at least a 35% reduction in event rate between arms.[23 25 27 39–43] Assumptions made in these calculations include a baseline rate of 1.5 events per person year and that each physician will be able to recruit 2–3 participants.

Correlations within clusters in this study may occur; participants may choose their physician, which could influence age, gender and ethnicity of the participants specific to their cluster. Medical treatment and clinical

assessment may differ between physicians, and FHT/FHO may be geographically linked to participant socioeconomic status and other demographic factors. Therefore, sample size has been calculated to account for these correlations by incorporating a value for intraclass correlation coefficient (ICC) of 0.05 into estimations.[44–46]

We aim to recruit 100 physician clusters with 2 to 3 participants per cluster, allowing for 20% attrition powered to detect a 35% rate reduction in the primary outcome (90% power, 5% significance) with a maximum sample population of 280 patient–participants, 140 per arm.

Statistical analysis

Analysis will be on an intention-to-treat basis with two-sided significance of 0.05. Baseline data will be used to characterise the study population to identify any imbalance between arms. Continuous data will be displayed as mean±SD and IQR, and count (percent) for categorical variables.

Primary outcome

Due to over dispersion that occurs in this type of count data, the primary outcome (all-cause ED visits, hospitalisations and mortality event rate) will be analysed using a negative binomial regression model with random effects to account for clustering and for individuals experiencing multiple events.[47] Results comparing the two study arms will be assessed through incidence rate ratios derived from the model. The primary outcome will be investigated for effect modification by type of HF (reduced vs preserved).

Secondary outcomes

Negative binomial regression models, following the same framework outlined for the primary outcome, will be used to compare other HSU outcomes between study arms; HF-related hospitalisations, HF-related ED visits, physician visits, urgent-care facility visits, all-cause hospitalisations and all-cause ED visits. All-cause mortality will also be compared between arms.

Change in health status scores (KCCQ, physical component summary and mental component summary scores of the SF-12, NYHA classification, EQ-5D-5L and EQ-VAS, AHFKQ and the Mediterranean diet questionnaire) will be dichotomously categorised dependent on attainment of a clinically relevant or predetermined improvement and analysed using logistic regression.[48] Reliability will be assessed using a quadrature check and in the event of a failure, a generalising estimating equation model will be fitted. Sensitivity analyses will also be performed modelling change in scores as continuous variables using mixed effects linear regression.

The random effects account for any clustering that may occur by physician and ICC influence will be determined. All models will include additional parameters to account for correlations that may arise from repeated measurements on the same individuals. In addition to the univariable analyses for primary and secondary outcomes, adjusted analyses will be conducted for possible differences in baseline variables (eg, age, gender, Charlson Comorbidity Index, HF classification) balancing number of variables with number of events to ensure model stability.[49] A per-protocol secondary analyses will be performed for all outcomes and for participants completing 6 months of follow-up and for participants completing 12 months of follow-up. Missing HSU data should be minimal as this will be obtained from administrative data.

Trial status

The initial proposed study start date was April 2020, however, the COVID-19 pandemic led to its postponement and subsequent protocol amendment. There will be remote attendance only for control participants and any data with potential for information bias will be collected by a single RA. The RA will be blind to group allocation and this same data will be collected remotely by the same RA for the intervention group to minimise observation bias (figure 2). The first participant was enrolled in May 2021 and the trial is anticipated to run until April 2023.

A second amendment to the protocol received ethics approval in September 2021. The former protocol outlined recruitment of 50 physician clusters with 4–5 patient–participants per cluster and a total sample size of 250 patient–participants. Due to difficulties meeting the desired cluster size of 4–5 patients the approved amendment allows for recruitment of 100 family physician clusters with a lower cluster size of 2–3 patients retaining the same power and precision as the previous protocol (a maximum cluster size of 5 participants will remain for patients enrolled and consented prior to the amendment). In addition, there has been primary care provider interest in the programme and, therefore, recruiting 100 physicians should be feasible. Any future protocol amendments (approved by ethics) will be communicated to all relevant members of the study team and the trial registry will be updated and approved by the study sponsor.

ETHICS AND DISSEMINATION

This study will be conducted in accordance with the principles of the Declaration of Helsinki. Patients and family physician participants may withdraw from the study at any time. We do not anticipate any adverse effects associated with the intervention. On the contrary we expect patients to experience improved HF-related health outcomes as all intervention components adhere to best practice guidelines. However, individuals with HF are often older and multimorbid and so hospitalisations and deaths are expected in this study cohort. The study team will monitor and report any adverse events if they appear to be related to the intervention or trial, as directed by the study sponsor.

Findings from this study will be published in peer-reviewed scientific journals and presented at national and international conferences. The results will be presented

to the stakeholder community through presentations at meetings and performance reports. Data and statistical code will be available on request from the corresponding author.

OTHER CONSIDERATIONS

This study protocol proposes a forward-thinking intervention; a provision of interdisciplinary, standardised, guideline-based components delivered at the primary care level to optimise HF management. The strengths of the study lie with the development of IDM that incorporates a structured electronic clinical decision support, POSS designed in accordance with guideline recommendations. This tool will be critical in standardising the intervention and minimising information bias during data collection. In addition, HFEs with specialised HF-focused training will be central for coordinating collaborative management with other members of the multidisciplinary team.

This relatively small-scale study comes with inevitable study design challenges. Contamination bias is a potential pitfall, as physicians in the intervention group and the control group could belong to the same FHT/FHO and be sited together. Contamination is possible if a study participant has a consultation with a physician who is randomised to a different trial arm. This scenario should only occur out of hours on an urgent care basis. We anticipate contamination to be minimal, as such contact is unlikely to address IDM components, but instead be restricted to acute disease stabilisation. Consented physicians will be asked to avoid trial discussion with physicians in the opposite arm. If any contamination occurs, we expect it to likely bias toward the null. An additional consideration is that physicians in the control arm may be inclined to change their management due to awareness that their patients are being monitored. Again, this change would likely bias toward the null if control physicians alter management to align more closely with the IDM arm.

Due to COVID-19 pandemic concerns, baseline and health service use data will be collected in person for the intervention group and by telephone for the control group. Collection of these data by telephone was considered for all participants, however, this may have impacted intervention integrity as these data are used to inform management. Different modes of data collection could potentially introduce measurement bias, therefore, to minimise this risk all self-reported data collected for both groups will be validated from the primary care EMRs.

Finally, the study population excludes HF patients without recent hospitalisation and/or ED visits, we do not know if these patients could benefit from the programme. We plan to evaluate this population in the future if the programme demonstrates safe and effective outcomes and is subsequently rolled out to the broader HF community.

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Contributors CL, RSM, MFe, MFi, AJH and TT contributed to the design and development of the study protocol. CL, RSM, MFe, MFi, DS and CF contributed to the intervention program content, training and mentorship of the HFE and program standards. AJH, CL and MFe drafted the initial manuscript; all other authors provided critical revisions and approved the final revisions. All authors agreed to be accountable for all aspects of the work.

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