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Home-based rehabilitation for heart failure with reduced ejection fraction: mixed methods process evaluation of the REACH-HF multicentre randomised controlled trial

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ABSTRACT

Objective To identify and explore change processes explaining the effects of the Rehabilitation Enablement in Chronic Heart Failure (REACH-HF) intervention taking account of reach, amount of intervention received, delivery fidelity and patient and caregiver perspectives.

Design Mixed methods process evaluation parallel to a randomised controlled trial using data from the intervention group (REACH-HF plus usual care).

Setting Four centres in the UK (Birmingham, Cornwall, Gwent and York).

Participants People with heart failure with reduced ejection fraction (HFrEF) and their caregivers.

Methods The REACH-HF intervention consisted of a self-help manual for patients with HFrEF and caregivers facilitated over 12 weeks by trained healthcare professionals. The process evaluation used multimodal mixed methods analysis. Data consisted of audio recorded intervention sessions; demographic data; intervention fidelity scores for intervention group participants (107 patients and 53 caregivers); qualitative interviews at 4 and 12 months with a sample of 19 patients and 17 caregivers.

Outcome measures Quantitative data: intervention fidelity and number, frequency and duration of intervention sessions received. Qualitative data: experiences and perspectives of intervention participants and caregivers.

Results Intervention session attendance with facilitators was high. Fidelity scores were indicative of adequate quality of REACH-HF intervention delivery, although indicating scope for improvement in several areas. Intervention effectiveness was contingent on matching the intervention implementation to the concerns, beliefs and goals of participants. Behaviour change was sustained when shared meaning was established. Respondents' comorbidities, socio-economic circumstances and existing networks of support also affected changes in health-related quality of life.

Conclusions By combining longitudinal mixed methods data, the essential ingredients of complex interventions can be better identified, interrogated and tested. This can maximise the clinical application of research findings and enhance the capacity of multidisciplinary and multisite teams to implement the intervention.

Trial registration number ISRCTN25032672; Pre-results.

Strengths and limitations of this study

- A strength of this study is that it is underpinned by qualitative and quantitative systematic reviews conducted by a multidisciplinary and multiprofessional team and, supported by a patient and public involvement group including people with heart failure, builds on the existing evidence base for CR interventions.
- A further strength of the study is the use of multiple sources of both qualitative and quantitative data to illustrate change processes during intervention and implementation practices relevant to effectiveness.
- An additional strength is the longitudinal data collection over 12 months.
- A limitation is that we did not collect data from the facilitator training or conduct interviews with facilitators.
- An additional limitation is that there was a limited number of minority ethnic participants in both the trial and process evaluation.

INTRODUCTION

Heart failure (HF) is a long term condition associated with shortness of breath, fatigue and fluid retention which inhibits activities of daily living and leads to increased hospitalisations and premature mortality.[1 2] The prevalence of HF is increasing due to an ageing population, improved survival of people with HF after myocardial infarction, and more effective treatments for HF.[3] With improving prognosis, the focus in HF has shifted towards optimising health-related quality of life (HRQoL). Exercise based

cardiac rehabilitation (CR) in patients with HF have shown improvements in HRQoL and a reduction in hospitalisations.[1]

While evidence for the added value of centre and group based cardiac rehabillitation (CR) for patients with HF is strong, questions remain about the effectiveness of alternative modes of delivery.[3] The Rehabilitation Enablement in Chronic Heart Failure (REACH-HF) multicentre Randomised controlled trial (RCT) assessed the clinical effectiveness and cost-effectiveness of the addition of the REACH-HF intervention to usual care compared with usual care alone in patients with HF with reduced ejection fraction (HFrEF) and their caregivers.[4 5] The patient, caregiver and health economic outcome results of the REACH-HF trial are reported elsewhere.[5–7]

This paper reports on a process evaluation conducted in parallel to the REACH-HF trial. Recent reviews of RCTs for HF have identified a lack of process evaluations and associated qualitative studies assessing change processes.[8] Indeed, prior research has failed to identify essential programme characteristics showing a consistent pattern in modifying the effects of self-management interventions for people with heart failure.[9] Commentators have also noted a failure to explain how programme elements of CR interventions interact[10]; to adequately describe the real world complexity of living with HF and the burden of both self-management and adherence to intervention regimens.[11] The work reported here constituted part of the REACH-HF process evaluation that assessed intervention fidelity, patients' and caregivers' experiences of trial participation and sought to identify change processes that may be responsible for change in HRQoL (the trial primary outcome).[5–7]

METHODS

Design

Details of the REACH-HF multicentre trial have been published elsewhere.[4 5] In brief, 216 patients and 97 caregivers were recruited to the trial from four geographical regions (Birmingham, Cornwall, Gwent and York) across the UK. One hundred and seven patients with 53 caregivers were randomised to REACH-HF intervention and usual care (intervention group), and 109 patients and 44 caregivers to usual care alone (control group).

A mixed methods process evaluation using linked data from multiple sources to build individual case studies was undertaken,[12] paying particular attention to *fidelity* (the consistency of what was delivered with the planned intervention) and *adaptations* (alterations made to the intervention in order to achieve contextual fit)[13] (figure 1). The intervention group formed the sampling frame for the process evaluation. Nineteen patients were sampled for maximum variation, based on their geographical region and their scores for the primary outcome measure of the trial, the Minnesota Living with Heart Failure Questionnaire (MLHFQ)[14] and the Hospital Anxiety and Depression Scale.[15] The four regions enabled adequate

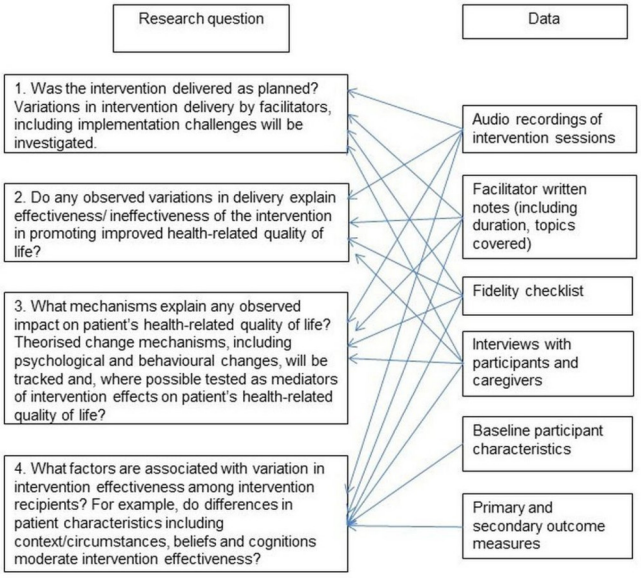

Figure 1 Sources of data used to address process evaluation questions.

participant enrolment to achieve the required sample size and afforded the opportunity to explore local contexts. Sampling different scores at baseline allowed us to explore different longitudinal change within and across cases. Seventeen caregivers were also purposively sampled.[7]

REACH-HF intervention

The REACH-HF intervention is a comprehensive self-care support programme comprising the 'REACH-HF Manual,' which includes lay explanations of HF and how people can learn to live with the condition to maximise their quality of life.[16] It also includes a choice of two exercise programmes (chair based and walking); information about managing medications, monitoring fluid build-up and other symptoms (to inform appropriate help-seeking), and managing stress, anxiety, and low mood (including a relaxation CD); a 'Family and Friends Resource' for caregivers; and a participant 'Progress Tracker' booklet to record daily physical activity, symptoms and other self-care-related actions. Facilitators visited patients at home to introduce the programme, and subsequently supported patients and caregivers in face-to-face or telephone sessions.

Participants were required to have a first face-to-face contact with facilitators and at least two facilitator contacts thereafter, with at least one face-to-face. It was expected that participants would typically receive 4 to 6 contacts each, although the facilitators could vary the number of contacts as they considered necessary around this guideline range.

Data collection

Qualitative data: For the 19 patients who constituted our sampling frame (two to three patients per facilitator across the four regions), facilitators were required to audio-record all face-to face meetings with the patient

(typically one 90 min and two to three 45 min sessions), and subsequent telephone contacts (typically three to six per patient). Qualitative interviews were conducted in peoples' homes (or by telephone if a visit was not possible), and field notes collated.

Quantitative data: quantitative data were collected at visits to the research centre. A 13-domain fidelity checklist was developed and piloted during the feasibility study, and used in the process evaluation to assess the facilitators' delivery of the intervention. The checklist and descriptions of the intended content of the intervention are published elsewhere.[16]The checklist items represented key intervention components defined by the intervention designers, including use of a person-centred counselling style, addressing the emotional consequences of heart failure and involving caregivers in the intervention process. One of the intervention designers (JW) applied the checklist to the audio recorded intervention sessions and another (CG) scored a subsample (around one third of the sessions). The coders compared and discussed the scoring to facilitate consistency. Fidelity scoring attributed a numerical value (0–6) for each of the 13 domains on the fidelity checklist. Fidelity of intervention was considered to be adequate if scored ≥3 for each domain. The score of 3 was agreed as an anchor-point for scoring between the coders and was interpreted for each domain in relation to detailed coding instructions. On the basis of fidelity scores (to achieve maximum diversity within and between patients, and where dissonance was identified by JW and CG), a purposive sample of audio recordings were used to identify examples of optimal and suboptimal delivery fidelity.

Patients and caregivers were contacted by the interviewer and, with their consent, interviewed at 4 and 12 months after the baseline facilitator visit. Interviews were conducted by experienced qualitative researchers and, with participant consent, audio-recorded and transcribed. The interviewers followed a topic guide based on the objectives of both REACH-HF and the process evaluation (table 1). Interviews sought to capture change over time.[17]

Data analysis

Quantitative data: using Stata V.14.2,[18] descriptive statistics were used to summarise the level of intervention received and fidelity of delivery.

Qualitative data: all available data were managed with Nvivo V.11 Pro.[19] Individual cases were created for each respondent,[12] including interview transcripts, contact sheets, audio recordings of facilitator-patient interactions and associated fidelity scores, summaries of the intervention sessions, field notes, clinical data such as case-report forms, and patient reported outcome measures. Interview transcripts were initially analysed using evaluative coding, which assigned a judgement about the merit or significance of the intervention from the participant's perspective.[20] This noted the presence or absence of a section of the intervention and the extent to which it was positively or negatively evaluated by the participant/caregiver. Second cycle coding[20] extended the mapping of variance across the dataset, and enabled within-case analyses (between patients and caregivers, and between 4 and 12 months) and cross-case analyses (between facilitators and sites, and also on the basis of variables of interest identified in the first round, eg, gender, age and multimorbidities) and the further identification of directional processes.[20] *Fidelity* was coded on the basis of the emphasis given to the core intended components of the intervention, while *adaptations* were coded in relation to the spirit of the intervention being adapted to the local context in order to achieve a 'good ecological fit'.[13] Data were anonymised and participants given pseudonyms.

Patient involvement

A patient and public involvement (PPI) group of 9 patients and caregivers led by a lay chair cocreated the REACH-HF intervention, the recruitment process, and the associated research. Research questions and topic guides were developed with the group. Patient representatives shared their experiences of how their needs were often not considered as part of healthcare consultations, and advised on how to ask sensitive questions.

RESULTS

Study participants

The flow of study participants is shown in figure 2. The characteristics of the intervention group patients who participated in the process evaluation are summarised in table 2.

Patients were predominantly male and classed as II or III on the New York Heart Association classification , with an average age of 70 years and mean left ventricular ejection fraction of 33%. Caregivers were typically the partner or direct relative, were of a younger mean age (63 years) and predominantly female. The qualitative sample was representative of the wider intervention group.

Level of intervention received

Across the intervention group, a mean 6.5 (SD 2.6) facilitated sessions were provided with 4.0 (SD 1.2) being face-to-face contacts. A similar number of facilitated intervention sessions were received by the subsample of process evaluation participants, (total: mean 7.0, SD 2.6, and mean face-to-face: 4.0, SD 1.8; telephone: 2.9, SD 2.6).

Face-to-face contacts lasted from 10 to 170 min, while telephone contacts ranged from 2 to 75 min. Participants in Birmingham received the lowest mean number of contacts (6.25, SD 1.2), and at Cornwall the highest mean contact (9.5, SD 3.1); the duration of contacts was comparable.

Fidelity of intervention delivery

Audio recordings of facilitator contacts were available for 110 out of 322 contacts (34%). Face-to-face contacts were

Table 1 Qualitative interview topic guide

Topic	Questions
Opening question Engagement with the intervention First interview	Before you started, what were your expectations of the REACH-HF programme? What did you want to know about? Once the programme started, How did you use the manual?
Second interview	Since we last spoke how have you been getting on? (Reflect on a topic recalled in that interview if little discussion starts—or something observed)
Relationship with REACH-HF facilitator First interview	Can you describe how the facilitator worked with you? What did you like or dislike about how the facilitator worked with you? What did you feel about your (husband, wife, son etc) being present? Did the facilitator help you meet your needs?
Second interview	Since we last spoke have you had any further contact with the facilitator? (explore if yes)
Involvement of Family and Friends Both interviews	Do you have any friends or family that help you manage your heart condition? If so: In what way did your family or friends get involved? How did you feel about it? What if any discussions did you have with your family or friends about what support you needed from them in managing your heart failure?
Using the manual First interview	As a result of using the manual and working with the facilitator what has *changed* about how you manage your heart failure? What do you think about the medication section? What do you think about the physical activity programme? How do you plan to keep your fitness up in the future under your own steam? What other support might be useful? What did you think about the progress tracker? How did you use it?
Second Interview	Can you tell me about what physical activity or exercise do you do now? What are you doing to keep track of your progress?
Processes Both interviews	Has taking part in the intervention affected your understanding of the condition/your situation? If so, probe further Has it made you feel any more or less confident about how you manage your heart failure? If so, probe further
Psychological adjustment to living with heart failure Both interviews	Has this programme changed the way you feel about having heart failure? If so, in what way? Has this programme changed the way you manage these feelings? If so, in what way? What do you think about the sections of the manual that are about managing stress? Were these helpful? If so how? How did you monitor your progress?
Moderators and Mediators First interview	Is there anything else that affects how you look after your heart?
Second interview	What do you do now to look after your heart? Does this differ from the first interview What other sources of information or support do you use? This is important if there are other heart failure management programmes being used

more consistently recorded than telephone contacts, but there were no other obvious patterns of recording (eg, all of the contacts in York were recorded, but there was a smaller number).

Fidelity was considered to be adequate (score of ≥3 out of 6) in most domains (summarised in table 3).

There was room for improvement, however, particularly with respect to involving the caregiver, addressing caregiver concerns and addressing caregiver well-being, where the mean scores were well below the agreed 'adequate' score (table 4).

Furthermore, there was variation in fidelity scores across participants and facilitators. There was no discernible 'fidelity style' for each facilitator/site (one to three facilitators per site) and all had participated in the 3-day training for the study. Six of the seven facilitators had nursing backgrounds (various hospital/community, rehabilitation/cardiac/cardiology configurations). The one physiotherapist had the highest fidelity scores, although this was too small a number of patients to be statistically significant.

Fidelity scores for participants in Birmingham were consistently higher (>3) than those for participants in Cornwall (<3). For all process evaluation participants, fidelity scores were lower in telephone contacts than with face-to-face consultations. Assessment of their content identified that they were typically more didactic in nature, and generally used to remind participants of key messages rather than to elicit or discuss any new concerns. This may reflect the briefer time spent in telephone sessions and their use as a method for briefly checking-in rather than raising or dealing with any more complex issues.

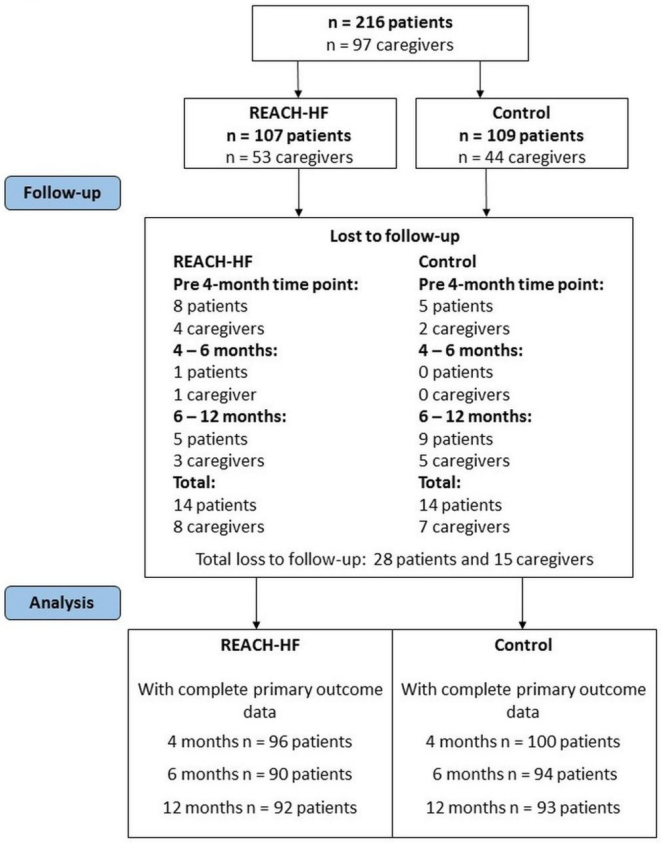

Figure 2 CONSORT diagram. CONSORT, consolidated standards of reporting trials; REACH-HF, Rehabilitation Enablement in Chronic Heart Failure.

The quality of delivery at the initial session with the facilitator set the tone for future sessions and was associated with perceptions of intervention effectiveness, as two examples illustrate. Mary received one of the lowest amounts of REACH-HF (a total of 293 min of contact time, over three face-to-face and three telephone-based intervention sessions), but her fidelity scores were high (scoring ≥5 in seven of 13 domains) at the initial intervention session and subsequently. The audio-recording indicated that the facilitator listened to her concerns, elicited her goals and beliefs, and employed a range of behaviour change techniques, before explaining the purpose of the manual and resources. At 4 months Mary explained how the support of the facilitator combined with the walking programme had re-orientated her understanding of HF:

> I've learnt a lot and I think it is a *very* good… manual, I think it's excellent and I think, … given to people – I *wished* I'd had it right at the beginning. Because it has changed my attitude… (Mary: 4 months).

Her family were strongly engaged in supporting the intervention and created a simplified one-page progress tracker, which Mary used postintervention. At 12 months she suggested that by 'sticking to the walking programme' she was 'feeling better in myself' and 'doing things which I couldn't have done a year ago'. At 12 months her HRQoL score as assessed in terms of MLHFQ total score had reduced from 50 at baseline to 18, indicating a considerable improvement.

In contrast, Dorothy received a larger amount of REACH-HF (440 min over four face-to-face and two telephone sessions), but fidelity scores were low at the initial intervention and afterwards (<2.5). Audio-recordings detail how the facilitator adopted a didactic approach with no individualised assessment. In subsequent sessions the facilitator failed to answer clinical questions and was unable to signpost Dorothy to appropriate resources. Dorothy's HRQoL was good (total MLHFQ score 16) initially suggesting a good HRQoL, despite her having one of the poorest ejection fractions in the sample (21%, indicative of severe decompensation). Interview data suggests, however, her good HRQoL were due to her lack of insight, which was repeatedly reinforced by the poor facilitation of the intervention, and at 12 months there was no evidence of change in either understanding or behaviour:

> I can't seem to get the seriousness of it… [exercise] it is recreation, isn't it? Mainly….it keeps, you know, things going…I can't explain it really now…I did have a diary at first 'cos they said keep a diary, but even that I don't tend to…No, have got a bit complacent… (Dorothy: 12 months)

Key processes

Analysing linked data over time[12 17] enabled us to identify key processes that explained the effects of the REACH-HF intervention: adaptation, competence, comorbidities and social context.

Adaptation

Change was sustained when the facilitator adapted the intervention to participant needs. In one example, Helen had underlying anxiety and misconceptions about the need for rest, and the facilitator literally took 'small steps', walking with the participant to build capacity:

> [Facilitator] said it'll, you know, it'll build your heart muscle up. You know, which I wasn't thinking that way. I was thinking: if I rest my heart and don't do anything, you know, it would - you know, keep me going a bit longer, you know…And the more I thought about walking, and my heart muscle and all, the more, well, I thought, "Well, I'll walk, and try to get it stronger. (Helen: 4 months)

In contrast, where participants suggested that they had already acquired expertise, or had been living with HF for years, some facilitators struggled to engage them or tailor the programme effectively:

> I didn't want to do [exercise]…I couldn't see the point in pushing myself to do it when I personally couldn't see I were going to get any extra benefit from it, as such… [Facilitator] were just doing her job and that were it… She weren't trying to interfere

Table 2 Baseline characteristics of patients in the intervention arm

Characteristic	REACH-HF n=107 (%)	Qualitative interview sample n=19 (%)
Age (years), mean (SD)	69.7 (10.9)	68.5 (9.8)
Female sex	26 (24)	7 (37)
Body Mass Index BMI (kg/m^2); mean (SD)	29.5 (6.6)	31.5 (7.4)
Main activity		
Retired	81 (76)	15 (79)
In employment or self-employment	18 (17)	2 (11)
Unemployed	5 (5)	1 (5)
Other	3 (3)	1 (5)
Ethnic origin		
White	100 (93)	19 (100)
Other (Black, Asian, other)	7 (7)	0 (0)
NYHA status		
Class I	24 (22)	0 (0)
Class II	63 (59)	13 (68)
Class III	20 (19)	6 (32)
Ischaemic aetiology of HF	48 (45)	9 (47)
Time since diagnosis of HF (years); mean (SD)	3.6 (4.2)	3.8 (3.9)
<1	35 (33)	6 (32)
1–2	18 (17)	1 (5)
2–5	28 (26)	7 (37)
5–10	14 (13)	3 (16)
>10	12 (11)	2 (11)
NTerminal-pro-BNP level (pg/mL); mean (SD)	1460 (1928)	1321 (1123)
Current smoker	6 (6)	1 (5)
Comorbidities (past or present)		
Diabetes mellitus	26 (24)	5 (26)
Myocardial infarction	29 (27)	7 (37)
Hypertension	45 (42)	9 (47)
Chronic renal impairment	14 (13)	3 (16)
Arthritis (osteoarthritis or rheumatoid)	45 (42)	11 (58)
Atrial fibrillation or atrial flutter	48 (45)	9 (47)
COPD	9 (8)	2 (11)
Depression	27 (25)	7 (37)
Number of comorbidities		
0	63 (59)	9 (47)
1	32 (30)	7 (37)
2	7 (7)	1 (5)
3 or more	5 (5)	2 (11)
Baseline use of drugs		
Beta-blocker	90 (84)	18 (5)
Angiotensin II receptor antagonist	31 (29)	8 (42)
ACE inhibitor	68 (64)	10 (53)
Baseline use of devices		
Implantable cardiverter defibillator (ICD)	10 (9)	3 (16)
Cardiac Synchronization Therapy (CRT)	10 (9)	1 (5)

Continued

Table 2 Continued

Characteristic	REACH-HF n=107 (%)	Qualitative interview sample n=19 (%)
Combined CRT/ICD	5 (5)	2 (11)
Pacemaker	11 (10)	1 (5)
Location		
Cornwall	30 (28)	7 (37)
Gwent	23 (22)	3 (16)
Birmingham	27 (25)	4 (21)
York	27 (25)	5 (26)
Caregiver present at randomisation	53 (50)	13 (68)

COPD, chronic obstructive pulmonary disease; HF, heart failure; NYHA, New York Heart Association.

with anything. I think she, she knew she were wasting her time, not being rude to her. (Michael: 4mth)

Key to both fidelity and adaptation were the competences of the facilitator, the participant and their caregiver, the existence of comorbidities and wider contextual factors such as material or social deprivation.

Competence

The facilitators' competence was key to participants' skills acquisition and behaviour change. Rachel, who has postpartum cardiomyopathy and was swimming to achieve the required pretransplant weight loss, explained how the facilitator told her that swimming was dangerous, although it took her 'a few weeks to convince me though'. The facilitator's challenging approach was appreciated, and Rachel subsequently attributed both her positive mental attitude and weight loss to the difficult conversations with her facilitator:

> [I]t helped to have someone just there 'cos your GPs busy… [GP] actually said: 'I don't quite know what to do and you're a very rare case, and you probably know more about it than what I do'. You don't want to hear that from a GP…Whereas [Facilitator] would go: 'I'll go back and find that out', but she knew most of the answers anyway. She was very with it.(Rachel: 12mth)

Having a friendlier and less challenging facilitator could, in contrast, have inhibited learning in this case. Post intervention, several participants without strong social support described how they had come to depend on the facilitator in a way that inhibited the development of self-efficacy; with some described feeling abandoned or isolated:

> I was supposed to go in for the pacemaker and then they decided that I didn't need it…I was looking forward to an operation…I felt it was gonna be a bit of a safety net…[I feel] abandoned! [Cries]…There's so many things that…turn up, just from day to day. And it's usually something daft and it's usually something you think: I can't ring the doctor for that. I don't want to bother them for that. So I suppose it would just be useful to have that contact…with someone who definitely knows what they are talking about… (Esther: 12 month)

Where facilitators were able to use participants' existing networks of health professionals and family members, participants expressed confidence in their newly acquired ability to self-manage:

> I got the manual here, the big manual here. But they're explaining it to me, and seeing it in black and white it was like 'Oh yeah', 'Cos I know when you go down to see [Cardiac Nurse] I know they, you know, that she would answer questions if I asked but you're always conscious of the fact that there's a queue outside waiting to see her. (Mary: 4 month)

However, referrals to unfamiliar health and social care professionals did not always materialise, were not always followed up by the facilitator, and could leave participants feeling as though they no longer had an advocate:

> Maybe I got the wrong impression…like with (Facilitator) and the nurses… they've got the title of heart nurses…I don't know whether I'm allowed to ask them questions and whether they would get involved on my behalf…I'm almost looking for the advocate that says: 'I know what you want. I'll get it sorted.' And you know…I don't even know who to talk to… What it really boils down to: I don't know where…to go to get the information. (John:12 month)

Comorbidities

Most participants had multiple comorbidities, and some valued the simplicity of the REACH-HF programme, and specifically the accessibility of the information provided. Mary has arthritis, chronic back pain and breast cancer, and engaged with 'simple explanations' about medicines in the manual:

> P: Yeah, medication, information on that, which was brilliant. What they are is simple explanations, there's no, you know, high falutin medical jargon in there,

Table 3 Fidelity of intervention delivery summary scores for patients in the process evaluation

	Participant Involvement	Assessment of individual needs	Tailored treatment plan	Building understanding of HF	Support progress monitoring	Review progress	Physical activity plan	Address patient emotion	Medication issues	Involve caregiver	Address caregiver emotion	Address caregiver well-being	Closure
Mean	3.3	4.1	2.9	3.3	2.9	3.2	4.2	3.4	3.3	1.6	2.2	1.1	3.4
Min	1.3	2.5	1.8	1.5	1.8	2.2	3.0	1.0	2.0	0.0	0.0	0.0	2.0
Max	4.9	5.0	5.1	5.0	5.0	4.8	5.5	5.0	5.0	3.1	4.0	3.3	5.0
n	20	15	20	17	20	18	15	17	17	16	14	16	14

HF, heart failure.

it's basically straightforward, you read it, you understand it… yes, you don't remember the whole book, obviously not, but you can go back to it at any time that you want to, anything that crops up that you're not sure of, I just go in the other room where I've got it on the table, and I open it up and read it. I don't even put it away, I keep it out so that I got it there… (Mary: 4 months)

In contrast, Stephen, who has arthritis, diabetes and chronic obstructive pulmonary disease (COPD), wanted to 'be a little bit fitter and a bit more active', but his need to manage multiple conditions inhibited his ability to fully engage with the intervention:

[I'm] a little bit more active, a little bit less tired… But, that still remains the same, that still remains the major problem for me….And I've got knee problems as well so… that stops me doing a lot really. I mean that was the biggest thing on the walk test really, that's what…curtailed things for me really…Oh the cough, yeah, I've got a cough which is… drive me around the bend, yeah… Most of the time, like now, it's…. it's just an annoyance, but if I get a bad cold …. it's horrendous. It always ends up here, at the top of the chest straightaway and I've got about four or five weeks of purgatory, you know, it's really bad. (Stephen: 4mth)

Social context

Sustaining change was easier for participants with favourable material or social circumstances. For example, Peter is retired, owns his own house in a rural setting and regularly plays golf as a form of gentle exercise and relaxation:

In the last 12 months I've been fine…we have been away, we went to South Africa for five weeks…we had a wonderful time…I am relatively fit because I go and play golf most days…(Peter:12 mth)

However, sustaining change was much harder for those with limited material or social means. Simon has COPD and requires oxygen therapy, but his wife smoked in the house and neither of them engaged with REACH-HF:

I'm one of them typical blokes: 'Oh, it'll be alright'… 'You know, I know what I've got, I know what's gonna happen, sort of thing. But… I don't wanna talk about, like, you know?' (Simon:12 mth).

DISCUSSION

This process evaluation increases understanding of how the REACH-HF intervention operated in practice, in terms of reach, level of intervention delivered, fidelity and patient perspectives. We observed that intervention attendance was high, with most participants receiving the minimum intended amount of REACH-HF. However, an appropriate 'dose' of REACH-HF is contingent on fidelity of intervention delivery and skilled facilitation, rather

Table 4 Number and duration of REACH-HF sessions for patients in the intervention arm

	REACH-HF (n=107)	Qualitative interview sample (n=19)
Number of sessions per participant[1]; mean (SD), n; [min, max];		
Total sessions		
Overall	5.6 (2.7), 107; [0, 13]	6.5 (2.2), 19; [4, 11]
Cornwall	6.4 (2.4), 30; [0, 12]	8.0 (2.6), 7; [4, 11]
Gwent	5.3 (3.0), 23, [0, 12]	6.7 (2.1), 3; [5, 9]
Birmingham	5.8 (3.3), 27; [0, 13]	6.3 (1.3), 4; [5, 8]
York	4.6 (1.5), 27 [2, 9]	4.6 (0.5), 5; [4, 5]
Face-to-face sessions[1]		
Overall	3.6 (1.4), 107; [0, 7]	3.9 (1.1), 19; [2, 7]
Cornwall	3.1 (1.0), 30; [0, 5]	3.9 (0.7), 7; [3, 5]
Gwent	3.9 (1.8), 23; [0, 7]	4.7 (2.1), 3; [3, 7]
Birmingham	3.6 (1.6), 27; [0, 7]	4.0 (0.8), 4; [3, 5]
York	3.8 (1.2), 27; [1, 7]	3.6 (1.1), 5; [2, 5]
Telephone sessions[1]		
Overall	2.0 (2.1), 107; [0, 9]	2.6 (2.1), 19; [0, 7]
Cornwall	3.4 (2.0), 30; [0, 8]	4.1 (2.4), 7; [0, 7]
Gwent	1.4 (1.8), 23; [0, 6]	2.0 (0.0), 3; [2, 2]
Birmingham	2.1 (2.4), 27; [0, 9]	2.3 (1.7), 4; [0, 4]
York	0.9 (0.8), 27; [0, 3]	1.0 (0.7), 5; [0, 2]
Duration of sessions (minutes; combined across participants); mean (SD) n, [min, max]		
Face-to-face sessions[1]		
Overall	70 (28), 380; [15, 170]	72 (32), 75; [20, 170]
Cornwall	75 (25), 92; [15, 145]	83 (27), 27; [30, 135]
Gwent	69 (26), 89; [20, 160]	59 (31), 14; [20, 140]
Birmingham	69 (33), 97; [15, 170]	76 (38), 16; [30, 170]
York	66 (26), 102; [20, 135]	62 (28), 18; [20, 120]
Telephone sessions[1]		
Overall	20 (9), 215; [2, 50]	21 (12), 50; [2, 50]
Cornwall	21 (10), 102; [5, 50]	23 (12), 30; [5, 50]
Gwent	14 (8), 32; [2, 33]	14 (12), 6; [2, 33]
Birmingham	20 (9), 58; [2, 45]	17 (8), 9; [4, 28]
York	19 (7), 23; [5, 35]	21 (10), 5; [8, 33]

REACH-HF, Rehabilitation Enablement in Chronic Heart Failure.

than the duration or frequency of contact alone. Importantly, the overall fidelity score at the initial 'assessment' session was indicative of the overall fidelity score (across all sessions) for an individual participant. This highlights the importance of the first intervention session in setting the tone for subsequent sessions. Intervention effectiveness was dependent on the facilitator's style of engagement, and the extent to which the trial materials were matched to or adapted to the existing beliefs and goals of participants.[21] Behaviour change was sustained when facilitators established shared meaning with participants. Respondents' comorbidities, existing networks of support and socio-economic circumstances were also key to any changes in quality of life but, importantly in terms of measuring effectiveness, this may not always be reflected in the patient reported quantitative outcome measures. There was room for improvement with respect to involving the caregiver, and refinement of the REACH-HF intervention may be now be required.[7]

This study has a number of strengths. First, is the ability to examine the implementation in detail through the use of a wide range of data sources, including qualitative data from patient interviews and facilitated contacts; observational field notes; and quantitative data about key trial

processes and practice-level effectiveness. By combining longitudinal mixed methods data, the essential ingredients of complex interventions can be better identified, interrogated and tested.[12] This can maximise the clinical application of research findings and enhance the capacity of multidisciplinary and multisite teams to implement the intervention.

Second, this research is underpinned by qualitative and quantitative systematic reviews conducted by a multidisciplinary and multiprofessional team,[1 2] supported by a PPI group including people with HF, and builds on the existing evidence base for CR interventions. Research has suggested that comprehensive CR interventions may offer added benefits over single component interventions.[10 11] We propose this multicomponent home-based CR intervention can be optimised for the patient when both fidelity and adaption are maximised using an initial rigorous personalised assessment, skilled facilitation and the appropriate use of programme elements.

Third, this process evaluation was conducted in parallel with the REACH-HF trial and has been able to investigate process elements and their associations with outcomes. Existing studies of self-management interventions for patients with HF (using composite or clinical endpoint scores) have shown limited effectiveness (ie, they could not identify effective programme characteristics),[9 22–24] and a criticism is that few have conducted parallel mixed methods process evaluations, which have the potential to illuminate important contextual factors, such as patient needs, comorbidities and social context.[8] Where process evaluations have been conducted in relation to CR,[23] and other chronic conditions,[24–27] qualitative findings have helped to explain the quantitative outcomes and suggest future directions for research. As with previous research,[28 29] a key finding here is the dissonance between researchers', physicians' and patients' understanding of HRQoL. This may account for the outcome measures used in trials of interventions for the self-management of HF not always reflecting the effectiveness of the intervention at the level of the patient's experience (as seen with Dorothy). Specifically, if trials of self-management interventions for heart failure are premised on filling the knowledge gaps of often elderly patients with poor health literacy and inhibited cognitive function, then more needs to be done to enable patients to express their own goals and values and interpretations of HRQoL in ways that are clinically meaningful and measurable.[30–33] More generally, high quality process evaluations conducted in parallel with clinical trials have the potential to identify which interventions or elements are effective, and improve or eradicate those that are not.[13]

This study also has limitations. We did not collect data from the facilitator training or conduct interviews with facilitators. Furthermore, the facilitators did not record all intervention sessions or their duration as instructed, thus the estimated fidelity of delivery may be an over-estimation of the actual fidelity. This limits our insight into the interaction between a practitioner's existing professional repertoire and their engagement with and delivery of REACH-HF.[6] A further limitation is the small number of minority ethnic participants in both the trial and process evaluation.

More research is now required to optimise the 'workability' of the REACH-HF intervention and integration of the intervention components into the facilitators' clinical practice. This will ensure that fidelity and adaptation are maximised in the complex context of HF.[30] Other studies that have involved facilitated interventions for HF have augmented facilitator training via the provision of regular multidisciplinary feedback,[34] and the use of videoconferencing and peer discussion of difficult cases.[35] The uptake of CR is lower among people from minority ethnic backgrounds,[36] which has been attributed to: confusion about the aim, structure and content of the rehabilitation programmes; language barriers; poor mobility; prohibitive illness; distance from the rehabilitation centre; need for permission to attend; and lack of follow-up if a session was missed.[37–39] More research is required to understand the specific support needs of people from more diverse ethnic backgrounds and the extent to which cultural beliefs may moderate or mediate the effectiveness of REACH-HF.

CONCLUSIONS

The findings of this process evaluation indicate that the REACH-HF intervention for patients with HFrEF and caregivers was adequately delivered, well received and could be implemented more widely. However, there was considerable scope for improvement, as indicated by the fidelity scores and in-depth qualitative analysis. Behaviour change appeared to be sustained when shared meaning between the participant and facilitator was established, although patients' comorbidities, socio-economic circumstances and existing networks of support were key to any changes in HRQoL, which may not always be reflected in quantitative outcome measures. For example, where a facilitator was able to elicit a participant perspective, and tailor the intervention accordingly, this was often contingent on the nature of the wider contextual issues: if a 'problem' was within the scope of the intervention or facilitator (ie, anxiety) then tailoring was appropriate although fidelity could be compromised. However, if the problem was not within scope (ie, socio-economic disadvantage), then tailoring was more difficult. More now needs to be done to ensure fidelity and identify those patients for whom effectiveness may be more difficult to achieve.

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Contributors HD, RT, PJD, KJ, JM, JW, NB, CG, CA, and SJS designed the trial, were responsible for its conduct, and obtained trial funding. CG led the design of the intervention, with strong contributions from JW, PJD, the Heart Manual Department (Edinburgh), and the REACH-HF service user advisory group. JF, JW, NB, CG and CA designed the qualitative study and conducted the data analysis. FCW undertook the statistical analysis. JF led the mixed methods analysis. KP represented patient and public involvement on the Programme Management Group and liaised with the patient involvement group throughout the study. He commented upon the manuscript. All authors contributed to writing and editing the manuscript, with the lead taken by JF. All authors commented on the manuscript and agreed the final version. JF and RT are the guarantors.

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