A facilitated home-based cardiac rehabilitation intervention for people with heart failure and their caregivers: a research programme including the REACH-HF RCT

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Scientific summary

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Scientific summary

Background

In the UK, nearly 1 million people live with heart failure, costing the NHS over £2.3B per year. Heart failure has two main phenotypes: heart failure with reduced ejection fraction is characterised by depressed left ventricular systolic function ('reduced ejection fraction'), whereas heart failure with preserved ejection fraction is diagnosed after excluding other causes of dyspnoea with normal ejection fraction. Although evidence-based therapies for heart failure with reduced ejection fraction result in improved life expectancy and quality of life, evidence-based treatments for heart failure with preserved ejection fraction are lacking.

A 2014 Cochrane review found improvements in quality of life and reduced hospital admissions in people with heart failure with reduced ejection fraction who participated in exercise-based cardiac rehabilitation compared with those who received usual care alone. Cardiac rehabilitation comprises three key elements: exercise to rebuild physical capacity, psychological support and support for key self-care behaviours. In 2010, the National Institute for Health and Care Excellence recommended centre/group exercise-based cardiac rehabilitation for those with heart failure with reduced ejection fraction and heart failure with preserved ejection fraction. However, referral to and uptake of cardiac rehabilitation for people with heart failure remain suboptimal. Uptake improves when patients have a choice of centre- or home-based cardiac rehabilitation after myocardial infarction or revascularisation, and updated National Institute for Health and Care Excellence guidance in 2018 recommended offering home-based cardiac rehabilitation for patients with heart failure. The Rehabilitation Enablement in Chronic Heart Failure (REACH-HF) investigators therefore evaluated a facilitated, home-delivered, self-care cardiac rehabilitation intervention for patients with heart failure and their caregivers.

Aims and intended outputs

The overarching aim of the REACH-HF programme was to increase the evidence that cardiac rehabilitation for heart failure can enhance current low uptake and inform future service commissioning.

We aimed to answer the following research questions:

1. What are the necessary intervention components of a home-based, self-care manual for patients with heart failure (1A) and for their caregivers (1B)?
2. How feasible is the REACH-HF intervention in patients with heart failure with preserved ejection fraction?
3. What is the clinical effectiveness and cost-effectiveness of the REACH-HF intervention compared with usual care in patients with heart failure with reduced ejection fraction? What is the impact for caregivers of using the intervention compared with usual care?
4. What is the long-term cost-effectiveness of the REACH-HF intervention, other home-based cardiac rehabilitation and centre-based cardiac rehabilitation compared with usual care and home-based cardiac rehabilitation in patients with heart failure with reduced ejection fraction?

To answer these questions, we:

1. developed a novel, evidence-informed, facilitated, self-care home-based cardiac rehabilitation intervention (the REACH-HF intervention) for people with heart failure and their caregivers and undertook an uncontrolled feasibility study in patients in heart failure with reduced ejection fraction (work package 1)
2. conducted a single-centre pilot, randomised controlled trial of the intervention to determine the feasibility of a full trial of its clinical effectiveness and cost-effectiveness in addition to usual care in patients with heart failure with preserved ejection fraction (work package 2)
3. undertook a multicentre randomised controlled trial and process evaluation to determine the clinical effectiveness and cost-effectiveness of the intervention in addition to usual care in patients with heart failure with reduced ejection fraction and their caregivers (work package 3)
4. used evidence synthesis and modelling methods to collate evidence on home- and centre-based cardiac rehabilitation and assess the longer-term cost-effectiveness of the REACH-HF intervention, other home-based cardiac rehabilitation and centre-based cardiac rehabilitation versus usual care in patients with heart failure with reduced ejection fraction (work package 4).

Results

Work package 1: development of an evidence-informed, home-based, self-care cardiac rehabilitation programme for people with heart failure and their caregivers (REACH-HF)

Methods

We used the intervention mapping framework to develop a home-based, self-care manual for patients with heart failure with reduced ejection fraction ('the REACH-HF intervention') and their caregivers. We used formal and informal literature reviewing, individual qualitative interviews, focus groups and workshops with various stakeholders (patients, caregivers, service providers and experts in the field) to develop a model of targets for change and intended processes of change (a logic model). We identified and 'mapped' change techniques to each intended process of change and strategically organised the intervention components.

Key findings

We created the REACH-HF intervention: a comprehensive, theory-based, user-centred, home-based, self-care support programme for people with heart failure and their caregivers, which includes three core printed components – the REACH-HF Manual, a participant 'Progress Tracker' booklet and a 'Family and Friends Resource' for caregivers – as well as a facilitators' training course. The intervention was tested in a feasibility study in patients with heart failure with reduced ejection fraction. Attendance was high: all patients attended three or more face-to-face sessions and typically received four telephone contacts.

Once the identified modifications to the manual and facilitator training were incorporated, the revised intervention was used in both randomised controlled trials, in which it was well accepted by patients, caregivers and health-care professional facilitators.

Work package 2: single-centre, pilot randomised controlled trial to assess the feasibility of a definitive trial of the clinical effectiveness of the REACH-HF intervention in addition to usual care in patients with heart failure with preserved ejection fraction

Methods

We undertook a pilot randomised controlled trial and process evaluation in a centre in Dundee with a specialist interest in caring for patients with heart failure with preserved ejection fraction. The trial recruited 50 participants and their caregivers from outpatient clinics and a Scottish register/database; 25 participants were randomly allocated to receive a modified form of the REACH-HF intervention

that included information relevant for patients with heart failure with preserved ejection fraction in addition to usual medical management for heart failure, and 25 were randomly allocated to usual care alone. Patient outcomes, including health-related quality of life (primary) and psychological well-being, exercise capacity, physical activity, heart failure-related hospitalisation and costs (secondary), were collected by blinded assessors at baseline and 3 and 6 months post randomisation. Outcomes were also collected for caregivers. A mixed-methods process evaluation was undertaken in parallel with quantitative assessment of intervention fidelity and qualitative exploration of heart failure with preserved ejection fraction patients' and caregivers' experiences. Data included audio-recorded intervention sessions, demographic information, intervention fidelity scores and qualitative interviews following completion of the intervention in a purposeful sample of 15 patients with heart failure with preserved ejection fraction and seven caregivers.

Key findings

The study recruited 50 participants with symptomatic heart failure with preserved ejection fraction (left ventricular ejection fraction $\geq$ 45%) (mean age 73.9 years, 54% female) and 21 caregivers. Study retention and intervention uptake were excellent (90% and 92%, respectively).

At 6 months, data from 45 patients showed a mean between-group difference in favour of the intervention for the primary outcome – Minnesota Living with Heart Failure Questionnaire score – although the confidence interval was wide and included 0 (between-group mean difference −11.5, 95% confidence interval −22.8 to 0.3). Eleven participants (four intervention, seven control) were admitted to hospital over the 6 months of follow-up; four of these admissions (all in the control group) were related to heart failure. The estimated average cost of the REACH-HF intervention per patient with heart failure with preserved ejection fraction was £362.61.

Intervention fidelity analysis indicated adequate delivery of most REACH-HF components.

In the context of this single-centre pilot not fully powered to demonstrate between-group differences in patients or caregivers, these findings should be considered indicative.

Interpretation

These findings supported the feasibility of and rationale for delivering the facilitated home-based REACH-HF intervention for patients with heart failure with preserved ejection fraction and their caregivers and progression to a full multicentre randomised controlled trial of its clinical effectiveness and cost-effectiveness.

Work package 3: multicentre randomised controlled trial and process evaluation of the clinical effectiveness and cost-effectiveness of the REACH-HF intervention in addition to usual care in people with heart failure with reduced ejection fraction and their caregivers

Methods

The trial recruited people with heart failure with reduced ejection fraction from four centres (i.e. Birmingham, Cornwall, Gwent and York). Participants were randomly allocated to the REACH-HF intervention plus usual care or usual care alone. Those randomised to the intervention usually had a home-based consultation with a cardiac rehabilitation or heart failure nurse or physiotherapist trained to facilitate it. The facilitator assessed participants' individual needs and provided instruction in use of appropriate sections of the Heart Failure Manual. During the 12 weeks after randomisation, the facilitator answered questions from participants or caregivers during home visits or by e-mail or telephone. The primary outcome was disease-specific health-related quality of life measured using the Minnesota Living with Heart Failure Questionnaire at 12 months. Secondary outcomes included death or admissions with decompensated heart failure or acute coronary syndrome, N-terminal pro-B-type natriuretic peptide levels, Incremental Shuttle Walk Test, psychological well-being, physical activity level, generic health-related quality of life, caregiver outcome, health-care utilisation, adverse events and costs.

Key findings

The study recruited 216 participants, predominantly men (78%), with an average age of 70 years and mean left ventricular ejection fraction of 34%. Overall, 185 (86%) participants provided data for the primary outcome.

Adding the REACH-HF intervention to usual care resulted in clinically superior disease-specific health-related quality of life at 12 months compared with usual care alone. At 12 months, there was a significant and clinically meaningful between-group difference in the Minnesota Living with Heart Failure Questionnaire score of −5.7 points (95% confidence interval −10.6 to −0.7 points) favouring the intervention ($p = 0.025$). The Minnesota Living with Heart Failure Questionnaire physical score also significantly favoured the intervention (mean difference at 12 months −3.2, 95% confidence interval −5.7 to −0.6; $p = 0.016$) but the emotional score did not (mean difference at 12 months −0.8, 95% confidence interval −2.2 to 0.6; $p = 0.273$). Post hoc analysis showed that 48 (52%) participants in the REACH-HF group and 31 (33%) in the control group achieved a reduction of 5 Minnesota Living with Heart Failure Questionnaire points.

Other than patient self-care ($p < 0.001$), no significant difference was seen in other secondary outcomes, including clinical events ($p > 0.05$) at follow-up, compared with usual care. Eight (4%) patients died (four in each group). Nineteen participants in the REACH-HF group and 24 in the control group had one or more hospital admissions, totalling 33 hospital admissions (four heart failure related) in the REACH-HF group and 35 (10 heart failure related) in the control group. The Self-Care of Heart Failure Index maintenance score at 12 months favoured the intervention ($p < 0.001$). Within-group improvements from baseline were seen with REACH-HF for the Hospital Anxiety and Depression Scale anxiety and depression, Incremental Shuttle Walk Test and Self-Care of Heart Failure Index (management and confidence), but these were not statistically significant compared with the control group at 12 months. No differences were seen in the other secondary outcomes (EuroQol-5 Dimensions, HeartQoL and physical activity). Patterns of primary and secondary results were similar at 4 and 6 months. We found no significant interaction effect on the Minnesota Living with Heart Failure Questionnaire at 12 months between treatment and N-terminal pro-B-type natriuretic peptide level, presence of caregiver, recruitment site or duration of heart failure.

The mean cost of the REACH-HF intervention was £418 per participant. The costs at 12 months were, on average, £401 higher in the intervention group than in the usual care alone group.

Limitations

Lack of blinding because of the complex nature of the intervention and control was a key limitation, introducing possible patient expectation bias. Our findings should be interpreted with caution, as the sex balance among patients with heart failure in the UK is almost equal, whereas 78% of recruits were male and we recruited only seven people from ethnic minorities.

Interpretation

The REACH-HF home-based facilitated intervention for heart failure with reduced ejection fraction was clinically superior in disease-specific health-related quality of life at 12 months, offering an affordable alternative to traditional centre-based programmes to address current low uptake of cardiac rehabilitation for heart failure.

Work package 4: longer-term cost-effectiveness of REACH-HF, home-based cardiac rehabilitation and centre-based cardiac rehabilitation versus usual care in people with heart failure with reduced ejection fraction

Methods

We used model-based analyses to capture disease progression using health states representing important event-related activities of heart failure. A Cochrane systematic review of exercise-based

cardiac rehabilitation (home and centre based) undertaken as part of our programme informed data inputs to the evidence synthesis. A Markov model developed using a patient lifetime horizon integrated evidence from the REACH-HF main trial, a systematic review/meta-analysis of randomised trials, estimates of mortality and hospital admissions, and UK costs (2015–16 prices). Taking a UK National Health and Personal Social Services perspective, we estimated the incremental cost per quality-adjusted life-year gained, assessing uncertainty using probabilistic and deterministic sensitivity analyses. We estimated the cost-effectiveness of home-based cardiac rehabilitation versus usual care, REACH-HF intervention versus usual care, and centre-based cardiac rehabilitation versus usual care. Using the common comparator of usual care, we indirectly compared trial-based evidence for centre-based cardiac rehabilitation and the REACH-HF intervention in our multicentre randomised controlled trial to derive the relative effect of centre-based cardiac rehabilitation versus our intervention. The cost-effectiveness of centre-based cardiac rehabilitation versus usual care was considered, for consistency, using a common decision-analysis framework that we developed.

Key findings

In base-case analysis, the REACH-HF intervention was associated with a per-patient mean quality-adjusted life-year gain of 0.23, an increased mean cost of £400 compared with usual care, and a cost per quality-adjusted life-year of £1720. Probabilistic sensitivity analysis indicated a 78% probability that the intervention plus usual care versus usual care alone has cost-effectiveness below the willingness-to-pay threshold of £20,000 per quality-adjusted life-year gained. Results were similar for home-based cardiac rehabilitation (based on our meta-analysis) versus usual care. Sensitivity analyses indicate that the findings are robust to changes in model assumptions and parameters.

Interpretation

Modelling predicts a reduction in hospital admissions consistent with published trials of home-based cardiac rehabilitation. Adding the REACH-HF intervention and home-based cardiac rehabilitation programmes is likely to be cost-effective compared with usual care alone in patients with heart failure with reduced ejection fraction.

Future steps

We are disseminating our findings to the NHS Systematic collection of real-world data would track future changes in uptake and adherence of cardiac rehabilitation in patients with heart failure. Monitoring implementation of a home-delivered, evidence-based intervention can increase understanding of how changes in service delivery might affect patient and caregiver outcomes. The positive findings of our single-centre pilot randomised controlled trial in patients with heart failure with preserved ejection fraction suggest that a full multicentre randomised controlled trial of the REACH-HF intervention in people with heart failure with preserved ejection fraction is a logical, achievable next step.

Conclusion

We developed and evaluated a comprehensive, facilitated, home-based cardiac rehabilitation intervention for patients with heart failure and their caregivers. Overall, 185 (86%) participants provided data for the primary outcome. The improvement in the Minnesota Living with Heart Failure Questionnaire score with the REACH-HF intervention at 12 months was significant and clinically meaningful. The maintenance score on the Self-Care of Heart Failure Index, a measure of self-care, was also significantly in favour of the REACH-HF intervention group at 12 months. Within-group improvements from baseline in the REACH-HF group for the Hospital Anxiety and Depression Scale anxiety and depression, Incremental Shuttle Walk Test and Self-Care of Heart Failure Index (management and confidence) did not reach statistical significance compared with the control group at 12 months. Four deaths occurred in each group.

In the REACH-HF group, 19 participants had one or more hospital admissions, compared with 24 in the control group. Overall, there was no statistically significant difference in hospital admissions: 33 in the REACH-HF group (four heart failure-related) and 35 in the control group (10 heart failure related). The mean cost of the intervention was £418 per participant. The EuroQol-5 Dimensions scores at 12 months showed no difference in quality-adjusted life-year gain between groups, with usual care dominant, so the REACH-HF intervention was not cost-effective using this short-term perspective. However, economic modelling showed that the intervention was associated with a per-patient mean quality-adjusted life-year gain of 0.23 and a cost per quality-adjusted life-year gain of £1720 – below the threshold of £20,000 per quality-adjusted life-year gained recommended by the National Institute for Health and Care Excellence.

With the caveats above, these findings suggest clinical effectiveness and long-term cost-effectiveness of the REACH-HF intervention for patients with heart failure with reduced ejection fraction.

The REACH-HF intervention offers a new evidence-based cardiac rehabilitation option, which, being home based, could increase uptake of cardiac rehabilitation in patients with heart failure not attracted to hospital-based group programmes.

Our pilot randomised controlled trial in heart failure with preserved ejection fraction supports the rationale for a full multicentre randomised controlled trial of its clinical effectiveness and cost-effectiveness. Health economic modelling shows long-term potential cost savings for the NHS from introducing home-based cardiac rehabilitation intervention for patients with heart failure with reduced ejection fraction. This could address the low uptake of cardiac rehabilitation in people with heart failure by offering patients, clinicians and commissioners an alternative to hospital-based cardiac rehabilitation.

Trial registration

This trial is registered as ISRCTN86234930 and ISRCTN78539530.

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