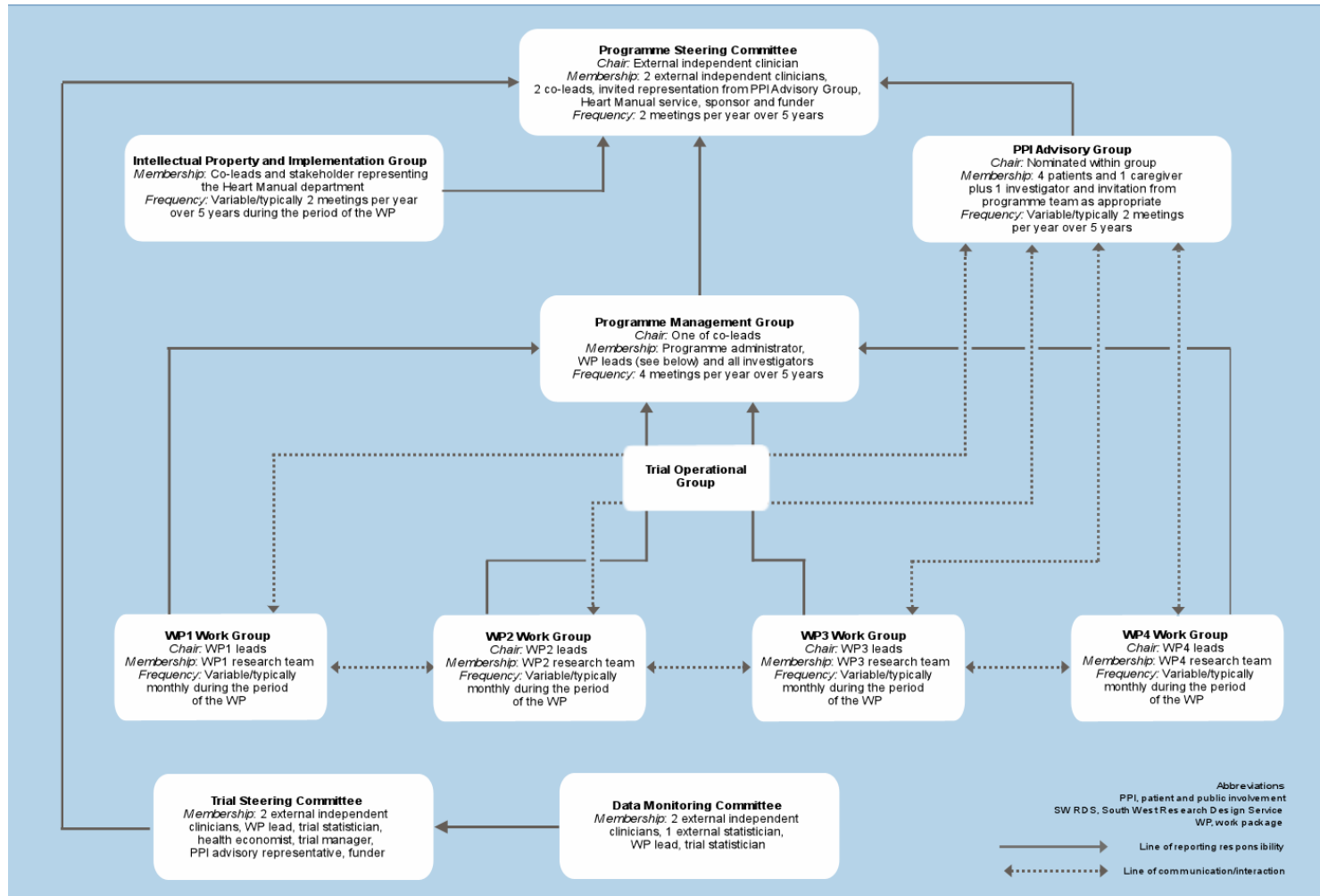


1 **Supplemental information and additional reports**

2 **Programme management**

3 Committees included an overarching Programme Management Group (PMG), Patient and Public
4 Involvement (PPI) Advisory Group, Programme Steering Committee (PSC), and Data Monitoring
5 Committee (DMC) for the trials (WP2 and WP3), and each work package had its own management
6 group. The research costs allowed the investigators to meet face to face at least twice a year, with
7 communication through teleconferences and emails between face-to-face meetings. Most meetings
8 took place in Exeter, which was the most central location for most applicants. Where possible, we
9 tried to plan meetings on the same day and at the same location to reduce carbon emissions and
10 expenses. The programme management structure is illustrated in **FIGURE A**.



1

2 **FIGURE A** Diagram depicting the REACH-HF programme management structure.

3 PPI, patient and public involvement; SW RDS, South West Research Design Service; WP, work package.

External committees

Programme Steering Committee

The PSC was independently chaired by Professor Martin Cowie and included the programme co-leads (Rod Taylor and Hasnain Dalal), as well as four external stakeholders – Professor Suzanna Hardman, former Chair of the British Society of Heart Failure and Consultant Cardiologist; Professor Sir Roger Boyle, former National Director of Heart Disease; Professor Graham Dunn, Statistician; and Liz Clarke, national patient representative.

The PSC oversaw progress of the overall programme, meeting biannually between 2013 and 2015 and annually thereafter until 2017.

Data Monitoring Committee

The role of the DMC was advisory – the committee made recommendations about the conduct of the trials, but the responsibility ultimately lay with the co-chief investigators, PSC and sponsor (Royal Cornwall Hospitals NHS Trust). The purpose of the DMC was to safeguard the interests of the trial participants in WP2 and WP3, assess the safety and efficacy of the interventions during the trials, and monitor the overall conduct of the trials to protect their validity and credibility.

Members of the DMC were independent and were constructively critical of the ongoing trials but also supportive of the trials' aims and methods. The DMC reviewed progress and accruing data and gave advice on the conduct of the trials to the PSC. The DMC undertook a review of the progress of the two trials in WP2 and WP3 to:

- assess data quality, including completeness (encouraging collection of high-quality data)
- monitor recruitment figures and losses to follow-up
- monitor compliance with the protocol by participants and investigators
- monitor evidence for treatment harm (for example, SAEs and deaths)
- recommend whether the trial should continue to recruit participants or whether recruitment should be terminated
- advise on modifications to the protocol suggested by investigators or the sponsor (for example, changes to recruitment procedures, inclusion criteria, endpoints, data collection, etc)
- monitor continuing appropriateness of patient information
- monitor compliance with previous DMC recommendations.

The DMC reviewed the statistical analysis plan(s) provided by the trial statistician and gave written approval of the final version prior to any formal analysis being undertaken.

Given the nature of the trials, the DMC were not required to monitor for treatment differences in the main efficacy outcome measures through review of accumulating outcome data, and no interim data analyses were conducted.

The composition of the DMC was agreed by the study funder. The DMC comprised three members independent of the project team: Dr Ann-Dorthe Zwisler (Chair), Senior Researcher, PhD, MD, Cardiologist, Research Programme on Health and Morbidity in Denmark, National Institute of Public Health, University of Southern Denmark; Professor Alan Montgomery, Professor of Medical Statistics and Clinical Trials, Faculty of Medicine & Health Sciences, School of Medicine, University of Nottingham, UK; and Dr Gill Furze, Professor in Adult Nursing and Health Care, President, British Association for Cardiovascular Prevention and Rehabilitation, Faculty of Health and Life Sciences, Coventry University, UK.

Internal committees

Work groups for each work package were managed by the work package lead and included all members of the relevant research teams. Monthly work package meetings were planned during their period of research. To ensure satisfactory progress and achievement against milestones, work package groups reported to the PMG.

The PMG comprised the programme co-leads, co-applicants, work package leads, trial site investigators, programme management coordinator and the project administrator. Meetings of the PMG were held 2–4 times per year, chaired by one of the co-leads. Trial management staff from the Peninsula CTU attended PMG meetings once the WP2 and WP3 phases were initiated.

The Trial Operational Group (TOG) comprised the programme co-leads, Peninsula CTU trial management staff, programme management coordinator and the project administrator. Trial site investigators attended TOG meetings as required. Where possible, meetings were held via teleconference/videoconference to reduce the carbon dioxide emissions associated with travel and expenses.

Work package 1

Feasibility study report

A multicentre single-arm intervention study with parallel process evaluation to assess the feasibility and acceptability of the REACH HF manual for patients, facilitators and caregivers: end of study report

A paper on the feasibility and acceptability of the novel REACH-HF intervention for patients and caregivers has been published (https://static-content.springer.com/esm/art%3A10.1186%2Fs40814-016-0075-x/MediaObjects/40814_2016_75_MOESM5_ESM.pdf).¹ The unpublished results, which were redacted in this publication, are provided as supplementary material 2.

Work package 2

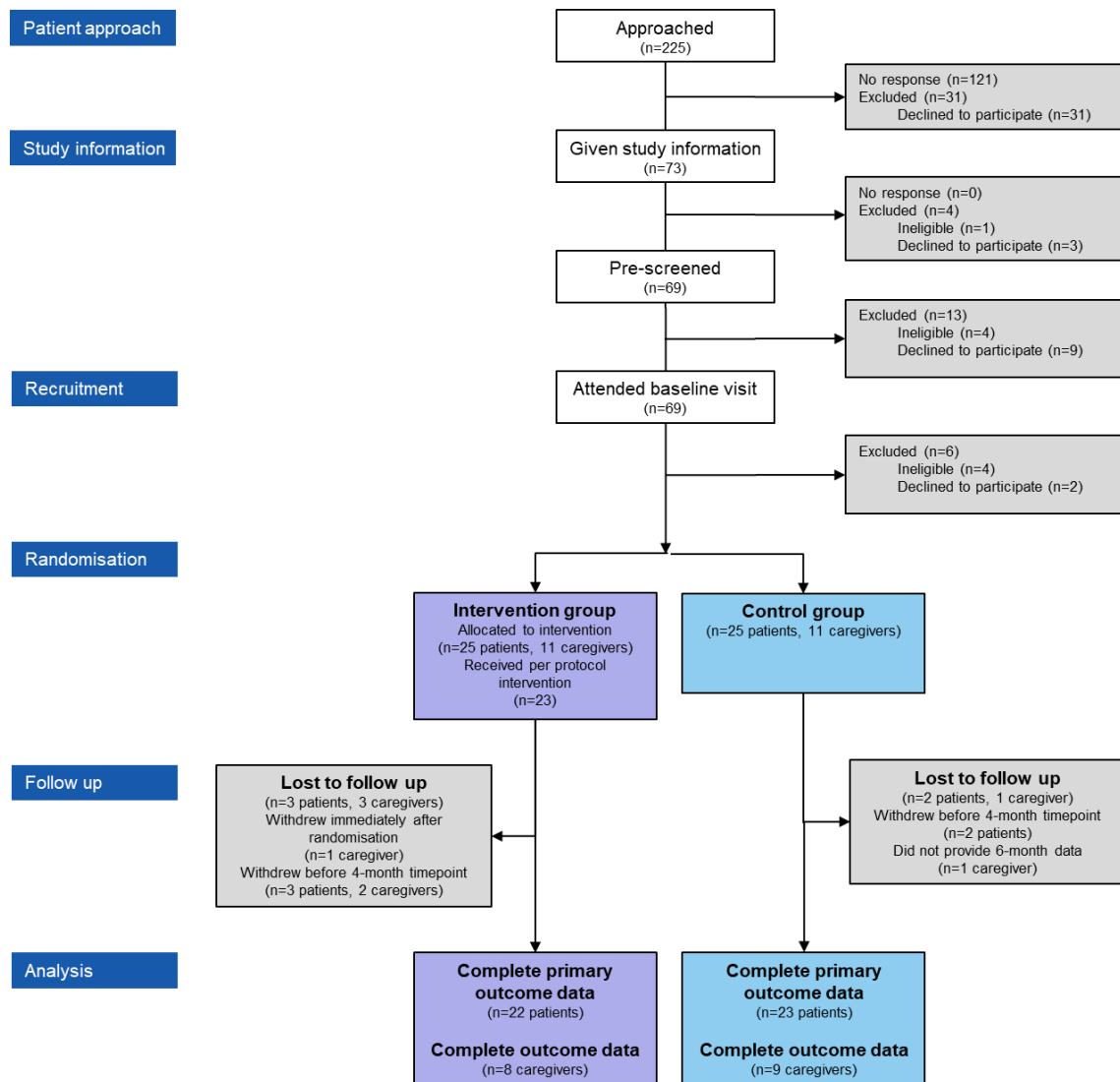


FIGURE B CONSORT diagram for REACH-HFpEF pilot trial

REACH-HFpEF, Rehabilitation EnAblement in CHronic Heart Failure with preserved ejection fraction.

Feasibility study process evaluation

REACH-HF Feasibility Study Process Evaluation: final report – September 2014

This is provided as supplementary material 3.

TABLE A Themes identified from six patients included in the fidelity analysis of the REACH-HFpEF pilot trial

Themes	Comments
Understanding their condition	<ul style="list-style-type: none"> • Both patients and caregivers identified the need for information to aid their understanding of the condition and to enable proactive symptom monitoring and self-care. • To others, the diagnosis of HF was a surprise, ‘...I was shocked, I couldn't believe it. I just couldn't believe because I've always been very fit’. • To some, the diagnosis came as a relief, because it normalised and explained their symptoms – e.g. tiredness and breathlessness – making them less anxious. • Several patients liked the description of HF in the HF Manual, along with the facilitator’s explanation, which aided their understanding of HF, thus equipping them better to untangle, identify and act on symptoms of HF. One caregiver stated, ‘I just feel once he started to understand more about heart failure, with the [Heart] Manual, that, yes, he sort of – I don't know, sort of maybe accepted it more...I think sometimes he sort of panics, thinking, oh, you know, should I be feeling this way? Whereas having the [Heart] Manual has, I think, sort of made him realise, yes, this is normal for me to feel like this and be like this.’
Emotional consequences of HF	<ul style="list-style-type: none"> • Adjusting to their HF and the limitations imposed by it was challenging for many participants. • Men in particular felt a strong loss of identity due to changes in their physical ability, social and professional roles. • Some patients and caregivers reported anger or low mood, often related to feelings of frustration associated with the limitations that HF imposed on their lifestyle. • The REACH-HF intervention helped them to recognise their altered mood, and working with the facilitators enabled them to

	<p>better manage these emotions, sometimes drawing on their existing coping strategies, such as mindfulness or relaxation.</p> <ul style="list-style-type: none"> • Regaining a sense of purpose was important in aiding positive emotions and adjustment.
<p>Response to the intervention and facilitator</p>	<ul style="list-style-type: none"> • Although many participants engaged with the Intervention at some level, this varied across the components. • Participants confirmed that the HF Manual provided information and reassurance, 'offering something for everyone'. In combination with the participant Progress Tracker booklet, it aided symptom monitoring and supported self-care. • Patients and caregivers accounts again reinforced their need to understand how to manage HF by knowing what to look for and what to do in case of deterioration or in an emergency. Improved understanding meant caregivers felt more confident in supporting the patients. One wife reported, "The facilitator' was very helpful for me in so many different ways. Helping me to understand heart failure...she encouraged me to go out walking...just the reassurance that things were better, that there was somebody there that was willing to, erm, say, well, okay, you're doing well. Even just the smallest amount of encouragement' and 'my husband always felt better after 'the facilitator' went away. Because she felt...almost like a little security blanket, if you want to say. That somebody was there, somebody was asking'' Feeling that someone 'cared', listened, answered questions and provided feedback and encouragement was important to the patients and caregivers. • The facilitator was viewed as an educator, a source of support and reassurance, as well as a motivator and enabler. They helped to reframe participants' thinking to enable engagement in activity, symptom monitoring and self-care of their long-term condition through realistic goal-setting and pacing. There was

	<p>also evidence that the specific unmet needs of caregivers were addressed, and how the caregivers themselves responded to the intervention with increased awareness and management of addressed their own 'care and support' needs.</p>
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Detailed costs in WP2 trial

This is provided as supplementary material 4.

Work package 4

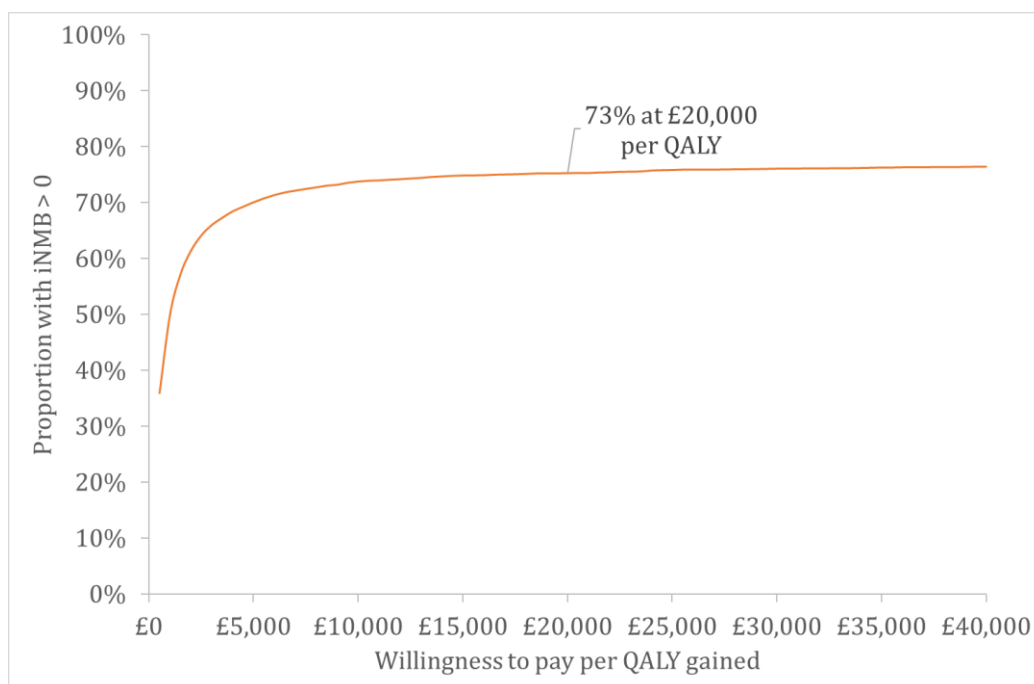


FIGURE C Cost-effectiveness acceptability curve (CEAC).

The CEAC illustrates the probability of home-based cardiac rehabilitation being cost-effective compared with usual care estimated over 5,000 samples in the probabilistic sensitivity analysis for each quality-adjusted life-year (QALY) value threshold.

Facilitator contact sheet

This is provided as supplementary material 5.

Resource use questionnaire

This is provided as supplementary material 6.

Healthcare and community health services inflation index

Taken from the Unit Costs of Health and Social Care 2016 (TABLE B):²

'The hospital & community health services (HCHS) index Hospital and community health services (HCHS) pay and price inflation is a weighted average of two separate inflation indices: the pay cost index (PCI) and the health service cost index (HSCI). The PCI measures pay inflation in the HCHS.'

The PCI is a weighted average of increases in unit staff costs. The HSCI measures the price change for each of 40 sub-indices of goods and services bought by the HCHS. The pay cost index and the health service cost index are weighted together they provides a combined pay & prices inflation figure – the HCHS.

TABLE B Pay and prices index²

Year	Pay and prices index
2005–06	240.9
2006–07	249.8
2007–08	257.0
2008–09	267.0
2009–10	268.6
2010–11	276.7
2011–12	282.5
2012–13	287.3
2013–14	290.5
2014–15	293.1
2015–16	297.0

Search strategy for cost-effectiveness models review

Medline

- 1 exp Heart Failure/
- 2 ('cardiac failure' or 'heart failure').ti,ab,kw.
- 3 1 or 2

- 4 (cost or costs or costing or econom* or budget* or financ* or pharmacoeconom* or pharmaco-econom* or price or pricing or expenditure* or affordab* or fee or fees or charg* or monetary*).ti,hw,kw.
- 5 (economic* adj2 (burden* or barrier* or restriction* or resources)).ti,ab.
- 6 ((cost or costs) adj3 (utilit* or effective* or benefit* or minimi* or model*)).ti,ab.
- 7 ((decision* or cost*) adj3 (model* or analy*)).ti,ab.
- 8 ('decision tree' or markov* or 'monte carlo' or multistate or multi-state or 'discrete event simulation' or 'discrete-event simulation' or DES).ti,ab,kw.
- 9 4 or 5 or 6 or 7 or 8
- 10 3 and 9
- 11 Animals/
- 12 Humans/
- 13 11 not (11 and 12)
- 14 10 not 13
- 15 limit 14 to ed=20100101-20160923

Embase

- 1 exp Heart Failure/
- 2 ('cardiac failure' or 'heart failure').ti,ab,kw.
- 3 1 or 2
- 4 (cost or costs or costing or econom* or budget* or financ* or pharmacoeconom* or pharmaco-econom* or price or pricing or expenditure* or affordab* or fee or fees or charg* or monetary*).ti,kw.
- 5 (economic* adj2 (burden* or barrier* or restriction* or resources)).ti,ab.
- 6 ((cost or costs) adj3 (utilit* or effective* or benefit* or minimi* or model*)).ti,ab.
- 7 ((decision* or cost*) adj3 (model* or analy*)).ti,ab.
- 8 ('decision tree' or markov* or 'monte carlo' or multistate or multi-state or 'discrete event simulation' or 'discrete-event simulation' or DES).ti,ab.
- 9 4 or 5 or 6 or 7 or 8
- 10 3 and 9
- 11 animal/
- 12 human/

- 13 11 not (11 and 12)
- 14 10 not 13
- 15 limit 14 to dd=20100101-20160923
- 16 limit 15 to english language
- 17 limit 16 to dd=20140101-20160923
- 18 limit 16 to dd=20121022-20131231
- 19 limit 16 to dd=20121018-20121021
- 20 limit 16 to dd=20121015-20121017
- 21 limit 16 to dd=20110601-20121014
- 22 17 or 18 or 19 or 20 or 21
- 23 16 not 22
- 24 17 or 18 or 19 or 20 or 21 or 23

CINAHL

- S16 S14 AND S15
- S15 EM 20100101
- S14 S10 not S13
- S13 S11 not (S11 and S12)
- S12 (MH 'Human')
- S11 (MH 'Animals')
- S10 S3 AND S9
- S9 S4 OR S5 OR S6 OR S7 OR S8
- S8 TI (('decision tree' or markov* or 'monte carlo' or multistate or multi-state or 'discrete event simulation' or 'discrete-event simulation' or DES)) OR AB (('decision tree' or markov* or 'monte carlo' or multistate or multi-state or 'discrete event simulation' or 'discrete-event simulation' or DES))
- S7 TI ((decision* or cost*) W3 (model* or analy*)) OR AB ((decision* or cost*) W3 (model* or analy*))
- S6 TI ((cost or costs) W3 (utilit* or effective* or benefit* or minimi* or model*)) OR AB ((cost or costs) W3 (utilit* or effective* or benefit* or minimi* or model*))
- S5 TI (economic* W2 (burden* or barrier* or restriction* or resources)) OR AB (economic* W2 (burden* or barrier* or restriction* or resources))

S4 TI ((cost or costs or costing or econom* or budget* or financ* or pharmacoconom* or pharmaco-econom* or price or pricing or expenditure* or affordab* or fee or fees or charg* or monetary*)) OR MH ((cost or costs or costing or econom* or budget* or financ* or pharmacoconom* or pharmaco-econom* or price or pricing or expenditure* or affordab* or fee or fees or charg* or monetary*))

S3 S1 OR S2

S2 TI ('cardiac failure' or 'heart failure') OR AB ('cardiac failure' or 'heart failure')

S1 (MH 'Heart Failure+')

EconLit

Query Results

S3 S1 AND S2

S2 (ZD '20100101') or (ZD '20100201') or (ZD '20100301') or (ZD '20100401') or (ZD '20100501') or (ZD '20100601') or (ZD '20100701') or (ZD '20100801') or (ZD '20100901') or (ZD '20101001') or (ZD '20101101') or (ZD '20101201') or (ZD '20110101') or (ZD '20110201') or (ZD '20110301') or (ZD '20110401') or (ZD '20110501') or (ZD '20110601') or (ZD '20110701') or (ZD '20110801') or (ZD '20110901') or (ZD '20111001') or (ZD '20111101') or (ZD '20111201') or (ZD '20120101') or (ZD '20120201') or (ZD '20120301') or (ZD '20120401') or (ZD '20120501') or (ZD '20120601') or (ZD '20120701') or (ZD '20120801') or (ZD '20120901') or (ZD '20121001') or (ZD '20121101') or (ZD '20121201') or (ZD '20130101') or (ZD '20130201') or (ZD '20130301') or (ZD '20130401') or (ZD '20130501') or (ZD '20130601') or (ZD '20130701') or (ZD '20130801') or (ZD '20130901') or (ZD '20131001') or (ZD '20131101') or (ZD '20131201') or (ZD '20140101') or (ZD '20140201') or (ZD '20140301') or (ZD '20140401') or (ZD '20140501') or (ZD '20140601') or (ZD '20140701') or (ZD '20140801') or (ZD '20140901') or (ZD '20141001') or (ZD '20141101') or (ZD '20141201') or (ZD '20150101') or (ZD '20150201') or (ZD '20150301') or (ZD '20150401') or (ZD '20150501') or (ZD '20150601') or (ZD '20150701') or (ZD '20150801') or (ZD '20150901') or (ZD '20151001') or (ZD '20151101') or (ZD '20151201') or (ZD '20160101') or (ZD '20160201') or (ZD '20160301') or (ZD '20160401') or (ZD '20160501') or (ZD '20160601') or (ZD '20160701') or (ZD '20160801')

S1 TI ('cardiac failure' or 'heart failure') OR AB ('cardiac failure' or 'heart failure')

Cochrane Library

#1 MeSH descriptor: [Heart Failure] explode all trees

- #2 ('cardiac failure' or 'heart failure'):ti,ab,kw
- #3 #1 or #2
- #4 (cost or costs or costing or econom* or budget* or financ* or pharmacoekonom* or pharmaco-econom* or price or pricing or expenditure* or affordab* or fee or fees or charg* or monetary*):ti,kw
- #5 (economic* near/2 (burden* or barrier* or restriction* or resources)):ti,ab
- #6 ((cost or costs) near/3 (utilit* or effective* or benefit* or minimi* or model*)):ti,ab
- #7 ((decision* or cost*) near/3 (model* or analy*)):ti,ab
- #8 ('decision tree' or markov* or 'monte carlo' or multistate or multi-state or 'discrete event simulation' or 'discrete-event simulation' or DES):ti,ab,kw
- #9 #4 or #5 or #6 or #7 or #8
- #10 #3 and #9 Publication Year from 2010 to 2016

Work package 3

Statistical analysis plan

This is provided as a standalone file on the project page of the NIHR Journals Library website.

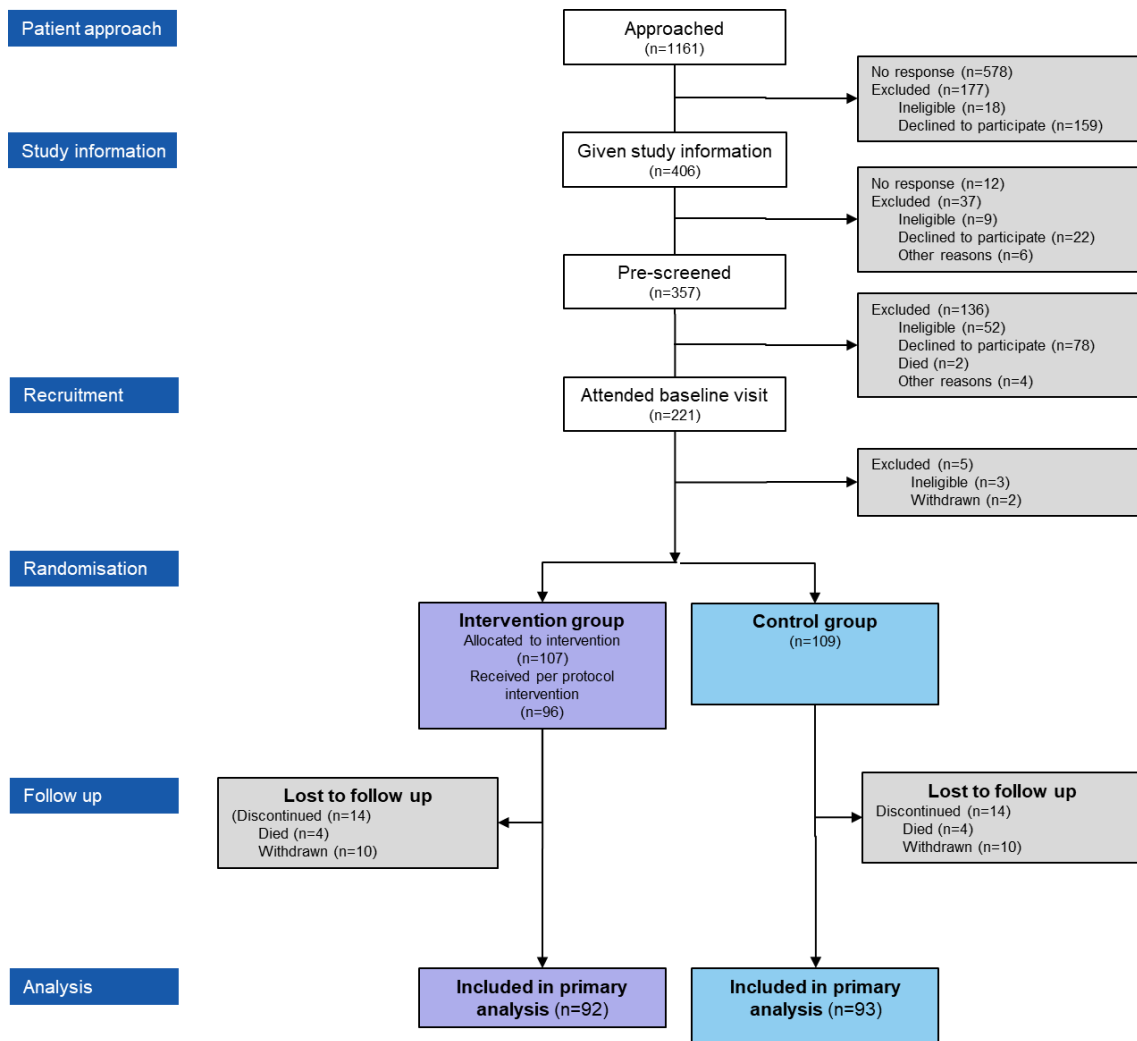


FIGURE D CONSORT diagram for REACH-HFrEF main trial

REACH-HFrEF, Rehabilitation EnAblement in CHronic Heart Failure with reduced ejection fraction.

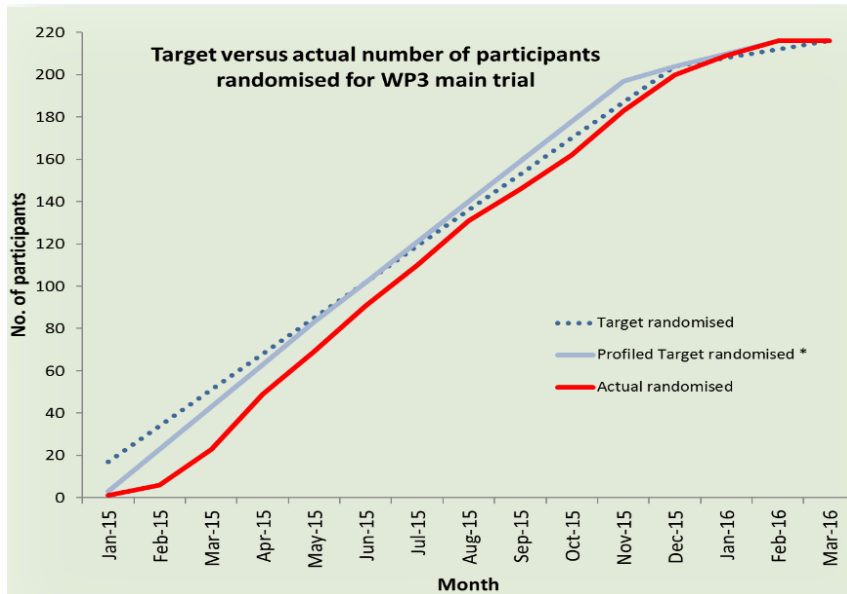


FIGURE E Target versus actual number of participants randomised for REACH-HFrEF main trial
 REACH-HFrEF, Rehabilitation EnAblement in CHronic Heart Failure with reduced ejection fraction; WP, work package.

Rehabilitation EnAblement in CHronic Heart Failure (REACH-HF)

Novel home-based self-care and rehabilitation intervention in patients with HFrEF and their caregivers

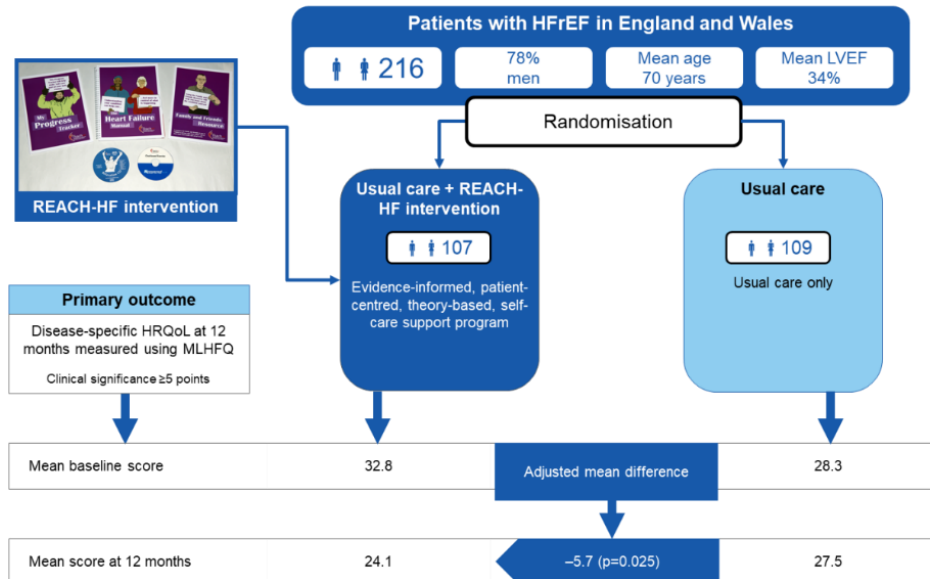


FIGURE F Infographic for REACH-HF RCT in patients with HFrEF

HFrEF, heart failure with reduced ejection fraction; HRQoL, health-related quality of life; LVEF, left ventricular ejection fraction; MLHFQ, Minnesota Living with Heart Failure Questionnaire; REACH-HF, Rehabilitation EnAblement in CHronic Heart Failure.

TABLE C Topic guide for caregiver qualitative interviews

Topic	Questions	Prompts
<p>Caregiver role pre REACH-HF</p> <p>2nd Interview</p>	<p>Pre REACH-HF</p> <p>Thinking back to before the programme started; can you describe your role in supporting your (husband, mother, son, and neighbour as relevant)?</p> <p>How did you learn what to do?</p> <p>What did you feel about your role?</p> <p>During the last interview you said.....</p> <p>How has your role changed since the last interview?</p> <p>What do you feel about your role?</p>	<p>Specifically – emotional support, physical support, medicines management, supporting physical activity</p> <p>Explore other sources of learning about the role such as from heart failure specialist nurses, GP, hospital consultant, friends and family.</p> <p>Make it clear if talking about role pre, during or post REACH-HF.</p>
<p>Engagement with the intervention</p>	<p>Before you started, what were your expectations of the REACH-HF programme?</p>	<p>Expect and explore ambivalence, uncertainty, reluctance, expectation of help and support.</p> <p>Explore priorities and goals.</p>
<p>Impact of the REACH-HF programme</p>	<p>During REACH-HF</p> <p>What sections of the manual and resource did you use and why?</p> <p>Which sections were not used and why?</p> <p>What did you learn from the programme?</p>	<p>How were the sections used?</p> <p>Was there anything you did not like about the REACH-HF programme?</p>

<p>2nd Interview</p>	<p>Post REACH-HF</p> <p>How did the programme affect your role in supporting your ***?</p> <p>How has being involved in REACH-HF affected your involvement in appointments with other health professionals including consultants or specialist nurses or GP?</p> <p>Has the programme changed the way you think or feel about your role? (Key question, confidence, sense of burden)</p> <p>Have you used the manual or friends and family resource since the last interview? How what and why used?</p> <p>Where else have you looked for information about the condition or your role?</p> <p>Internet, GP, nurse</p> <p>How do you feel about your role now? (Look for evidence of development of expertise and confidence)</p>	<p>What learning has been put into practice?</p> <p>Look for signs of development of expertise. How does the caregiver feel about becoming an 'expert' in managing heart failure?</p> <p>Control/agency</p> <p>Medicines</p> <p>Stress/anxiety</p> <p>Exercise</p> <p>Symptom monitoring and control</p>
<p>Relationship with cared for person</p>	<p>Tell me about any discussions with the person you are caring for about how you may support them in managing his/her heart failure?</p>	<p>What did the caregiver do to cope with resistance? (Where present)</p> <p>How did they manage their own feelings? What if anything has</p>

<p>2nd Interview</p>	<p>Since you started the REACH-HF programme, has what you do to support (name of cared for person) affected your relationship?</p> <p>Has anything changed about your relationship with the person you are caring for?</p> <p>How do you feel about it?</p> <p>Is there anything that stops you doing your role?</p> <p>Is there anything that helps you do your role?</p>	<p>changed in the way you manage heart failure together?</p>
<p>Relationship with Reach-HF facilitator</p> <p>2nd Interview</p>	<p>Can you describe how the facilitator worked with you?</p> <p>What did you like or dislike about how the facilitator worked with you?</p> <p>How were your needs included in the sessions?</p> <p>How do you feel now the facilitator is no longer in contact?</p> <p>Have you been in contact with the facilitator?</p> <p>How do you feel now the facilitator is no longer in contact?</p> <p>Explore potential abandonment</p>	<p>Explore the difference between the caregiver being included or just watching on.</p> <p>Did the facilitator show that he/she cared about the caregiver?</p>

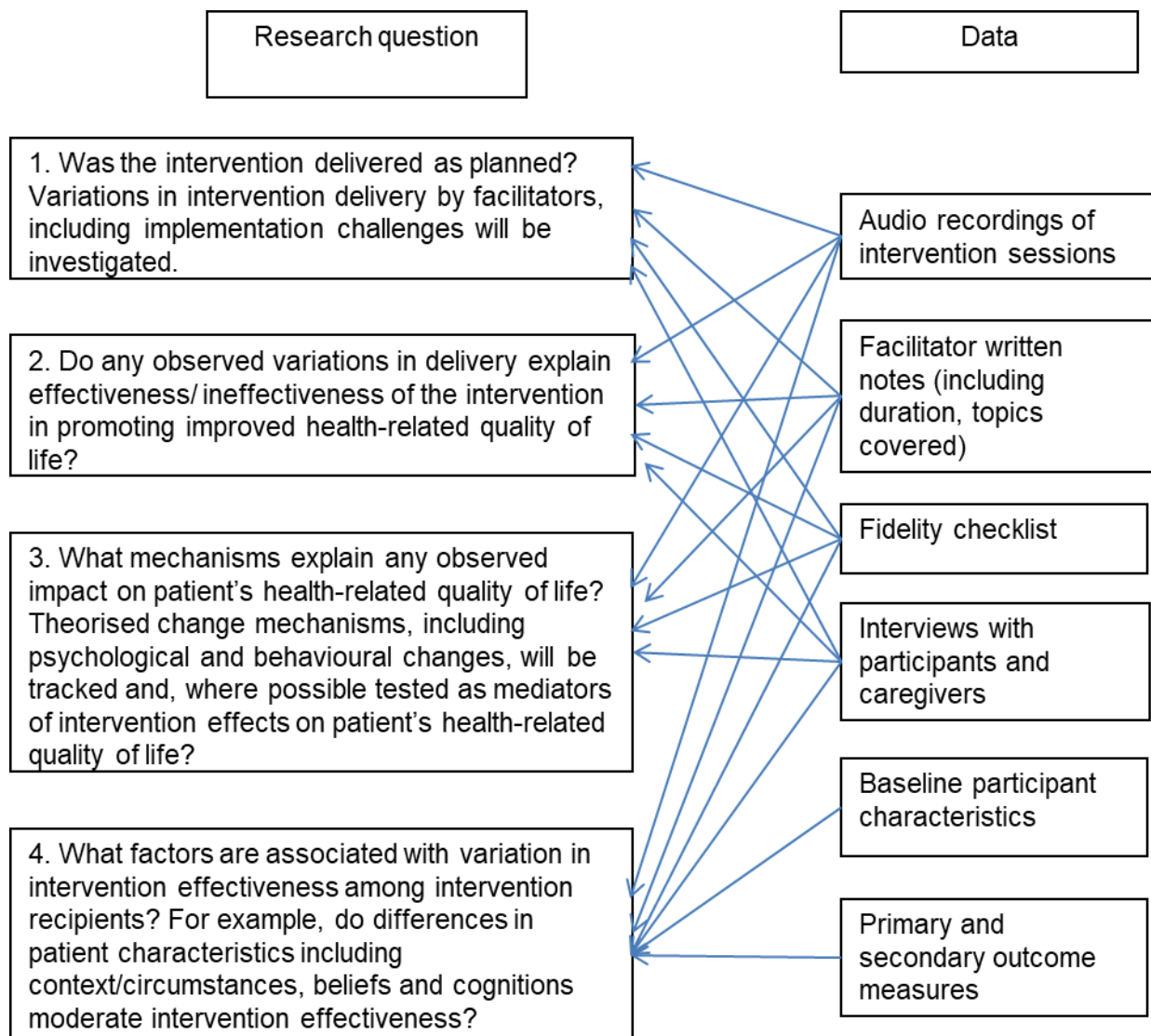


FIGURE G Sources of data used to address process evaluation questions

Newsletters

These are provided as supplementary material 7.

Podcasts from BMJ

Cardiac rehab

<https://soundcloud.com/bmjpodcasts/cardiac-rehab>

What it's like to receive cardiac rehabilitation

<https://soundcloud.com/bmjpodcasts/cardiac-rehab-patient>

References

1. Greaves CJ, Wingham J, Deighan C, Doherty P, Elliott J, Armitage W, *et al.* Optimising self-care support for people with heart failure and their caregivers: development of the Rehabilitation Enablement in Chronic Heart Failure (REACH-HF) intervention using intervention mapping. *Pilot Feasibility Stud* 2016;**2**:37.
2. Curtis L, Burns A. *Unit costs of health & social care 2016*. Canterbury: Personal Social Services Research Unit, 2016.