ESC HEART FAILURE
ESC Heart Failure 2020; **7**: 3151–3160
Published online 22 July 2020 in Wiley Online Library (wileyonlinelibrary.com) **DOI:** 10.1002/ehf2.12897

STUDY DESIGN

Rationale and design of a risk-guided strategy for reducing readmissions for acute decompensated heart failure: the Risk-HF study

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Abstract

Aims Heart failure (HF) readmission commonly arises owing to insufficient patient knowledge and failure of recognition of the early stages of recurrent fluid congestion. In previous work, we developed a score to predict short-term hospital readmission and showed that higher-risk patients benefit most from a disease management programme (DMP) that included enhancing knowledge and education by a nurse. We aim to evaluate the effectiveness of a novel, nurse-led HF DMP in selected patients at high risk of short-term hospital readmission, using ultrasound-guided diuretic management and artificial intelligence to enhance HF knowledge in an outpatient setting.

Methods and results Risk-HF is a prospective multisite randomized controlled trial that will allocate 404 patients hospitalized with acute decompensated HF, and ≥33% risk of readmission and/or death at 30 days, into risk-guided nurse intervention (DMP-Plus group) compared with usual care. Intervention elements include (i) fluid management with a handheld ultrasound (HHU) device at point of care; (ii) post-discharge follow-up; (iii) optimal programmed drug titration; (iv) better transition of care; (v) intensive self-care education via an avatar-based 'digital health coach'; and (vi) exercise guidance through the digital coach. Usual care involves standard post-discharge hospital care. The primary outcome is reduced death and/or hospital readmissions at 30 days post-discharge, and secondary outcomes include quality of life, fluid management efficacy, and feasibility and patient engagement. Assuming that our intervention will reduce readmissions and/or deaths by 50%, with a 1:1 ratio of intervention vs. usual care, we plan to randomize 404 patients to show a difference at a statistical power of 80%, using a two-sided alpha of 0.05. We anticipate this recruitment will be achieved by screening 2020 hospitalized HF patients for eligibility. An 8 week pilot programme of our digital health coach in 21 HF patients, age > 75 years, showed overall improvements in quality of life (13 of 21), self-care (12 of 21), and HF knowledge (13 of 21). A pilot of the use of HHU by nurses showed that it was feasible and accurate.

Conclusions The Risk-HF trial will evaluate the effectiveness of a risk-guided intervention to improve HF outcomes and will evaluate the efficacy of trained HF nurses delivering a fluid management protocol that is guided by lung ultrasound with an HHU at point of care.

Keywords Acute decompensated heart failure; Risk management; Hospital readmission; Disease management programmes; Lung ultrasound; Fluid management

Received: 7 March 2020; Revised: 17 June 2020; Accepted: 24 June 2020
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Introduction

The frequency of short-term (30 day) hospital readmission rates remains high in heart failure (HF),[1–3] with these events associated with worse outcomes and greater risk of mortality.[3–5] Fluid congestion is the primary cause of readmissions, which incur health care costs in Australia that exceed $1 billion per annum.[3,6] Disease management programmes (DMPs) that are led by trained nurses and other health care professionals have improved health outcomes in chronic diseases including HF. Differences in 30 day readmission rates for HF in Australia vary from <20% to >30%, with these variations being attributable to differences in the availability and the exact nature of DMPs between centres.[7] Indeed, the cost and heterogeneity of DMPs are potential contributing factors to the failure to prevent short-term readmissions. As the highest risk of readmission is early after discharge, the untimely application of DMPs may also contribute,[2] especially if patients with poor self-care lack engagement with the health care team. The simplest DMP versions, such as those based on telephone follow-up, may be ineffective, especially in high-risk patients.[2,3] In part, this may reflect the role of patient engagement as an important contributor to patient outcome.[8] Therefore, intensity of HF-DMPs should be titrated to risk of readmission.

Rationale of the Risk-HF study

Predictive models identifying high-risk patients may be useful in post-discharge management, as adjusting the intensity of the available DMPs according to the risk of these patients could potentially result in better outcomes. Routinely collected clinical data have recently been used to predict rehospitalization and death; the risk factors associated with these two outcomes can differ considerably.[5] Failure to prescribe beta-blockers on discharge, older age, and high levels of blood urea nitrogen and N-terminal pro-brain natriuretic peptide are associated with mortality, whereas older age, previous HF hospitalization, low systolic blood pressure (BP), presence of oedema, and lower estimated glomerular filtration rate are associated with readmission.[5] Mild cognitive impairment (MCI) and socio-economic factors are very important influences on readmission risk[9] and have been incorporated into a risk algorithm for predicting HF readmission.[7] In a previous study, an extended multidisciplinary intervention 'DMP-Plus' was shown to be effective in high-risk patients who had not had admission for HF in the last 6 months.[7] In this study, we seek to apply this to all patients admitted for HF, combined with ultrasound-guided fluid management and the use of a mobile health app to facilitate self-care.

Methods

Trial overview

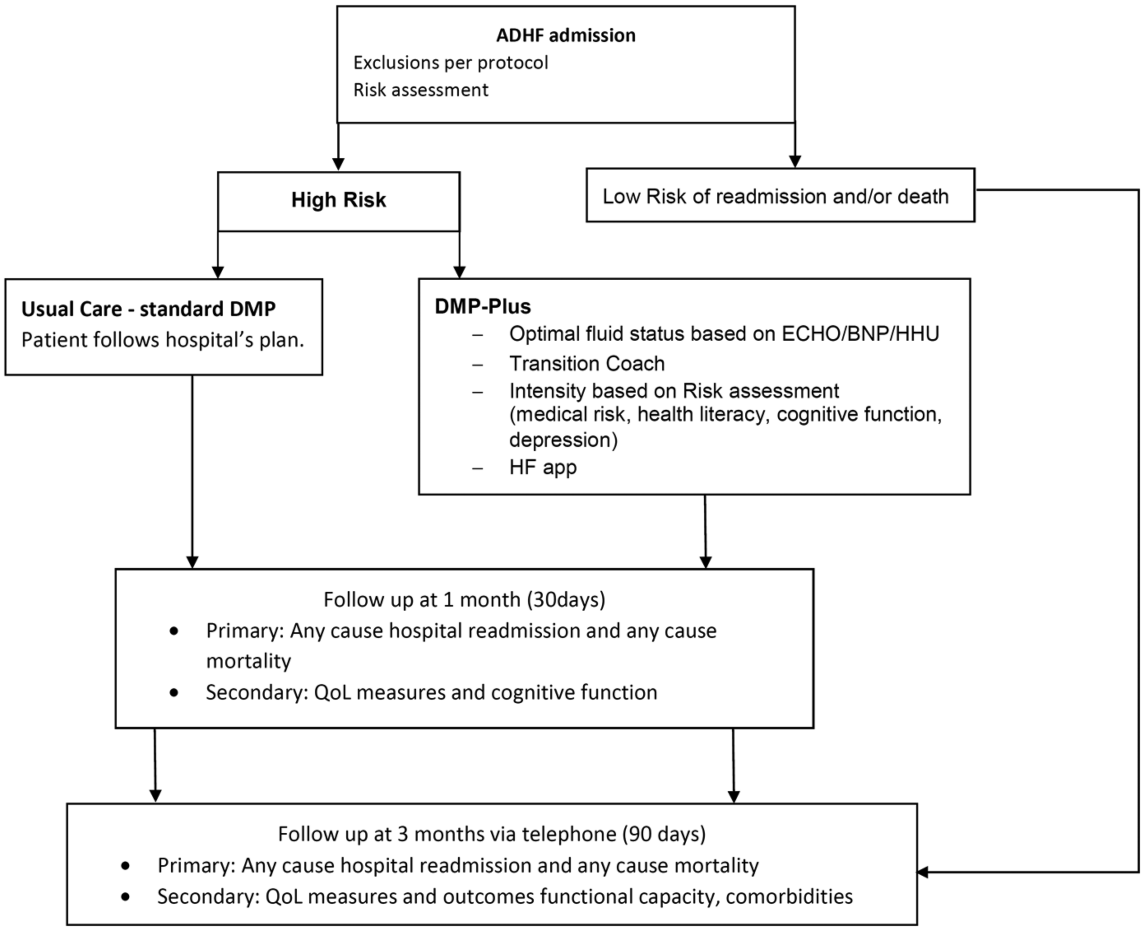
The Risk-HF study is a multisite open, parallel group, randomized controlled trial (RCT) that will evaluate the effectiveness of a DMP-Plus nurse-led programme (intervention arm) vs. usual care (control arm). The planned trial is to improve outcomes in patients admitted with acute decompensated heart failure (ADHF). The trial is registered with the Australia and New Zealand Clinical Trials Registry (ACTRN12618001273279). The study design is shown in *Figure 1*, and the investigation conforms with the principles outlined in the Declaration of Helsinki (*Br Med J* 1964; ii:177). The final study protocol (version 4; October 2019) was approved by the Alfred Hospital Ethics Committee (HREC/18/Alfred/61).

Endpoints

The primary endpoint is hospital readmission and all-cause mortality (HF and non-HF) at 30 days post-discharge. The main secondary endpoint is hospital readmission and all-cause mortality (HF and non-HF) at 90 days post-discharge. All-cause hospital readmission and days alive out of hospital will be recorded for the primary and secondary endpoints. Other secondary endpoints are listed subsequently, and they are assessed pre-discharge and post-discharge.

1 Self-education and self-management. Patient responses pre-education and post-education will be captured by the HF app. Improvements will indicate that patients benefit from the novel education approach.
2 Fluid management guided by nurses. Handheld ultrasound (HHU) of the lungs and inferior vena cava (IVC) assessment will be captured and used to guide diuretic management. The analysis will investigate whether there is an interaction between HHU-guided management and HF readmission and/or death.
3 Quality of life (QoL) measures mood and cognitive assessment. Improvements in scores post-discharge will indicate that patients have better QoL and improved mood and cognition. Association will be sought with other endpoints.
4 Patient engagement. The efficacy of artificial intelligence (AI)-guided education will be assessed based on participant responses within the app (or patient responses in phone follow-up) and interaction with the primary endpoint.

Figure 1 Study design; from screening to endpoint evaluation 90 days post-discharge. ADHF, acute decompensated heart failure; DMP, disease management programme; HF, heart failure; QoL, quality of life.



Hypothesis

Patients at high risk for short-term readmission and/or death (i.e. ≥33% risk) will benefit from selective use of 'DMP-Plus' when the intensity is adjusted for risk and is not uniformly applied to all HF patients.

Study procedures

Screening

Patients admitted to participating hospitals with ADHF confirmed by the treating physicians will be reviewed for study eligibility. On admission, patients will be screened for inclusion/exclusion criteria. Education with AI is optional; hence, patients will not be excluded if they are not capable of using a smartphone or tablet device. In the event a patient has suitable technical skills but does not possess a compatible device, the study will provide the patient with a tablet device that has the AI programme pre-installed. Patients who meet the inclusion/exclusion criteria (*Table* 1) will provide signed informed consent and will be assessed for risk, on the basis of the following parameters: mood, cognitive status, living alone, discharged during winter, biomarkers (urea and albumin levels), life-threatening arrhythmia on admission, heart rate (HR), New York Heart Association (NYHA) class, ultrasound assessment [left atrial volume index (LAVI) and right atrial pressure (RAP)]. These parameters were assessed and validated in our previous work, which showed that they had a particularly important role in readmission and/or death.[7] The cut-off value of predicted risk (33%) represents the median value estimated from an Australia-wide validation in HF patients.[7] For the Risk-HF study, we consider all HF patients with a predicted risk above the median level as high risk. The risk assessment process begins immediately post consent. Social factors (living alone and discharge during winter) will be recorded post consent via oral interview, along with medical background information (arrhythmia on admission) and mood assessments (cognition and depression). Clinical and laboratory parameters (NYHA, urea, and albumin) will

Table 1 Inclusion–exclusion criteria

Inclusion criteria
1. 18 years of age or older
2. Admission with a primary diagnosis of ADHF confirmed by the treating physicians, in accordance with the HF guidelines[1,10]
Exclusion criteria
1. Unable to provide written informed consent to participate in this study
2. Patients who need palliative care
3. Participating in another clinical research trial where randomization to study arms would be unacceptable
4. Patients who live in an aged care facility (e.g. nursing home)
5. Moderate to severe primary mitral or aortic valve disease
6. Concomitant unstable angina, acute myocardial infarction
7. Cardiac device malfunction
8. Endocarditis
9. Patients with left ventricular assist device (LVAD)
10. Patients with asymptomatic left ventricular (LV) dysfunction
11. Potentially reversible LV dysfunction, such as post-partum, alcoholic cardiomyopathy, hyperthyroidism
12. Abuse of substances
13. Concomitant terminal non-cardiac illnesses that could influence 12 month prognosis (e.g. advanced malignancy)
14. Inability to acquire interpretable images (identified from baseline echo)
15. In the investigators' opinion any other condition that may affect the safety of the study for the patient or personnel.

be recorded on discharge day and will consist the most recent value to discharge. The LAVI will be recorded from echocardiography obtained during the hospital admission or up to 6 months prior to the index admission. The RAP will be assessed with portable ultrasound. Subsequently, patients with a score of ≥33% for risk of readmission and/or death will be eligible for randomization, whereas those at ≤32% will be ineligible for randomization and therefore will only be followed up via telephone at 90 days. All randomized patients will be followed up over a period of 90 days post-discharge.

Recruitment will occur for a period of 24 months or until the target sample size is met.

Randomization

High-risk patients will be randomized in a 1:1 ratio of intervention vs. control, using a Prospective Randomized Open Blinded End-point (PROBE) design in block sizes of 6. Randomization will be stratified by HF with reduced ejection fraction (HFrEF) or HF with preserved ejection fraction (HFpEF) and by enrolment site.

Data collection

Measures

Demographic and clinical details (presence of coronary artery disease, cardiac valve dysfunction, history of diabetes and total cholesterol level, type and duration of HF, previous HF hospitalization, length of hospital stay, history of prior alcohol abuse, and past medical history including history of malignancy and history of prior radiotherapy or chemotherapy) will be recorded from hospital medical records. NYHA class will be used for HF severity and the functional capacity as well as a criterion for high risk.[11,12] A physical examination will be performed including BP assessment, HR, respiratory rate, electrocardiogram (ECG) with arrhythmia assessment, and chest X-ray review. All medications will be recorded, including diuretics, anticoagulants, antiarrhythmics, angiotensin-converting enzyme inhibitors, angiotensin receptor blockers, beta-blockers, statins, diabetes treatment, or other drugs known to provoke fluid retention (e.g. non-steroidal anti-inflammatory drugs). All cardiac interventions including pacemaker (type), implantable cardioverter defibrillator, or any surgical procedures will be recorded.

Social and environmental history

Age, sex, language background, country of birth, years living in Australia, marital status, years of education, residential address, financial status, medical insurance, and presence of any home health care services. Geographic location and social and economic status will be evaluated with the remoteness index.

Questionnaires

Cognitive function will be assessed with Montreal Cognitive Assessment (MoCA) tool.[13] A score of 22 to 25 suggests MCI, which despite that it is often unrecognized, is associated with death and hospital readmission within 30 days of discharge for HF.[1,9] MoCA will be administered by accredited personnel on the basis of MoCA criteria.

Depression will be evaluated with Patient Health Questionnaire (PHQ-9) to provide symptom severity, diagnosis, and physical/affective symptoms. The scale has a total score of 27 and scores of 5 or above are indicative of mild (5-9), moderate (10-14), moderate to severe (15-19) or severe (20-27) depression. Patients with abnormal scores of 10 or higher will be referred to the hospital care team to provide further support.[14]

Anxiety will be assessed with Generalized Anxiety Disorder (GAD)-7. The GAD-7 scale has a total score of 21. Scores of 5 or above are considered abnormal and indicative of mild (5-9), moderate (10-14) and severe (15-21) anxiety. Patients with scores of moderate or severe anxiety will be referred to the hospital care team for further support.[15] Prior history of anxiety or depression and subsequent treatment will be recorded and will be accounted for in the analysis.

Self-care behaviours will be measured with the nine-item version of European Heart Failure Self-care Behaviour Scale (EHFScBS-9), a validated tool to measure the self-care behaviours of HF patients.[16] QoL (specific to HF symptoms) will be measured with Kansas City Cardiomyopathy Questionnaire (KCCQ).[17] Knowledge of HF will be assessed using the Dutch Heart Failure Knowledge Scale (DHFKS), which is a 15-item scale.[18] Activity will be assessed with Duke Activity Status

Index.[19] Cleland's patient journey will be used to calculate days alive post-discharge, out of hospital—a composite endpoint of mortality, hospitalization, and well-being.[20]

Biochemistry

Biochemistry markers [blood urea (mmol/L) and albumin (g/dL)] will be recorded from patients' medical records, and patients with elevated markers will meet the biochemistry criterion for high risk.

Cardiac function

Baseline two-dimensional echocardiography will be used to measure left ventricular ejection fraction, LAVI (mL/m^2), RAP (mmHg), pulmonary arterial systolic pressure, and estimated LV filling pressure (E/e'), using standard techniques and procedures.[21] In addition, with the use of a portable echo device, B-lines will be counted from lung ultrasound images performed by imaging in eight chest locations.[22] The presence of >5 B-lines will lead to review of discharge plans.

Functional capacity

Pre-discharge functional capacity assessment will be based on a hand grip strength test, evaluated with a Jamar digital dynamometer.

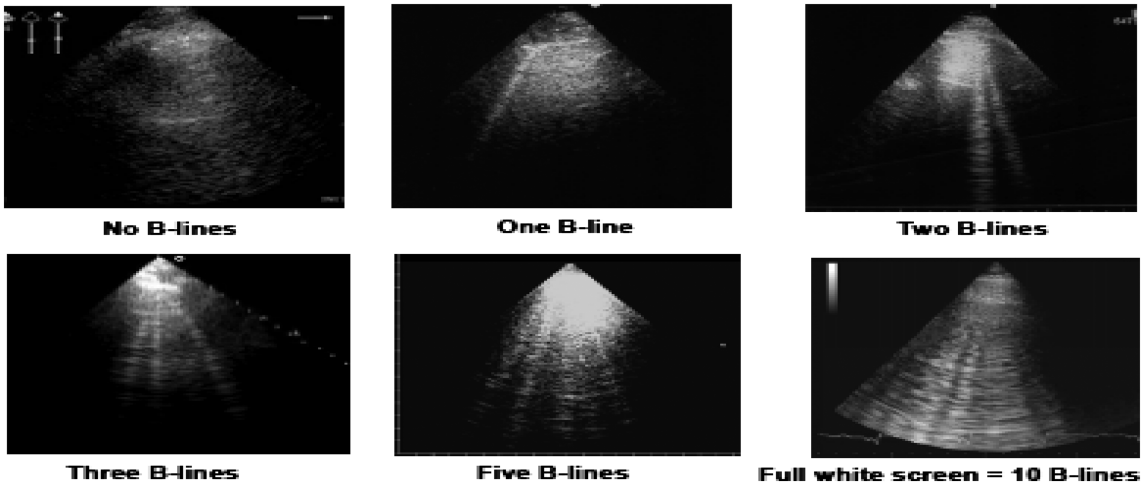
Intervention arm (DMP-Plus)

The DMP-Plus programme will be delivered by an HF nurse working for this study. The nurse will act as a 'transition coach' by visiting the patient in hospital prior to discharge, ensuring appropriate medication reconciliation, ensuring that the patient is as close to euvolaemic as possible, scheduling the follow-up plans, and ensuring appropriate HF education. The study HF nurse will follow up the patient at home twice in the first month and will initiate two phone call follow-ups for assessing the patient's condition. The study HF nurse will ensure protocol adherence, will detect any problems, and will determine if there are any gaps in patient's HF education. There will be an assessment of psychosocial risk factors including mood, cognitive status and social factors (e.g. financial or relationship changes), home surveillance and assessment of functional capacity, fluid status, cardiac rhythm, and nutritional status.

Assessment of volume status will be based on the use of an HHU device (Lumify, Philips, Best, the Netherlands) by trained registered nurses (RNs), who will perform a nine-site LUngs and IVC Assessment (LUICA) pre-discharge. Lung congestion will be determined by the presence of B-lines as shown in *Figure* 2. Five or more B-lines or a 'full white screen' will be an indication of ongoing congestion, such that the patient is potentially not ready for discharge. The treating physicians will be notified to reconcile discharge plans and titrate optimal fluid treatment on discharge. The RNs were trained prior to assessing patients for the Risk-HF study by an accredited and experienced intensivist. This training included reading of study materials[23,24] and hands-on practice that involved the assessment of 30 cases with a variety of lung conditions, in the ICU and cardiac wards. Images obtained were reviewed by the expert, as well as feasibility scans, to ensure accuracy and validity. Training images were compared with a traditional ultrasound device and non-significant differences observed. On training completion, our nurses were able to adequately scan patients and differentiate diagnoses. Subsequently, following completion of 30 scans and completion of reading materials, our RNs enrolled to a lung ultrasound course provided by the University of Melbourne.

Findings obtained from our patients will be shared with the treating physician to guide fluid treatment in hospital and post-discharge, including guiding diuretic management. Other lung abnormalities such as pleural effusion will be

Figure 2 LUS assessment. LUS, lung ultrasound.



discussed with the treating physician. The IVC will be evaluated post-discharge to determine the estimated RAP in accordance with guidelines.[25] Abnormal levels will be considered when RAP is 8 mmHg or above, and results will be given to treating physicians to optimize fluid and diuretic management.

During the follow-up phase, patients will be subject to the LUICA. Changes in volume status will be discussed with the treating team to guide optimal diuretic treatment. Volume status will be evaluated from a combination of the patients' clinical findings (jugular venous pressure, swelling of the abdomen or ankles, and weight increase) in association with our LUICA. An increased total number of B-lines in two locations on the same side with or without weight gained or ankles/abdomen swelling will be considered as worsening of HF. Similarly, the presence of 5 or more B-lines (*Figure* 2), on one or more scanned spots, will be an indication of early lung congestion. The HF RN will liaise with the treating physician or study principal investigator to increase diuretic treatment accordingly. In case of 'full white screen' or innumerable B-lines, a short admission to rapid access outpatient clinics (if available), or referral to the local general practitioner, will facilitate access to intravenous diuretics.

Elevation of IVC diameter and subsequent elevations of estimated RAP will also be an indication of early congestion. The same procedures will be followed to guide optimal fluid treatment.

All scans obtained will be reviewed on the same day by an independent sonographer or trained personnel. To date, this will be the first multisite RCT of guided fluid management in an outpatient setting during home visits, among high-risk HF patients, led by trained nurses. Recently, results from a single-centre randomized control study showed that patients had better outcomes when fluid treatment optimized prior to discharge and receiving intravenous diuretics during follow-ups in an outpatient HF clinic.[26]

An unscheduled visit by our study personnel will be arranged if an unplanned hospital admission occurs in all randomized patients.

Medical therapy

All HF therapy is at the discretion of the treating physician. Standard medical therapy[1,10] will be administered; but in the DMP-Plus arm, the standard will be pre-planned uptitration (*Table* S1), with revision if monitoring (symptoms, BP, side effects, and adherence) indicates a need to change.

Results of the heart failure app pilot study

The DMP-Plus will involve education and monitoring delivered by our HF app (*Figure* 3), supported by mobile devices. It has undergone reliability testing and can be understood by persons as young as 10 to 16 years. The authors disclose no commercial interest in the app. Success in this training programme will lead to a novel educational approach in HF patients and could potentially be a new engagement strategy. The HF app is a digital training health coach, specifically developed for HF patients, aiming to deliver and build self-management skills and engagement with the patients, so that they can improve their self-care and avoid re-hospitalizations. In addition to educational information as defined by national guidelines,[6] the digital coach HF app delivers goal setting, homework tasks, self-monitoring, and questionnaires for HF to allow patient progress and outcomes to be measured (*Table* 2). Patients engage daily with the app over a 52 day programme. It reminds them to weigh themselves daily and record the result, with recommendations to notify their nurse or doctor if $\geq$2 kg is gained within 2 days. The programme duration takes 10 sessions to complete over ~8 weeks. Our feasibility study in 21 patients aged 75 and over, hospitalized with HF, showed that participants had better results at the completion of the programme. Specifically, 13 showed improved health-related QoL, 12 better self-care behaviours, and 13 improved HF-specific knowledge (*Figure* S1A–C).

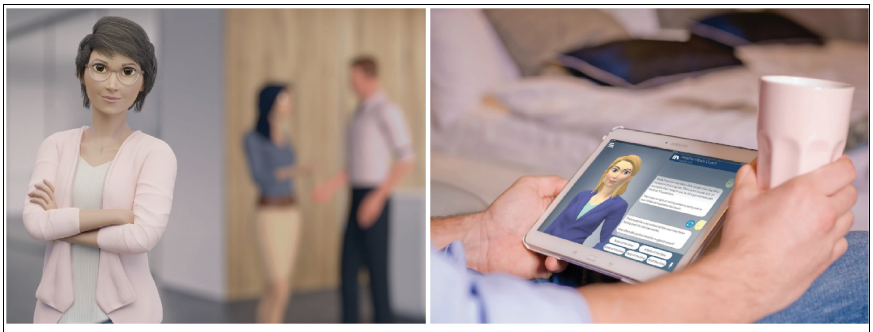
Detailed verbal instructions will be given to the patient by the study cardiac nurse to help the patients set up their account. The HF app collects and stores information (*Table* 2) about patients' psychological status, mood, and QoL related to having HF as well as HF self-care behaviours, via responses provided by questionnaires and daily weight monitoring.

The app frequently reviews patients' performance and re-administers the questionnaires at the end of the 52 day period. This approach will provide strong evidence about the everyday needs and feelings of high-risk HF patients and will show whether these patients can benefit from an HF-specific self-education digital programme. It will help the care teams to develop new engagement strategies with the HF patients. We anticipate that all patients randomized on this group will utilize the HF app. However, if a patient is not capable of using a smartphone or a tablet device, they will still be able to participate on the study, and education similar to what the HF app delivers will be given via oral interview. App usage will be reviewed and accounted for in statistical analyses; therefore, we did not stratify our randomization model to account for HF app users.

Usual care arm (control)

The routine hospital and post-hospital plan will be delivered in the control arm. Control patients will be only followed up via telephone at 30 and 90 days post-discharge. They will then be discharged from the study. Approved questionnaires will be administered over the phone. In the event that a

Figure 3 Avatar-based HF app. The digital coach (left) provides training that prompts appropriate self-care. The HF app can be delivered on tablet devices (right) and includes interactive components that permit daily evaluation. HF, heart failure.



Avatar-based HF-app. The digital coach (left) provides training that prompts appropriate self-care. The HF-app can be delivered on tablet devices (right), and includes interactive components that permit daily evaluation.

patient from the control arm requires hospital admission, they will be followed up in hospital, and reasons for hospital readmission will be recorded.

Medical therapy will follow standard guidelines.[1,10] A titration schedule will be applied to patients with HFrEF.

Follow-up

All randomized patients during the follow-up period will be subject to a follow-up schedule that involves home visits and phone call assessments. Follow-up measures are outlined in *Table* 3.

Adverse events and serious adverse events

All adverse events (AEs) and serious AEs (SAEs) will be recorded. Safety evaluations will be performed by recording AEs and SAEs and by monitoring laboratory parameters, physical examinations, ECGs, and vital signs. Events that will be recorded as AEs and/or SAEs will include sudden death (any cause), death resulting from a cardiac cause, acute pulmonary oedema, worsening/recurrence of HF requiring hospitalization, life-threatening arrhythmias requiring treatment, conduction disturbances requiring a permanent pacemaker implantation, and any cause (HF and non-HF) of hospitalization that required an overnight stay. Events will be reviewed every week for the follow-up period.

Statistical analysis

The analyses will be performed using standard software (STATA, StataCorp, College Station, TX). Analysis will be based upon intention to treat. Time-to-event analyses (Cox proportional hazards to model mortality or competing risk regressions to model readmission) will be used to investigate study outcomes. The 30 day readmission rates in each arm will be compared using a χ^2 test; and QoL, mood, HF knowledge, self-care, and cognition, using the pre-intervention and post-intervention scores of the KCCQ, GAD-7 and PHQ-9, DHFKS, EHFScBS, and MoCA respectively, will be compared with a *t*-test and Mann–Whitney test. Survival analysis will be used to compare admissions and other events over 30 days. The effect size of the guided-DMP arm will be investigated using Cox models for readmissions and survival. QoL measures over time will be analysed using the generalized estimating equation approach. The use of the HF app will be reviewed, and its association with outcomes will be addressed.

Sample size calculation

The readmission rate in Australia following index admission for ADHF is ~25%.[3] Application of the DMP-Plus is assumed to reduce admission by 50%.[27] Using a two-sided alpha of 0.05 and statistical power of 0.8, with a 1:1 ratio of intervention to control arms, this study would need 168 patients in

Table 2 Heart failure app key features

1. Self-reported questionnaires. Questionnaires administered at the start and end of the programme are the EHFScBS, the KCCQ, and the DHFKS
2. Education for HF (causes, symptoms, common treatments, fluid management, weight management, and healthy lifestyle advice)
3. Tailored management (medication adherence, weight management, and physical activity)
4. To-do ('homework') tasks (weight measurement and oedema)
5. Goal-setting assignments (doing enjoyable activities, eating less salt, and daily walks)

Table 3 Timetable

Study procedures	Screening/ baseline	Home visit 1 (Day 14)	30 day outcome visit	90 day outcome visit	Early discontinuation	Unscheduled readmission[a]
Informed consent	X					
Risk assessment	X	X	X			X
MOCA	X		X	X		X
Demographics	X					
Medical history and risk factors	X	X	X			X
Co-morbidities	X	X	X	X	x	X
Biomarkers	X	X[b]	X[b]		X[b]	X
Physical exam	X	X	X	X		X
12 lead EKG	X					X
Hand grip	X	X	X			X
Questionnaires	X	X	X	X	x	X
Echocardiogram—handheld echo-LUICA	X	X	X		X	X
Vital signs (BP, HR, and RR)	X	X	X	X	X	X
Medications	X	X	X	X	X	X
AE/SAE assessment	X	X	X	X	X	X
Heart failure assessment (fluid status–HF signs symptoms–gaps in HF knowledge)	X	X	X	X	X	X
Medication compliance	X	X	X	X	X	X

BP, blood pressure; ECG, electrocardiogram; HR, heart rate; MOCA, Montreal Cognitive Assessment; RR, respiratory rate.
[a]If occurs.
[b]If available at local clinics.

each arm. Accounting for a probable attrition of 20%, this RCT would need 202 patients in each arm, or altogether 404 patients. Approximately 40% of all patients admitted for ADHF are at >60% risk of hospital readmission,[27] and it is anticipated that 50% of these will agree to participate. Therefore, this study needs to screen 2020 patients for eligibility.

Discussion

The Risk-HF study is based on proven DMPs[27] and risk models.[7] The novel features of the study are (i) evaluation of a risk-guided DMP at multiple sites, (ii) use of an HHU device for home visits and the assessment and guidance of fluid status by LUICA, and (iii) use of an AI-based training programme to provide HF education and patient engagement.

The research-specific outcomes arising from this project will help define the optimal ways to invest scarce community resources for the management of patients with HF. The findings will improve hospital and primary care integration in the management of this condition, to identify early signs of deterioration and congestion, keep patients safe at home, reduce hospitalizations, and improve health outcomes and reduce health expenditure. This study will present engagement strategies that might help professionals to be involved in treating HF to build a strong rapport with HF patients. Finally, the integration of hospital and community services partnership approach used in this trial may inform similar approaches in other chronic diseases including chronic lung disease and diabetes.

Conclusion

Fluid congestion is a common cause of HF readmission, and efforts should focus to predict and detect crises at early stages. Lack of patient engagement with the treating team, poor self-care management, and non-adherence to fluid restrictions and/or medical treatment are common causes that lead to poor outcomes. To date, this is the first study that will evaluate the efficacy of guided diuretic treatment by trained nurses, post-index admission for ADHF, and by using an HHU device at point of care in inpatient and outpatient settings. The Risk-HF study will validate the Ethelred risk algorithm in a multicentre RCT and will provide evidence of efficacy of these novel approaches in fluid management, HF education, and targeting high-risk patients on the basis of routinely collected clinical and social data.

Conflict of interest

Georgios Zisis, Quan Huynh, Yang Yang, Christopher Neil, Jocasta Ball, Melinda J. Carrington, Graeme Maguire, and Thomas H. Marwick have no conflicts of interest regarding this work.

Funding

This study is supported in part by a 'Keeping Australians out of Hospital' grant from the Medical Research Future Fund (1176629), Canberra, Australia, and a National Health and

Medical Research Council (NHMRC) Partnership grant (1059738), Canberra, Australia. Q.H. is supported by Early Career Fellowships, National Heart Foundation of Australia (NHFA), National Heart Foundation, Melbourne, Australia. J. B. is supported by an NHMRC/NHFA Early Career Fellowships (1112829). M.J.C. is supported by a NHFA Future Leaders Fellowships (100802).

Supporting information

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Figure S1. HF-app pilot study results. Participants responses in EHFScB, KCCQ, DHFKS questionnaires.
Table S1. Dose and mode of medications administration

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