Title page

THE COMPLEXITIES OF IMPLEMENTATING CARDIAC REHABILITATION FOR HEART FAILURE

by

Paulina Daw

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School of Sport, Exercise and Rehabilitation Sciences
College of Life and Environmental Sciences
University of Birmingham
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Abstract

Background

There is a global underutilisation of cardiac rehabilitation in heart failure. Many patient-level factors contribute to this phenomenon (e.g., work obligations, caring responsibilities and travel costs). Less is known about wider system influences pertaining to how cardiac rehabilitation programmes are set up (e.g., commissioning structures) and run (e.g., providing group centre-based sessions only). Offering alternative modes of delivery, such as home-based programmes, can lead to an increase in the uptake of cardiac rehabilitation in this clinical population. In 2019, four 'Beacon Sites' were set up in the United Kingdom's National Health Service to deliver the home-based Rehabilitation EnAblement in CHronic Heart Failure (REACH-HF) programme to 50 patients at each site. Data generated at the Beacon Sites were used to evaluate the process of implementation in real-world clinical practice. The conducted project builds on prior research studies which led to the creation of the REACH-HF intervention (systematic review and intervention development study) and confirmed its efficacy (feasibility study, pilot trial, randomised controlled trial and process evaluation) and its cost-effectiveness (in-trial cost-effectiveness study with statistical modelling of long-term cost-effectiveness).

Methods

The projects undertaken in this thesis consisted of a systematic review and a mixed methods implementation evaluation study. The mixed methods study consisted of a qualitative study (semi-structured interviews with REACH-HF practitioners in the Beacon Sites and an online

survey with healthcare professionals who attended the REACH-HF remote training during the COVID-19 pandemic) and a quantitative study (quantitative analysis of routinely collected audit data).The systematic review used narrative synthesis and a triangulation protocol and aimed to identify and qualitatively describe provider- and system-level barriers and enablers influencing the delivery of cardiac rehabilitation for patients with heart failure.

Results

Seven articles met the inclusion criteria for the systematic review. A narrative synthesis of the data uncovered multi-level factors affecting the delivery of cardiac rehabilitation for heart failure. The mesosystem influence of the 'organisation of healthcare system' was the most prevalent category both in terms of barriers and enablers.

The mixed methods study used data from 17 interviews, 17 survey responses and pre-post outcome measures for 132 patients. There were large variations in how the Beacon Sites delivered the programme and some of the adaptations were inconsistent with the intervention delivery protocol, potentially reducing intervention effectiveness. Substantial differences in implementation patterns (magnified by the COVID-19 pandemic) and patient characteristics between the Beacon Sites and the REACH-HF trial impacted the ability to establish the real-world effectiveness of the programme. Nonetheless, the study identified a complex interacting matrix of factors affecting the implementation of REACH-HF.

Discussion

The project uncovered different factors that have the potential to influence (both positively and negatively) the general delivery of cardiac rehabilitation for heart failure and the specific implementation of REACH-HF. Where possible, the identified barriers were matched with

enablers and translated into practical solutions for improving the general and home-based cardiac rehabilitation provision for heath failure patients. The project's main output is an implementation guide – the REACH-HF Service Delivery Guide, which is published on the National Institute for Health and Care Excellence Shared Learning website.

Conclusions

My thesis generated knowledge that could help to improve the availability and delivery of cardiac rehabilitation (in particular home-based provision) for patients with heart failure (in particular patients with heart failure with reduced ejection fraction). It may also help to bridge the gap between research findings and clinical practice.

Acknowledgements

First and foremost, I would like to thank my supervisors, Prof. Colin Greaves and Dr Jet Veldhuijzen van Zanten, who gave me this amazing opportunity to immerse myself in the world of research for the last three years. As a first generation immigrant who had to complete my undergraduate and Master's degrees whilst earning a living, this was as a very special chance for me to concentrate on, what will most likely be, my last leg of academic education. Thank you both for readily sharing your research knowledge with me and offering support and encouragement throughout my PhD, without your ever generous time, support and patience I would not have been able to do it. I would also like to thank my third (unofficial) supervisor, Dr Alexander Harrison, who provided me with the quantitative data and supported me during the conduct of the quantitative phase of the project.

The doctoral project would not have been possible without many busy and important players dedicating their time and effort to set up and support the Beacon Sites. Therefore, I would like to thank the REACH-HF team for their time, dedication and support in making the Beacon Site project come to life. Namely, Prof. Colin Greaves, Dr Hasnain Dalal, Prof. Rod Taylor, Prof. Patrick Doherty, Dr Alexander Harrison, Dr Samantha van Beurden, Dr Sinéad McDonagh, Dr Carrie Purcell, the Heart Manual Department team as well as the all National Health Service staff working at the Beacon Sites. Although the Beacon Site project did not focus on patient experiences, I would like to thank all the patients who opted in to receive the REACH-HF programme, as without them no implementation would have taken place.

I would also like to thank my husband whose unwavering support and high opinion of my academic abilities got me through the low points and times when I was doubting myself. Lastly, I would like to thank my son who for the last three years helped me to strike a work/life balance in a way that only a curious toddler could.

Layout of the thesis

The submitted thesis is presented as an 'Alternative Format Thesis', which 'allows a postgraduate researcher to incorporate sections that are in a format suitable for submission for publication in a peer-reviewed journal (i.e., already published, not yet published but of publishable standard, accepted for publication, or submitted for publication)' [1].

The thesis comprises a Background chapter (Chapter 1), a Methods chapter (Chapter 2), three empirical chapters (Chapter 3, 4 and 5) and a General discussion chapter (Chapter 6). The Background chapter maps out the main discourses in the realm of heart failure, cardiac rehabilitation and implementation science. The key concepts introduced in the Background chapter are considered within the current knowledge base and the scientific literature. The Methods chapter outlines and justifies the mixed methods design and the key analytical techniques used. It also describes the practical application of methods (i.e., descriptions of study settings, participants recruitment, measures and procedures) and is augmented with the student researcher's reflexivity notes. Methods described in Chapter 2 are further expanded on in Chapters 4 and 5 where the results of the qualitative and quantitative studies are also reported and considered, respectively. The methods and empirical chapters are arranged around either a published article, a manuscript currently undergoing a process of peer review or a manuscript being considered for publication by a scientific journal. Chapter 2 includes a protocol paper published in BMJ Open in June 2020 (doi: 10.1136/ bmjopen-2019-036137). Chapter 3 describes a secondary research study in the form of a narrative systematic review and includes the systematic review paper published in BMC Health Services Research in November 2021 (doi: 10.1186/s12913-021-07174-w). This chapter describes the context

and scope for the conducted systematic review as well as it justifies the chosen analytical approach. Chapter 4 presents a qualitative study. The manuscript integrated within Chapter 4 is currently undergoing peer review with BMJ Open. Chapter 5 describes a quantitative observational study and includes a manuscript which has undergone peer review and is being consider for publication by the editor of the BMC Cardiovascular Diseases. The final Overall discussion (Chapter 6) narratively integrates results from each component of the project considering their implications for clinical practice and service provision and outlines directions for future research.

Contributions

I confirm that my contributions to the conducted studies and papers that are included in the thesis are as detailed here. With the support from my supervisors, I designed all of the described studies (e.g., choosing methods, selecting the theoretical framework and preparing the study's documentation), secured all relevant ethical approvals for the project, gathered all of the data and analysed the vast majority (the only exception was the ANCOVA analysis described in Chapter 5, which, due to information governance restrictions, was conducted by a member of the National Audit for Cardiac Rehabilitation team). I drafted all of the manuscripts and chapters acted as lead author and corresponding author for each of the published (or submitted) articles. Acknowledgement of co-authors and their contributions to papers are stated at the end of each manuscript.

Table of contents

List of figures

List of tables

List of appendices

List of abbreviations

British Association for Cardiovascular Prevention and Rehabilitation (BACPR)

Colin J Greaves (CJG)

Confidence interval (CI)

Dartmouth Cooperative Functional Assessment (COOP)

Generalised Anxiety Disorder Assessment-7 (GAD-7)

Grace Emily Rachel Wood (GERW)

Heart failure with mid-range ejection fraction (HFmrEF)

Heart failure with preserved ejection fraction (HFpEF)

Heart failure with reduced ejection fraction (HFrEF)

Heart Manual Department (HMD)

Hospital Anxiety and Depression Scale (HADS)

Incremental Shuttle Walk Test (ISWT)

Metabolic Equivalent of Task (MET)

Minnesota Living with Heart Failure Questionnaire (MLHFQ)

National Audit of Cardiac Rehabilitation (NACR)

National Health Service (NHS)

National Institute for Health and Care Excellence (NICE)

New York Heart Association Heart Failure Classification (NYHA)

Normalisation Process Theory (NPT)

Patient Health Questionaire-9 (PHQ-9)

Paulina Daw (PD)

Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)

Rehabilitation EnAblement in CHronic Heart Failure (REACH-HF)

Six Minute Walk Test (6MWT)

Strengths, Weaknesses, Opportunity, Threats (SWOT)

Thomas Withers (TW)

United Kingdom (UK)

CHAPTER 1 – BACKGROUND

Heart failure

Causes and epidemiology of heart failure

Cardiovascular disease is an umbrella term that encompasses conditions affecting the heart and/or blood vessels. Such conditions include coronary heart disease, stroke, transient ischaemic attack, peripheral arterial disease and aortic disease [2]. Cardiovascular diseases are reported by the World Health Organisation as the number one cause of death worldwide [3]. Coronary heart disease (causing angina and heart attack), high blood pressure, cardiomyopathy (disease of the heart muscle), heart rhythm problems, damaged heart valves and congenital heart disease (birth defects) can affect the physiological function of the heart and lead to heart failure [4]. Behavioural risk factors associated with cardiovascular diseases include smoking, unhealthy diet and obesity, physical inactivity, and harmful use of alcohol [5].

Heart failure is a long-term clinical syndrome that is more common in the elderly population – the median age at diagnosis is 76 years [6]. The worldwide prevalence of heart failure amongst patients under 65 years of age is estimated at 1%, whereas for those aged 75-84 it is 6-7% and for those aged 85 years and over it is 22% [7]. The United Kingdom (UK) annual incidence of heart failure is reported as 0.12% of the total population for patients between ages of 55-64 and 1.2% for patients aged 85 years and over; there are 63,000 newly diagnosed heart failure cases each year [6]. A higher incidence is observed in men – the male

to female ratio is 1.8:1, respectively [6]. The prevalence of heart failure is increasing in both developed as well as in developing countries [8].

Despite advances in treatment for heart failure, the condition is associated with high mortality rates – 17%-45% of patients diagnosed with heart failure will die within a year of the diagnosis [8]. Chronic heart failure accounts for 10% and 28% of deaths in high-income and low- and middle-income countries, respectively [9]. The average life expectancy with heart failure is 5.5 years [10] and despite a short survival time heart failure is associated with a high level of disability and morbidity [11]. Advances in the medical treatment of cardiovascular diseases has led to more patients surviving acute cardiovascular events, such as heart attacks, resulting in higher rates of chronic heart failure diagnosis each year. Due to an ageing population and improvements in device and pharmacological treatment, heart failure prevalence rates are projected to increase by 50% in the next 20 years [6]. With approximately 64.3 million [12] patients living with heart failure in the world this complex syndrome has become a global public health priority [13].

Physiology

The heart is a muscle responsible for pumping blood around the cardiovascular system. The cardiac cycle is made up of two phases diastole (relaxation phase – the heart fills up with blood) and systole (contraction phase – the heart pumps out the blood through the aorta into the pulmonary artery) [14]. The amount of blood the heart pumps out during the systole phase is called the ejection fraction and for a healthy heart is around 60% of the total volume of blood present in the heart after a diastole phase. In patients with heart failure that amount

is reduced due to the left ventricle's inability to contract sufficiently, usually caused by damage to the heart muscle (often from a heart attack or valve problems). This is called heart failure with reduced ejection fraction (HFrEF) and also systolic heart failure. The ejection fraction in patients with HFrEF is usually below 40% [15]. Another type of heart failure is heart failure with preserved ejection fraction (HFpEF), also called diastolic heart failure. HFpEF occurs when the left ventricle is not able to relax normally (due to the stiffness of the muscle) in order to allow the heart to sufficiently fill up with blood during the diastole phase. The stiffness of the heart muscle is often associated with age-related structural and functional changes to the heart muscle (for example, a reduction in elastane and collagen production), and it can be accelerated by inactivity and/or cardiovascular diseases, for example, coronary artery disease or high blood pressure [16, 17]. Therefore, the symptoms in HFpEF are not caused by the heart's inability to eject the blood efficiently but are due to the reduced amount of blood available in the heart to circulate around the cardiovascular system. The ejection fraction in patients with HFpEF is usually around 50% [15].

More recently, a new type of heart failure (that falls between the two main types), heart failure with mid-range ejection fraction (HFmrEF), was put forward in the 2016 European Society of Cardiology Guidelines for the diagnosis and treatment of acute and chronic heart failure [18]. Patients diagnosed with HFmrEF have ejection fraction between 40% and 49% and a distinct clinical profile compared to patients diagnosed with HFrEF or HFpEF [15, 19, 20]. Following the introduction of the new category of heart failure, research studies highlighted that the HFmrEF is, in fact, more akin to HFrEF rather than HFpEF, especially in terms of aetiology and outcomes (i.e., patients with HFmrEF benefit from the same treatment

options as patients diagnosed with HFrEF [21, 22]). Presently, there are calls to rename the new category to heart failure with *mildly reduced* ejection fraction [23, 24].

The heart's inability to pump the blood efficiently reduces the amount of oxygen-rich blood circulating round the body, this can have a detrimental effect on other organs, for example, lungs, kidneys or liver. Observable signs of heart failure include a third heart sound (gallop rhythm), hepatojugular reflux (swelling of the neck vein, when pressure is applied to the patient's liver), hepatomegaly (enlarged liver), splenomegaly (enlarged spleen), ascites (abdominal oedema), pulmonary crackles and raised jugular venous pressure. The observable signs of heart failure are caused by abnormal heart dynamics, for example, severe mitral regurgitation (when the valve between heart chambers does not prevent the blood from leaking out), a low ejection fraction or restrictive diastolic filling (filling during the relaxation phase of the cardiac cycle) [25].

Heart failure, especially HFpEF, is often difficult to diagnose and requires obtaining a thorough medical history. Dyspnoea (shortness of breath), peripheral oedema (fluid retention) and fatigue are the three cardinal signs of heart failure. Other symptoms of heart failure include orthopnoea (breathlessness when lying flat), appetite disturbances, nausea, confusion, memory problems, paroxysmal nocturnal dyspnoea (severe shortness of breath at night), cough, palpitations and cyanosis (blue skin or lips caused by a lack of oxygen) [7]. If heart failure is suspected the National Institute for Health and Care Excellence (NICE) recommends performing a blood test to measure the level of N-terminal pro-B-type natriuretic peptide, which is a hormone produced by the heart [26]. However, performing an

echocardiogram on a patient with suspected heart failure is the most accurate way of diagnosing this condition, as it allows assessment of any structural abnormalities in the heart and a direct quantification of the heart's ability to pump efficiently. A common complication of heart failure is decompensation, usually caused by fluid retention leading to multiple systems failure, which can be life threatening.

The burden of heart failure

Burden on patients

Apart from higher death rates observed amongst this clinical population, patients with heart failure often experience a significant decrease in health-rated quality of life [27], inability to perform daily activities [28] and a myriad of social and psychological consequences of heart failure, for example, a lack of control, isolation and anxiety [29]. The reduction in health-related quality of life is mainly associated with the burdensome symptoms of heart failure, namely, shortness of breath, a lack of energy, pain, drowsiness and a dry mouth [30]. Women in particular suffer from a greater functional impairment and a more diminished health-related quality of life compared to men. This is due to several factors, including age difference (women with heart failure tend to be older) and survival time (women tend to live for longer after the initial heart failure diagnosis). In addition, women are more likely to be widowed (live on their own) and suffer from comorbidities, such as renal failure, obesity and depression [31, 32]. Furthermore, patients with heart failure often have a number of cardiac and non-cardiac comorbidities, which further impact on their quality of life and complicate their heart failure treatment [33].

Burden on caregivers

In parallel to medical treatment and professional care, patients with heart failure often require support in performing activities of daily living [28]. The burden of daily care often falls on non-professional support in the form of family and friends and can lead to a reduced quality of life and diminished physical and psychological (e.g., increased anxiety and depression) health in the caregiver [34-38].

Caregivers who are Caucasian, unemployed, single and those caring for more than one person experience significantly higher levels of self-reported caregiver burden [39]. Several studies confirmed that the burden of care is higher in caregivers supporting patients with more advanced heart failure, a greater symptom profile and a lower quality of life [34, 40]. The quality of a relationship between the patient with heart failure and their caregiver is 'positively associated with caregiver benefit and negatively associated with burden' [41].

The latest Care Act [42] and the clinical guidance on the diagnosis and management of heart failure issued by the NICE [26] recognise the role and needs of informal carers and encourage such carers to be involved in the decision-making about heart failure treatment/management. Unfortunately, caregivers continue to be largely excluded from heart failure treatment [43] and they continue to lack sufficient knowledge of heart failure and heart failure management [44].

Burden on the healthcare system

Debilitating heart failure symptoms, complex comorbidities and frailness often present in patients with heart failure, is making the treatment of this clinical population and the management of heart failure very difficult. Patients with heart failure often experience frequent hospitalisations, re-hospitalisations, disability and becoming institutionalised; heart failure can often be the cause of death [45]. Advanced pharmacotherapy, costly care and frequent hospitalisations account for the main healthcare expenditure of the management of heart failure [11]. In fact, hospitalisations associated with the worsening of heart failure symptoms, some of which are unnecessary [46], account for the main part of the financial burden of heart failure [47, 48]. Stewart et al. estimated that the treatment and management of patients with heart failure account for nearly 2% of the total National Health Service (NHS) budget [11, 26].

A number of precipitating factors are associated with the worsening (decompensation) of heart failure, which often leads to re-hospitalisations. Such factors include non-adherence to self-care routines (daily weighing and symptom monitoring) [49], failing to take prescribed medication [50], non-compliance with required dietary changes [51] and failure to seek timely medical care for worsening symptoms [52-54]. Modifications to lifestyle behavioural factors (i.e., obesity, a lack of physical activity and increased levels of emotional stress) are crucial in the prevention and treatment of heart failure [55]. These require not only appropriate professional and caregiver support, but also self-management from the patient.

Self-care in heart failure

Self-care is an essential component of contemporary heart failure management, it complements pharmacological treatment and it can improve the quality of life of patients as well as lowering mortality rates and reducing hospital readmission rates [56-60]. Self-care behaviour has been identified as contributing to the maintenance of a physiological equilibrium, psychological health and an improved health-related quality of life [61]. Sustained good quality self-care has been linked with improved health outcomes in this clinical population [62]. The care delivered by specialised heart failure teams results in a stronger adherence to self-care techniques [57]. However, informal caregivers also play a very important role in the daily self-care involved in heart failure management [63, 64]. It has been established that simple self-care measures can mitigate the risks linked with the worsening of heart failure thus reducing the burden of suffering for patients with heart failure and their caregivers as well as reducing the financial burden of heart failure on healthcare providers [51, 61, 65].

Self-care behaviours can be grouped into the following categories: adherence to medication, diet and exercise, monitoring and self-management of symptoms, daily weighing in order to assess fluid retention, and seeking help if symptoms deteriorate. Such self-care behaviours can be further expanded to include symptom recognition, fluid management, nutrition and weight management, smoking cessation and reduction in alcohol intake, an increase in physical activity, timely immunisations, the treatment of stress, anxiety and depression (which are often by-products of living with a long-term health condition), and sleep management. Despite some gaps in the evidence-base for the effectiveness of self-care

interventions [66], recommendations for self-care behaviours have become firmly embedded in guidelines for the treatment of heart failure and are accepted and mostly adopted by multidisciplinary healthcare providers worldwide [56, 67, 68].

Cardiac rehabilitation

Historically, cardiac rehabilitation consisted of a period of supervised exercise training aimed to help an individual to return to an acceptable level of activity following a cardiac event, for example, myocardial infarction [69, 70]. Since the 1930s, cardiac rehabilitation exercise programmes, which were offered primarily to middle-aged male patients with a view to help them return to gainful employment [71], underwent substantial transformations and evolved into multicomponent complex behavioural interventions [72, 73].

Contemporary cardiac rehabilitation programmes broadly comprise of three core components – exercise training, psychological interventions and psychosocial interventions [74]. These components often include exercise therapy, cardiovascular risk factor education, psychological support and tailored lifestyle change techniques aimed at reducing behavioural risk factors described earlier in the chapter (e.g., poor diet and inactivity) [5]. In 2017, the British Association for Cardiovascular Prevention and Rehabilitation (BACPR) outlined six core components for cardiovascular disease prevention and rehabilitation. They include health behaviour change and education, lifestyle risk factor management, psychosocial health, medical risk management, long-term strategies, and audit and evaluation [75]. Cardiac rehabilitation programmes meet the Medical Research Council's definition of complex interventions, as they have a number of interacting components, often demand sufficient

skills and knowledge from those delivering and receiving the intervention, target different patient groups and/or involve different healthcare professionals, produce variability in outcomes, and offer a degree of flexibility and tailoring in the application [76].

Experts agree that patient education is an important part of any cardiac rehabilitation programme. According to the BACPR the core component of 'health behaviour change and education' is central to the delivery of all other components of cardiovascular prevention and rehabilitation programmes [77]. Koongstvedt described patient education as 'the process by which health professionals and others impart information to patients that will alter their health behaviours or improve their health status' [78]. Patient education is often delivered in the form of self-management programmes that are aimed at increasing patient participation and confidence in the management of their chronic condition [79]. Self-management programmes are delivered in a way that complements and increases the potency of the medical/pharmacological treatment and are associated with improved health outcomes and decreased health complications [80].

Several systematic reviews have confirmed that educational interventions during cardiac rehabilitation can have a positive effect on behavioural change in cardiac patients. For example, offering patient education programmes is positively associated with an increase in physical activity, healthier dietary habits and smoking cessation in this patient group [81-84]. However, the 2014 review also pointed to an unclear relationship between patient educational programmes and cardiac symptoms, adherence to prescribed medication and psychosocial wellbeing [84]. This ambiguity could be linked with poor description of

educational components by developers of interventions, poor operationalisation of educational interventions by healthcare staff or reliance on patient self-reported measures to detect: improvement in health status and/or an increase in self-care behaviour.

Availability, types and uptake

A global survey confirmed that cardiac rehabilitation is only available in 50% of the countries in the world [85] and when available there are large variations in the content of such programmes [86, 87]. An overview of six Cochrane systematic reviews of cardiac rehabilitation, which included 148 randomised controlled trials involving 98,093 participants, concluded that there is a great variation in terms of the different components of cardiac rehabilitation programmes (tailored vs generic protocol based programmes), the delivery method of such programmes (centre-based, home-based, group, individual), the duration (one to 30 months) and the theoretical underpinnings of the patient education component (some were delivered by trained healthcare professionals in accordance with established educational theories, others used peers to share their lived experience of heart disease and different anecdotal tips on the management of the syndrome) [74]. There are also differences in terms of the content of psychological and psychosocial interventions offered as part of cardiac rehabilitation programmes. Some programmes are aimed at improving the patient's professional and non-professional/informal support systems [88, 89], some offer evidence-based treatment targeting psychological issues that might be present, for example, depression [90], whereas others offer specific lifestyle advice (e.g., smoking cessation or diet advice) [91, 92]. There are many variations in the content, delivery and outcomes of cardiac

rehabilitation programmes, hence such programmes meet the complex intervention criteria introduced by the Medical Research Council (as described earlier in the chapter).

Group-based programmes taking place in hospitals and community centres are the most common mode of delivery of cardiac rehabilitation [93]. Various studies have highlighted additional benefits associated with group-based delivery, namely, increased social support and motivation to exercise [94, 95]. Recently, alternative models of delivery, such as home-based programmes or programmes using telemedicine technology, are gaining recognition in the field [96], especially as their efficacy, cost-effectiveness and safety are similar to centre-based programmes [93, 97-100].

During the COVID-19 pandemic when many centre-based cardiac rehabilitation programmes were suspended, there was an increased interest in, and utilisation of, remote and technology-based interventions [101, 102]. There is an optimism amongst clinicians and researchers that the period of disruption to the delivery of centre-based programmes caused by the COVID-19 pandemic will result in lasting positive changes in how cardiac rehabilitation programmes are delivered [103, 104]. If sustained, such adaptations/improvements will contribute towards the NHS Long Term Plan's ambitious commitment to increase the uptake of cardiac rehabilitation amongst eligible patients to 85% by 2028 [105].

Cardiac rehabilitation for heart failure

The current national guidance (NICE, the Scottish Intercollegiate Guideline Network, the British Association for Cardiovascular Prevention and Rehabilitation), European guidance (the

European Society of Cardiology) and international guidance (the American College of Cardiology and the American Heart Association) recommend cardiac rehabilitation as a safe and efficacious treatment for patients with heart failure [18, 26, 75, 106, 107]. Despite evidence on the effectiveness (i.e., an increase in health-related quality of life and a reduction in hospitalisations), the safety and the cost-effectiveness [74, 108-111] of cardiac rehabilitation, the uptake in eligible patients with heart failure is suboptimal and estimated at less than 20% in Europe [112] and around 50% in the UK [113]. The referral rate for cardiac rehabilitation amongst patients hospitalised for heart failure between 2018 and 2019 in England, Wales and Northern Ireland was 13.3% [114]. The uptake of cardiac rehabilitation is particularly low in women, the elderly, patients living in remote/rural or low socio-economic areas, ethnic minorities, and patients with mental health comorbidities [113, 115-119].

There are many reasons for the low uptake of cardiac rehabilitation. Some of the reasons are linked with healthcare professionals and how the services are delivered. For example, 'a common misperception that women are naturally protected from cardiovascular disease and risk factors by oestrogen' or a confusion about who can benefit from cardiac rehabilitation might stop the clinician from recommending cardiac rehabilitation to their female patients [120, 121]. A lack of a standardised referral system and inadequate communication between healthcare professionals might also prevent a timely cardiac rehabilitation referral [122]. It is also reported in the literature that there is a persistent perception amongst clinicians that patients with heart failure are too ill to exercise (this is often linked with the previous practice of recommending bed rest to patients with heart failure [87, 123]) or that there are severe safety concerns linked with exercising this frail and complex clinical population [124]. Such

safety concerns have been reinforced by outdated and underpowered trials. For example, an underpowered exercise trial conducted by Jugdutt et al. reported adverse remodelling following a period of exercise in patients after anterior q-wave myocardial infarction [125]. The authors of the trial concluded that 'exercise training might be injurious in patients with an extensive transmural infarct that has not healed completely' [125]. Additionally, a continually scarce evidence-base, particularly in support of cardiac rehabilitation in HFpEF patients [124, 126], reinforces safety concerns and ignorance amongst clinicians about the benefits of cardiac rehabilitation in this patient population [127].

There are also patient-level factors which can negatively or positively impact the uptake, these include financial constraints, travelling distance to the cardiac rehabilitation centres and work obligations [128]. A review from 2015 investigated the non-adherence to cardiac rehabilitation programmes and linked it to the patient's 'psychological wellbeing, geographical location, access to transport, and a dislike of group based rehabilitation sessions' [129]. A qualitative study from 2006 found the patients preference between hospital-based and home-based cardiac rehabilitation programmes to be slightly in favour of the latter [130]. Patients who preferred home-based support believed that such a programme needed to fit around their lives. They disliked groups and were sceptical about being able to make practical arrangements to attend hospital-based sessions. They were also confident that they had enough self-discipline to benefit from cardiac rehabilitation undertaken in the comfort of their home. On the other hand, patients opting for the centre-based programmes believed that they lacked the self-discipline to engage with a home-based programme and they took comfort from supervised exercise sessions. These patients also yearned for

camaraderie and interaction during group sessions and were able to make necessary arrangements to attend such sessions [130]. This study shows that both ways of delivering cardiac rehabilitation have advantages and disadvantages and patient choices are linked with their circumstances, personality and preferences.

One way of increasing participation in cardiac rehabilitation is to offer alternative models of delivery, such as home-based interventions [96, 126, 131] and programmes using digital technology, to supervise, monitor and support self-care [104, 132, 133]. A systematic review conducted in 2015 explored alternative models of cardiac rehabilitation (i.e., telehealth, home-based, community-based, internet-based and complimentary therapies) and concluded that telehealth interventions that were multifactorial and individualised as well as community and home-based cardiac rehabilitation programmes, are 'effective alternative models of cardiac rehabilitation, as they have produced similar reductions in cardiovascular disease risk factors compared with hospital-based programmes' [134]. The Heart Manual is the most commonly used alternative to hospital-based cardiac rehabilitation programmes in the UK [129, 135].

The Heart Manual

The Heart Manual is a self-management programme for patients who suffered myocardial infarction and/or revascularisation, which was originally developed in 1992 [136]. The Heart Manual training for service providers is coordinated by staff from the Heart Manual Department (HMD) (NHS Lothian, Edinburgh). Since 1992 the manual has been updated in line with emerging evidence. In its current format, it is 'the most widely investigated,

validated and recommended programme for an increasing number of patients and health authorities and continues to provide, very importantly, an evidence-based approach, assisting the recovery of around 14,000 patients every year in the UK and abroad' [137]. The programme was recommended in a number of national guidelines [138], professional competence guidance [139] and government policies [140]. It has been endorsed by the American Association of Cardiovascular and Pulmonary Rehabilitation, the American Heart Association, the American College of Cardiology [96] as well as the National Audit of Cardiac Rehabilitation (NACR) [141].

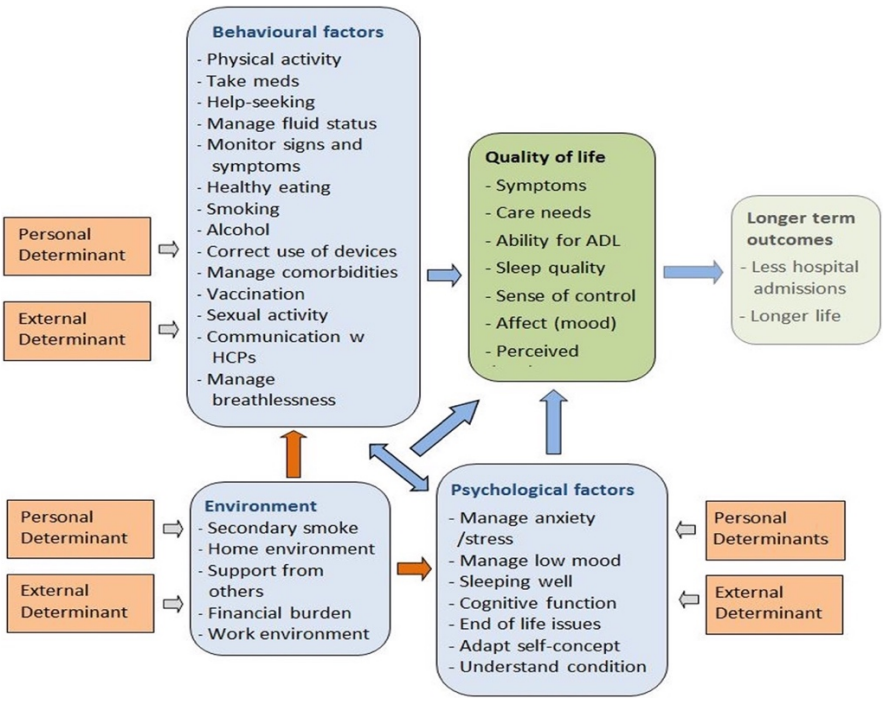
Rehabilitation EnAblement in CHronic Heart Failure (REACH-HF)

Below is a chronological summary of research activities, which took place prior to the current doctoral project, the beginning of this project is marked by setting up the Beacon Sites in January 2019 (described under the heading 'Beacon Sites' later on in the chapter). In January 2013, the National Institute for Health Research funded a research study under the Programme Grants for Applied Research scheme (project reference RP-PG-1210-12004). The project aimed to a) develop a novel home-based cardiac rehabilitation programme for patients with heart failure, b) pilot an effectiveness/cost-effectiveness trial of the intervention with patients with HFpEF and c) investigate the efficacy and cost-effectiveness of adding the innovation to HFrEF usual care in a full-scale randomised controlled trial [142]. The research team consisted of experts in research methodology (i.e., medical statistics, health economics, qualitative research, psychology, health behaviour change, evidence synthesis and modelling) and clinical practice (i.e., cardiology, primary care, cardiac rehabilitation, nursing and physiotherapy) [143]. Additionally, there was a strong involvement from members of the

HMD team, service users (i.e., patients with heart failure and their carers) and other key stakeholders (i.e., healthcare professionals working with patients with heart failure, commissioners and service providers, and experts in the field). The £2 million grant funded a systematic review, intervention development project, feasibility study, pilot trial involving HFpEF patients, randomised controlled trial (including cost-effectiveness analysis) with HFrEF patients, qualitative process evaluation and statistical modelling of long-term cost-effectiveness.

The intervention development team used the intervention mapping approach [144] to identify the key targets for change. In the case of heart failure self-care, this consisted of exercise training, monitoring for deterioration of heart failure symptoms, managing the psychological consequences of heart failure (e.g., stress and anxiety), medication management and a better general understanding of the condition [145]. The utilisation of mixed methods (i.e., systematic review, document/guidelines analysis, site visits, interviews and focus groups, and surveys) and meaningful involvement of key stakeholders resulted in the specification of the Rehabilitation EnAblement in CHronic Heart Failure (REACH-HF) programme. Figure 1 depicts the intervention's overview level causal model.

Figure 1 REACH-HF causal model (from Greaves et al., 2016)



Intervention components

The REACH-HF programme uses the main cardiac rehabilitation components (described earlier in the chapter) to improve self-care behaviours in patients with heart failure as well as to provide support and guidance to their caregivers. This home-based programme comprises of the following components (Figure 2): an in-depth booklet describing heart failure and the principles of heart failure self-care, two exercise training regimes (chair-based delivered via DVD or online videos and a walking programme), a stress management programme (delivered via CD or online audio), a progress tracker (to be used for goal setting, reviewing of progress and symptom tracking), and a family and friends booklet, which educates caregivers on the topic of heart failure and encourages ongoing self-care on their behalf. This holistic programme requires facilitation from a healthcare professional (most often, but not

exclusively, a cardiac rehabilitation nurse) who attended the REACH-HF facilitator training (either in-person over three days or online over two days). For the duration of 12 weeks, each patient with heart failure enrolled onto the programme and, if available, their caregiver receive a mixture of home visits and telephone calls, during which they will be offered exercise prescription, learn about heart failure and self-management techniques (that can lead to an improved quality of life) as well as discuss how to cope better with stress, anxiety and depression. The patient's progress can be easily reviewed during sessions with the progress tracker. The different components of the programme are delivered using the principles of person-centred care and person-centred communication style. The programme requires tailoring to the unique circumstances of each patient by the REACH-HF facilitator.

Figure 2 The REACH-HF resources

Trial outcomes

During the multi-centre randomised controlled trial, a total of 216 patients with HFrEF and 97 caregivers were randomised into the intervention arm – REACH-HF and usual care (n=107) and control group – usual care alone (n=109) [146]. The trial recruited mostly retired (76%) males (78%) from white ethnic backgrounds (94%) whose mean age was 70 years. The primary outcome measure used was the Minnesota Living with Heart Failure Questionnaire (MLHFQ) – a widely used and accepted patient-reported questionnaire that measures the perception of the impact of heart failure on a patient's quality of life [147].

At 12-month follow-up, based on the data from 185 (86%) participants, the between-group difference in the health-related quality of life was in favour of the treatment arm with a statistically significant and clinically meaningful reduction of 5.7 points on the MLHFQ score (95% CI -10.6 to -0.7, p=0.025). Additionally, following the secondary analysis, the maintenance score from a self-care measure, the Self-Care of Heart Failure Index [148], was also in favour of the intervention group.

Participants enrolled on the REACH-HF programme received on average 6.5 sessions facilitated by the REACH-HF practitioners. The average overall healthcare professional time required to deliver the intervention (clinical and non-clinical) was 8.25h. The total average cost of adding REACH-HF into the usual service delivery was estimated at £418 per participant; this amount included the clinical time, cost of training, travel and resources and fell within the NHS tariff for cardiac rehabilitation. A subsequent 'enhanced dissemination'

project involved appointing four cardiac rehabilitation teams to become the REACH-HF programme early adoption (beacon) sites [142].

Beacon Sites

The opportunity to become a Beacon Site was widely advertised through formal (conferences) and informal (communication with key stakeholders) channels. A total of 12 cardiac rehabilitation teams completed the application form, six were shortlisted and invited to a panel interview. Following a brief selection process, four Beacons Sites from diverse areas of England and Northern Ireland were appointed in January 2019. To allow participation in the Beacon Site roll-out, three healthcare professionals from each appointed cardiac rehabilitation team attended the REACH-HF training in May 2019. The training was delivered by the HMD team, NHS Lothian – the same training provider that delivered the REACH-HF training for healthcare professionals who took part in the REACH-HF clinical trial. The training included sessions on psychology, behaviour change, physical activity and exercise, engaging the caregiver, and how to successfully facilitate the delivery of the intervention. Following the initial training, the NHS staff working at the Beacon Sites were able to contact the research team, the REACH-HF trainers and the NACR team with any implementation and data-entry related questions. REACH-HF practitioners from three Beacon Sites were available to take part in an hour and a half long peer-support session facilitated by the REACH-HF trainers in December 2019. The purpose of this virtual meeting was to help embed the learning from the initial training and troubleshoot any implementation problems. Additionally, the chosen Beacon Sites received REACH-HF resources (training manuals and patient materials – printed booklets, DVDs and CDs) for the treatment of 200 patients (50 patients each).

In order to maximise the roll-out of the innovation, the Beacon Sites were required to have referral routes/access to patients with heart failure and be willing to offer the REACH-HF programme to 50 patients during the Beacon Site project (i.e., June 2019 to June 2020). This prerequisite created a potential bias towards larger well-established cardiac rehabilitation centres, which might not have been fully representative of the national cardiac rehabilitation provision. Yet, choosing cardiac rehabilitation teams which were more representative of a typical size or patient throughput found in such services nationally, might have limited the service's ability to engage and test out the intervention. For example, the team might not have been big enough to appoint three healthcare professionals to attend the REACH-HF training and become REACH-HF practitioners.

The Beacon Sites were expected to report high-quality patient data to the NACR as well as to allow research activities relevant to the REACH-HF implementation; including interviews, site visits and audio recordings of the REACH-HF sessions. The main aims of the Beacon Site project were to compare patient sample and patient outcomes to prior clinical trial data, to determine the fidelity of delivery and to identify barriers and facilitators impacting the implementation process.

Implementation science

Implementation science is a branch of applied health research which investigates the science of implementation of evidenced-based practices into real-world clinical settings. Implementation has been a topic of research in various disciplines for many years, for

example, medical sociology [149], communication studies [150], marketing [151], health promotion [152], organisation studies [153, 154] and management [155, 156]; early literature on implementation science, includes works by Rogers and Wolf [157, 158]. Despite having great potential to speed up the translation of research findings into clinical care, the process of implementation is often an afterthought during intervention design and efficacy trials [159].

The year 2005 is often quoted as the year of inception of this emerging discipline, as it coincided with the launch of Implementation Science – a journal 'dedicated to publishing evidence regarding methods for promoting the uptake of consolidated research findings into routine healthcare practice and health policy' [160]. Additionally, during the early 2000s, two important articles pertaining to the science of implementation were published. These included, published in 2004 'Diffusion of Innovations in Service Organizations' – a systematic review and recommendations by Greenhalgh et al. and 'A Synthesis of the Literature' published in 2005 by Fixsen et al. [161, 162]. Since then, national and international organisations issued various guidelines and reports exploring issues and concepts pertinent to implementation science. These include 'The Spread Challenge' [163] published by the Health Foundation, 'Crossing the Quality Chasm' published by the Institute of Medicine [164], two publications issued by the Medical Research Council ('Process evaluation of complex interventions' [165] and 'Developing and evaluating complex interventions' [166]) as well as the World Health Organisation's 'Implementation research in health', in which the implementation of evidence-based practice was described as one of the greatest challenges facing the global health community [167].

Implementation science developed as a response to four complex phenomena within the field of evidence-based medicine – ineffectiveness of the traditional research pipeline, under-utilisation of evidence-based practice, the assumption that robust interventions will lead to automatic change in behaviour and the issue of sustainability [168]. The traditional research pipeline follows a predictable linear pattern and is often conceptualised into the following steps: discovery (idea, basic research), development (clinical trial, efficacy study) and delivery (regulatory approval, patient care) [169]. In practice, however, very rarely does the journey between clinical innovation and change in clinical practice follow the develop-test-launch pattern [170]. In fact, only a fraction of evidence-based interventions become embedded in a routine service provision [171, 172]. This represents a significant waste of resources with a lot of funding spent on developing interventions that never reach their target population.

Even when healthcare innovations become implemented into routine clinical practice there is often a substantial time lag between the efficacy trial and the widespread adoption, often estimated at 17 years [172-175]. More recent research studies pointed out the many complexities associated with estimating a general time lag, for example, that there is a lack of agreement about what constitutes the beginning and end of such a time lag and that a single figure is not representative of different adoption speeds observed in relation to different disciplines [176, 177].

In summary, the ineffectiveness of the traditional research pipeline (i.e., many interventions successfully tested in research settings do not filter through to clinical practice) [174] and the

time lag in translating evidence-based interventions into clinical practice, together with the call for greater research and clinical accountability as well as an increasing need for offering cost-effective services [168] led to further interest and investment in the developing science of implementation. Despite the discipline being in its infancy, the body of empirical evidence is growing at a very rapid rate, for example, the Implementation Science journal saw an increase from 100 manuscripts submitted in 2006, which was one year after it started publishing in 2005, to over 750 manuscripts received in 2015 [178]. Alternative research pipelines have been design to guide a more efficient journey between discovery and clinical practice. One of them is the National Center for Complementary and Integrative Health Framework for Clinical Research (Figure 3) [179].

Figure 3 Alternative research pipeline (from Clark et al., 2021)

Definitions

The most commonly used definition of implementation science was put forward in 2006 by Eccles and Mittman. It describes the implementation in healthcare as 'the scientific study of methods to promote the systematic uptake of clinical research findings and other evidence-based practices into routine practice, and, hence, to improve the quality and effectiveness of health services. It includes the study of influences on healthcare professionals and organisational behaviour' [170]. This definition has been used as a starting point and a foundation and for all research activities in the thesis.

Building on the above definition, the Science of Implementation in Health and Healthcare (a division of the National Institutes of Health in the United States of America) highlighted that implementation science studies need to use 'innovative approaches to identify, understand and develop strategies for overcoming barriers to the adoption, adaptation, integration, scale-up, and sustainability of evidence-based interventions, tools, policies, and guidelines' [180]. Indeed, *innovation* (for example, in the form of pioneering technology-based intervention delivery methods or inventive implementation strategies) has become a dominant discourse present within this developing branch of healthcare research. This commitment to innovation is influencing novel research designs and methods that combine elements of clinical effectiveness and implementation research to enhance public health impact (e.g., pragmatic designs, effectiveness-implementation hybrid designs and inventive mixed methods studies [168, 181-183]) as well as interactive implementation strategies (e.g., audit and feedback, educational outreach, and reminders [184]). There is an expectation within the research community that such innovations will help to overcome the

ineffectiveness of passive implementation strategies and help narrow the research-to-practice gap [171, 183].

The importance of theory

The importance of using theoretical foundations whilst developing healthcare interventions is well-documented. Interventions based on theory outperform those that are atheoretical [185]. Many behaviour change interventionists are guilty of not linking, or linking insufficiently, the intervention with a theoretical model [186, 187]. This is often connected with the developers' inability to successfully choose the most suitable theory for a given intervention [188], compounded by a large number of overlapping models that are available [189] and a comparative lack of guidance on how to use them [190]. Even when selected, the application of a theoretical framework often lacks rigour [187, 191]. The plethora of different overlapping theories, models and frameworks as well as a relative lack of guidance as to how to choose and use them is also present in the realm of implementation science [192].

Meta-analysis conducted by Davies et al. discovered that only 22.5% of 235 implementation studies explicitly used theories of behaviour change [186]. An international survey conducted with implementation researchers highlighted that implementation theories, models and frameworks are often underused, misused or used in a tokenistic way [193]. The authors of the survey concluded that poor engagement with theories 'pose[s] a substantial scientific challenge for implementation science' [193]. Eccles et al. are in agreement about the importance of the implementation research having clear theoretical foundations, as a lack of

such foundations can lead to ‘an expensive version of trial-and-error, with no a priori reason to expect success, nor confidence in replicating success, if achieved’ [194].

Implementation theories, models and frameworks

An overwhelming number of theories, models and frameworks can be used to guide the evaluation of the implementation process. In their 2012 review, Tabak et al. reported over 60 implementation frameworks [195]. Others have since reported the existence of more than 100 different theories, models and frameworks in the field of implementation science [193]. Researchers are often faced with a dilemma as to which one of the many available options is the most suited for the implementation project they are designing and conducting. Up until very recently, the guidance on the issue was scarce and inconclusive. Nilsen organised the many implementation evaluation tools into five categories, namely, process and action models, determinant frameworks, classic theories, implementation theories, and evaluation frameworks [196].

Process models define the process of implementation in rational linear terms. Popular process models include the Canadian Institute of Health Research Model of Knowledge Translation [197] and the Knowledge-to-Action Framework [198]. Process models are the most akin to linear theories of behaviour change, in which change in behaviour comes as a direct result of dissemination of knowledge. Action models are types of process models that offer more practical guidance in planning for and evaluating the implementation process. Popular action models include the ACE Star Model of Knowledge Transformation [199] and the Quality Implementation Framework [200].

Determinant frameworks list a number of general determinants that are believed to negatively (barriers) or positively (enablers) affect the process of implementation and they do not propose any causal mechanism about how the change is actually taking place. Different frameworks pay varied attention to the degree of interaction between suggested determinants. Determinant frameworks include Promoting Action on Research Implementation in Health Services [201-205], the Consolidated Framework for Implementation Research [206] and the Theoretical Domains Framework [188, 207-209]. The Promoting Action on Research Implementation in Health Services framework has been widely applied and has undergone substantial development work. In many cases, determinant frameworks came to life as a synthesis of empirical literature capturing frequently reported contexts and factors affecting the process of implementation. Determinant frameworks place substantive focus on implementation contexts and they frequently claim their roots in classic theories of change (outlined below).

Classic theories of change endeavour to explain how the change happens. They describe change mechanisms without guiding the process of change. Classic theories take their origin from different disciplines outside of implementation science, such as psychology, sociology and organisational theory. Classic theories include the Theory of Diffusion [150, 157], the Theory of Reasoned Action [210], the Social Cognitive Theory [211] and the Institutional Theory [212].

Implementation theories are more focussed versions of determinant frameworks and can be used to describe and evaluate certain aspects of the implementation process. Popular implementation theories include the Capability, Opportunity, and Motivation Model of Behaviour Change [213] and Normalisation Process Theory (NPT) [214-220].

The last category consists of evaluation frameworks. They are designed to offer a structure to the process of evaluation. Two of the most commonly used evaluation frameworks in public health are Reach Effectiveness Adoption Implementation Maintenance [221] and Predisposing Reinforcing and Enabling Constructs in Educational Diagnosis and Evaluation-Policy Regulatory and Organizational Constructs in Educational and Environmental Development [222, 223]. It is worth mentioning that different implementation theories and determinant frameworks can be, and have been, used as evaluative tools. Examples of them include Promoting Action on Research Implementation in Health Services, the Consolidated Framework for Implementation Research, the Capability, Opportunity, and Motivation Model of Behaviour Change, the Theoretical Domains Framework and NPT.

Nilsen's categories can be further classified according to their intended function:

- describe and/or guide the process of translating research into practice (process and action models),
- understand and/or explain what influences implementation outcomes (determinant frameworks, classic theories, implementation theories),
- evaluate implementation (evaluation frameworks) [196].

The field of implementation science has been criticised for producing large quantities of implementation theories, models and frameworks, without sufficient evaluation of such tools and with very few studies utilising them in a prospective way. The latter can be done, for example, by utilising concepts from established theories, models and frameworks to assess the implementation context and to design implementation strategies or research tools (for example, surveys, topic guides for focus groups or interview questions). In a meta-narrative review from 2004 Greenhalgh et al. called for rigorous utilisation and evaluation of existing implementation frameworks, and a greater collaboration between researchers (developers) and clinicians (implementers) in co-creating knowledge [161]. It was proposed that doing so would give evidence-based interventions the best chance at becoming part of routine clinical practice.

Additionally, the rapid emergence of knowledge (in the form of theories, models and frameworks) led to a development of a substantial and often inconsistent taxonomy and a general lack of agreement about how to describe different phenomena in the field of implementation [161]. Such inconsistencies start with fundamental concepts and extend to more advanced debates [224]. For example, as many as 100 terms have been identified to describe implementation research [225]. They included applied dissemination research, effectiveness research, healthcare innovation research, innovation-adoption-diffusion research, knowledge translation research, translational science, dissemination research and improvement science.

Paradigm shift

In recent years, the field started to respond to the calls for amalgamation/integration of the terminology used and better guidance to aid a more meaningful engagement with the many theories, models and frameworks available [224, 225]. Rabin et al. created 'A Glossary for Dissemination and Implementation Research in Health' [226]. Implementation scientists can now choose from a number of empirically validated tools to design implementation studies. For example, a tool designed by Powell et al. to help implementation researchers select and tailor over 70 different implementation strategies [227] or a comprehensive compendium of research and evaluation designs for dissemination and implementation projects proposed by Brown et al. [182]. The latter includes experimental designs (e.g., randomised controlled trials, hybrid designs), quasi-experimental designs (e.g., interrupted time series), observational designs (e.g., surveys, focus groups, case studies) and mixed methods designs.

Guidance and tools are now available to support researchers in selecting from the plethora of theories, models and frameworks. In the 'Bridging research and practice models for dissemination and implementation research' article Tabak et al. organised implementation and dissemination theories, models and frameworks according to the rigidity/flexibility of the constructs, whether their primary focus is on dissemination and/or implementation, and how wide the tool casts the net in terms of the assessment of social ecological factors (some frameworks focus solely on individual level mechanisms, others include community and system level influences) [195]. The work of Tabak et al. and findings from an earlier review conducted by Mitchell et al. gave foundations to an interactive 'Dissemination & Implementation Models in Health Research & Practice' website (http://www.dissemination-

implementation.org) [195, 228]. This website was created in a collaborative effort involving staff from the ACCORDS Dissemination and Implementation Science Program at the University of Colorado, the Dissemination and Implementation Research Core at the Washington University Institute for Clinical and Translational Science, and the Dissemination and Implementation Science Center at UC San Diego; since its creation it has been a starting point for many successful implementation projects.

Following the process of designing and conducting implementation research projects, implementation researchers can now choose from a number of reporting guidelines designed with implementation science in mind. The two most commonly used are the Standards for Quality Improvement Reporting Excellence guideline and the Standards for Reporting Implementation Studies of complex interventions statement. The former, revised in 2015, is a publication guideline that evolved from a detailed consensus process [229]. Similarly, the latter emerged from the findings of a systematic review and an e-Delphi study [230, 231].

The next chapter (Chapter 2) will describe and justify research methods employed in the conducted doctoral project.

CHAPTER 2 – METHODS

Mixed methods research

Research methodology describes the process of deciding and justifying the most suitable methods (e.g., data collection techniques or data analysis protocols) to address the aims of a research study. An integral part of this process is deciding the theoretical underpinnings of the study. Transparency in describing this decision-making process can increase research rigour (i.e., research quality and validity) [232].

Pragmatism is the primary research philosophy of mixed methods research [233]. The paradigm of pragmatism, accepts that a single underlying physical reality may exist, but this may be viewed/interpreted differently by different people [234]. The constructed nature of that reality may be more important in determining outcomes such as health behaviours or implementation behaviours of healthcare professionals. These can be best uncovered/understood by employing different knowledge-generating methods, for example, by using quantitative methods to measure certain aspects of the phenomenon and qualitative methods for others. Pragmatism considers multiple perspectives and positions (including those of the researcher) and tasks itself with 'solving practical problems in the "real world"' [235]. The starting point of this problem-oriented research philosophy is that the best research methods are those that are best suited to answer the proposed research question(s). The consequences of research, for example, how useful the research findings are and the creation of concrete research outputs, are important enactments of pragmatism in mixed methods research.

The premise of mixed methods research is combining qualitative and quantitative methods and interpreting both sets of results in a coherent empirical study to answer pre-defined research question(s). Historically, the rationale for combining different research methods was linked with the idea of triangulation and increasing the validity of research findings [236]. In recent years, mixed methods research has been described, alongside qualitative and quantitative methods, as the 'third research paradigm' [233]. The field of healthcare evaluation research, due to its practical nature, was the first to adopt the use of mixed methods. It is now widely accepted that 'comprehensive evaluations should be process-oriented as well as outcome oriented, exploratory as well as confirmatory' [237]. Hence, the mixed methods design seemed the most suitable for addressing the aims of the current study (which included both process and outcome oriented questions).

Greene et al. suggested five broad reasons for using mixed methods. These included triangulation (employing different methods leads to verification of results), complementarity (results from one method clarify results from the other), development (results from one method inform the other method), initiation (discovering paradoxes and contradictions that can be used to reframe the research question), expansion (expanding the breadth of inquiry – using different methods for different inquiry components) [238].

In their mixed methods research process model, Johnson et al. proposed the following eight steps when designing mixed methods studies: determine the research question, decide whether a mixed design is appropriate, select either mixed method (i.e., separate qualitative

and quantitative phases) or mixed model (e.g., conducting a survey that includes quantitative and qualitative questions) research design, collect the data, analyse the data, interpret the data, legitimate the data and draw conclusions [239]. An important step when designing any mixed methods study is to decide whether one method will be dominant or whether qualitative and quantitative methods will have equal status (pure mixed methods). This decision is often made based on the dominant focus of the research study, for example, subjective vs objective, discovery vs verification, exploratory vs confirmatory or process-oriented vs outcome-oriented. Another aspect to consider is whether different methods will be employed sequentially or concurrently. In the case of the conducted study, qualitative methods were the dominant mode of gathering data and the different methods were used (mostly) simultaneously. Employing methods simultaneously was the most appropriate data collection approach and allowed the project to conclude within the available time frame.

The integration of results which derive from different components of mixed methods studies is a central issue when conducting such studies [240]. Fetters et al. considered three levels of possible integration and several more granular techniques.

1. Integration at design level
    a. basic techniques
        i. exploratory sequential
        ii. explanatory sequential
        iii. convergent
    b. advanced techniques

        i. multistage
        ii. intervention
        iii. case study
        iv. participatory and transformative
2. Integration at methods level
    a. connecting
    b. building
    c. merging
    d. embedding
3. Integration at interpretation and reporting level
    a. narrative
        i. weaving
        ii. contiguous
        iii. staged
    b. data transformation
    c. integrating through joint displays [241].

When considering integration at the design level, researchers can choose from three basic techniques (exploratory sequential, explanatory sequential and convergent) and four advanced techniques (multistage, intervention, case study, and participatory and transformative) – the basic and advanced techniques relate mostly to the timing of different phases of mixed methods studies as well as the role of one component in relation to other components. For example, one phase of the mixed methods study can build on the previous

one or the data from different phases can be merged/integrated in order that the quantitative and qualitative results can be compared. Integration at the methods level can occur through linking of different components during data collection and analysis. Several approaches can be employed during integration at the methods level, these include: connecting, building, merging and embedding. Lastly, integration at the interpretation and reporting level can involve integrating through narrative, integrating through data transformation and integrating through joint displays. If integration through narrative is chosen, there are three approaches of operationalising this type of integration (i.e., weaving approach – findings are described together and captured through, for example, common themes; contiguous approach – findings are placed in different sections of a single report; and staged approach – findings are published mostly separately with an occasional reference of salient points).

In terms of the study described in the thesis, the rationale for using mixed methods was linked with a commitment to understand different aspects of the implementation process (expansion) and to use results from one part of the study to contextualise/interpret results from other components of the study (complimentary). For example, whether significant adaptations to the intervention might have resulted in a reduced/improved effectiveness. The development aspect of mixed methods research was operationalised to a lesser extent – data from the initial interviews were used to design the implementation manual, the utility of which was then investigated in the survey (all of which are described in Chapter 4). The integration of findings in the current study was conducted at the interpretation and reporting level through the narrative staged approach: qualitative and quantitative findings were

presented separately (in Chapters 4 and 5) and brought together narratively in the Overall Discussion chapter (Chapter 6).

To summarise, during my PhD, I conducted a primary/empirical prospective observational-descriptive mixed methods implementation evaluation study, which used predominantly qualitative methods (i.e., in-depth semi-structured interviews and an online survey with qualitative and quantitative questions) [242]. The main quantitative part of the study included the interrogation of routinely collected numerical audit data. In terms of timing, different research methods were launched in parallel, with one exception – the preliminary analysis of the initial interviews was used to generate an implementation manual (the Rehabilitation EnAblement in CHronic Heart Failure (REACH-HF) Service Delivery Guide – Appendix 1) and questions exploring the value and usability of the guide were then included in the online survey.

Having considered the theoretical underpinnings and rationale of the research project, the next section of the chapter (in the form of a published protocol paper) will address the practical aspects of the chosen methods.

The protocol paper

Below is a protocol paper titled ‘Getting evidence into clinical practice: protocol for evaluation of the implementation of a home-based cardiac rehabilitation programme for patients with heart failure’. A version of this manuscript was published in BMJ Open (DOI 10.1136/bmjopen-2019-036137).

Abstract

Introduction

Cardiac rehabilitation improves health-related quality of life and reduces hospital admissions. However, patients with heart failure often fail to attend centre-based cardiac rehabilitation programmes. Novel ways of delivering healthcare, such as home-based cardiac rehabilitation programmes, may improve uptake of cardiac rehabilitation. REACH-HF is a new, effective, cost-effective, home-based cardiac rehabilitation programme for patients with heart failure.

The aim of this prospective mixed methods implementation evaluation study is to assess the implementation of the REACH-HF cardiac rehabilitation programme in the United Kingdom (UK) National Health Service (NHS) [242]. The specific objectives are to a) explore NHS staff perceptions of the barriers and facilitators to the implementation of REACH-HF, b) assess the quality of delivery of the programme in real-world clinical settings c) consider the nature of any adaptation(s) made and how they might impact on intervention effectiveness, and d) compare real-world patient outcomes to those seen in a prior clinical trial.

Methods and analysis

REACH-HF will be rolled-out in four NHS cardiac rehabilitation centres across the UK. Three healthcare professionals from each site will be trained to deliver the 12-week programme. In-depth qualitative interviews and focus groups will be conducted with approximately 24 NHS professionals involved in delivering or commissioning the programme. Consultations for 48 patients (12 per site) will be audio recorded and scored using an intervention fidelity checklist. Outcomes routinely recorded in the NACR database will be analysed and compared

with outcomes from a recent randomised controlled. Qualitative research findings will be mapped onto the Normalisation Process Theory (NPT) framework and presented in the form of a narrative synthesis. Results of the study will inform national roll-out of REACH-HF.

Strengths and limitations of the study

- This will be the first study to investigate the real-world implementation of a home-based cardiac rehabilitation programme in the UK and also include the evaluation of the real-world clinical effectiveness of the programme.
- The study will use NPT as a theoretical framework to guide data collection and interpretation.
- The qualitative findings will inform the development of an implementation manual for policymakers, planners, providers and commissioners of cardiac rehabilitation services for patients with heart failure.
- A possible limitation of the study is that the four centres that will be appointed to implement REACH-HF will be large, well-established cardiac rehabilitation treatment centres and might not be representative of the national cardiac rehabilitation landscape – a potential sample bias towards early adopters.
- This study may have limited generalisability outside the UK.

Introduction

Heart failure

Approximately 900,000 people are affected by heart failure in the UK [243]. Due to an ageing population, heart failure is becoming a national healthcare challenge [244]. Heart failure has a high impact on both patients and society; it can reduce exercise tolerance and health-related quality of life, increase the risk of mortality and unplanned hospital admissions, and is associated with high healthcare costs [109]. There is also a considerable burden on the friends and family of patients with heart failure [245]. Exercise-based cardiac rehabilitation programmes have been shown to enhance health-related quality of life in patients with heart failure and reduce unplanned hospital admissions [74, 109]. With sufficient adherence, these benefits are consistently achieved in trial settings with both centre- and home-based cardiac rehabilitation [109]. Although the National Institute for Health and Care Excellence (NICE) recommends that all patients with heart failure receive cardiac rehabilitation [26], due to the frailty and poor health of this clinical population as well as dislike of group-based exercise and practical constrains (e.g., transportation), participation in centre-based cardiac rehabilitation remains poor [246]. Underutilisation of cardiac rehabilitation amongst this clinical population has been highlighted in the 2010 NICE guideline, with the uptake of cardiac rehabilitation being much lower than predicted and estimated at 5.3% [247].

The REACH-HF programme

The REACH-HF programme is a new cardiac rehabilitation programme for patients with heart failure and their caregivers, aimed at achieving better health-related quality of life in the comfort of the patient's home. The 12-week, facilitated, home-based intervention was co-

developed with patients, caregivers and clinicians [145] using Intervention Mapping approach [144]. In recent randomised controlled trials, REACH-HF resulted in significant clinical improvements in health-related quality of life and was cost-effective, with the cost falling within the current NHS tariff for cardiac rehabilitation in the UK [146, 248]. REACH-HF, therefore, provides an affordable, evidence-based, patient-centred alternative to centre-based cardiac rehabilitation. This provides a way to address the latest NICE guidance recommendation that patients with heart failure are offered 'a personalised, exercise-based cardiac rehabilitation programme (…) in a format and setting (at home, in the community or in the hospital) that is easily accessible for the person' [26].

Implementation science: negotiating the research-to-practice gap

Research and development within the NHS is world leading. However, the NHS falls short when scaling up well-evidenced innovations or good practice [249]. The spread of innovations and evidence-based interventions across the NHS and other healthcare systems is subject to various challenges [250]. Firstly, moving complex interventions from research settings to real-world clinical implementation is a slow process [163]. Some of the barriers slowing down this process include the characteristics of the intervention itself such as its usability or fit with the existing processes in the organisation. Beyond this, individual or organisational barriers include the attitudes towards change and the innovation itself, resources available, expertise, time, and competing priorities [251].

Secondly, following uptake, the same intervention does not always perform in exactly the same way across different organisations. For example, there may be differences in the

characteristics of the patients involved, such as differences in socio-demographic factors (e.g., age, ethnicity or socio-economic status), or in clinical factors (e.g., severity of illness or complex comorbidities) [252]. In clinical trials patients tend to be included based on predetermined criteria and such criteria are rigorously checked prior to study participation. However, in practice a broader patient population may end up using the intervention. There may also be differences in the characteristics of the organisations delivering the intervention (these factors are often referred to as implementation contexts, e.g., the size of a catchment area, access to resources, staff and expertise), compared with those available in clinical trials [220]. With these differences in population characteristics and access to resources, unplanned adaptations may occur to better fit the new context. This initially slows down the process of implementation, but it also means that the intervention is no longer delivered as it was under clinical trial conditions [253]. Such unplanned adaptations often result in the interventions initially failing to reproduce the results that were found within the context of randomised controlled trials [162]. With a varied and ever changing healthcare landscape, it is crucial to understand the full complexity of implementing innovations into real-world clinical practice [254]. It is particularly important to explore how much of the intervention can or cannot change (and in what ways) without jeopardising the benefits of the intervention [255]. Healthcare evaluations and improvement projects often consider performance at the level of the individual healthcare professional [256], targeting the professional's knowledge, routines and attitudes [257]. However, there is a need for wider-reaching systems-level evaluations of the implementation process that also take into account community, organisational, system and policy level influences [161].

Overall, implementation science aims to examine the process of implementation of healthcare innovations, in particular, barriers and facilitators as observed in real-world clinical settings [171]. To narrow the research-to-practice gap, implementation scientists recommend that the process of implementation is considered and built into the intervention design and development, the context and systems of implementation are assessed during the implementation efforts, and key stakeholders are involved in the intervention development stage through to dissemination, implementation and evaluation [161].

Aims of the project

The current project aims to implement REACH-HF in four UK NHS cardiac rehabilitation services to a) explore the facilitators of, and barriers to, implementation of REACH-HF in existing UK cardiac rehabilitation services, b) assess the implementation fidelity and c) the extent and nature of any potential adaptations to the intervention content and how such adaptations impact on effectiveness, and d) compare real-world outcomes to the clinical trial findings.

Methods and analysis

Design

A mixed methods implementation evaluation study using in-depth semi-structured interviews and focus groups with key NHS staff, analysis of pre-post intervention changes in routinely collected outcome data via the British Heart Foundation founded National Audit of Cardiac Rehabilitation (NACR) and a fidelity assessment using a checklist applied to recordings of provider-patient interactions [242].

In-depth semi-structured interviews and focus groups will be used to identify facilitators of, and barriers to, implementation. Audio recordings of REACH-HF clinical encounters will be used to assess fidelity. Quantitative data obtained from the NACR will be used to compare real-world outcomes to the clinical trial findings. Data gathered from all of the above study activities (interviews, focus groups, fidelity assessment, patient outcomes) will be used to assess the extent and nature of adaptations to the intervention content and how such adaptations are associated with effectiveness.

Setting and site recruitment

The study will be conducted in four UK NHS cardiac rehabilitation centres which will be early adopters of the REACH-HF programme and known as 'Beacon Sites'. Representativeness of four home nations was desired as it would have captured four unique implementation contexts. However, Scotland was excluded from the site recruitment process, due to not participating in the NACR audit (on which the proposed study relied for some of the data collection). The opportunity to apply to become a Beacon Site will be promoted at national (UK) conferences and local meetings of cardiac rehabilitation practitioners. Interested cardiac rehabilitation services will be sent an information pack including an application form. Applicants will be asked to provide information on their NACR National Certification Programme for Cardiac Rehabilitation status, number of referrals made to the cardiac rehabilitation service (for both cardiac patients and patients with a primary diagnosis of heart failure), whether the service is offering home-based programme, length of current programmes, number of programme completions, number of pre- and post-treatment

assessment completions as well as to comment on willingness to engage in research and host site visits for other interested parties. The National Certification Programme for Cardiac Rehabilitation is a certification programme issued jointly by the British Association for Cardiovascular Prevention and Rehabilitation (BACPR) and the NACR. The certification programme rates cardiac rehabilitation services on seven Key Performance Indicators. These are the NACR measurable indicators based on the BACPR core components. Programmes need to meet at least four Key Performance Indicators to be granted an amber status and all seven to be granted a green status [258].

The sites will be recruited from across the UK using a two-stage application process (application form followed by panel interview for shortlisted sites). As an incentive, sites will be offered free intervention materials for the treatment of 50 patients (i.e., the REACH-HF patient manual, the family and friends resource, audio with relaxation techniques and chair-based exercise DVD). In addition, the selected sites will be offered free training (including training manuals) for three health professionals to deliver REACH-HF, post-training support and formative feedback on performance. The three-day training will be delivered by the Heart Manual Department (HMD) team, NHS Lothian in Edinburgh.

To be eligible, sites have to be:

- NACR electronically registered sites with high-quality status from the past audit period (green or amber status) operating in England, Wales or Northern Ireland.
- Committed to delivering REACH-HF to 50 patients over the 12-month Beacon Site project period.

- Able to release three healthcare professionals (or more) with relevant experience in cardiac rehabilitation and/or heart failure for three days training plus one self-directed pre-training day.
- Able to engage in research to evaluate performance (e.g., recording some intervention sessions, staff participation in interviews).
- Willing to host site visits and/or share information and/or experiences with other interested NHS parties.
- Conduct baseline and post-treatment assessment of health-related quality of life using the Minnesota Living with Heart Failure Questionnaire (MLHFQ) [259] and exercise capacity using the Incremental Shuttle Walk Test (ISWT) [260] for all patients receiving the REACH-HF programme.

Study population

Healthcare providers

The aim is to recruit up to 24 healthcare professionals. The target number was decided pragmatically/opportunistically following consultations with healthcare professionals working in the NHS and taking into account the size of a typical cardiac rehabilitation team as well as the burden of research participation and the likely numbers that could be recruited in a 12-month time period. The total number will include the 12 health professionals delivering REACH-HF and other key NHS staff involved in the delivery, planning and commissioning of cardiac rehabilitation for patients with heart failure. To identify key staff involved in cardiac rehabilitation services, the study will use a combination of opportunity sampling (all available

staff trained to deliver the REACH-HF programme) and snowball sampling (staff who are identified by existing participants as having a key role in delivering or commissioning of cardiac rehabilitation) [261]. This sampling strategy will be applied until saturation in the themes and concepts generated in the qualitative analysis is reached.

Patients

The study will include up to 200 patients with heart failure who are referred to the cardiac rehabilitation centres for rehabilitation and receive REACH-HF treatment. The patient sample size was pre-determined by the set-up of the Beacon Sites and reflects the availability of funding to supply the chosen sites with the relevant patient-facing resources to deliver the intervention. Although, the planning of the sample size was not under my control, a sample size of 200 would provide 94.2% power to detect a mean difference of five points (assuming a standard deviation of 20 and a 5% significance level). A five-point reduction in MLHFQ scores – is considered to be a minimum clinically important difference/reduction in symptoms in patients with heart failure. Out of the 200 patients, cardiac rehabilitation consultations of up to 48 patients (12 per site) receiving REACH-HF intervention will be audio recorded.

Intervention

REACH-HF is a home-based, health professional facilitated, 12-week cardiac rehabilitation programme supporting self-care in patients with heart failure, which has been co-developed with patients, caregivers and clinicians. The programme is described in detail elsewhere [100, 145, 146, 248, 262, 263] and is summarised below.

The programme consists of:

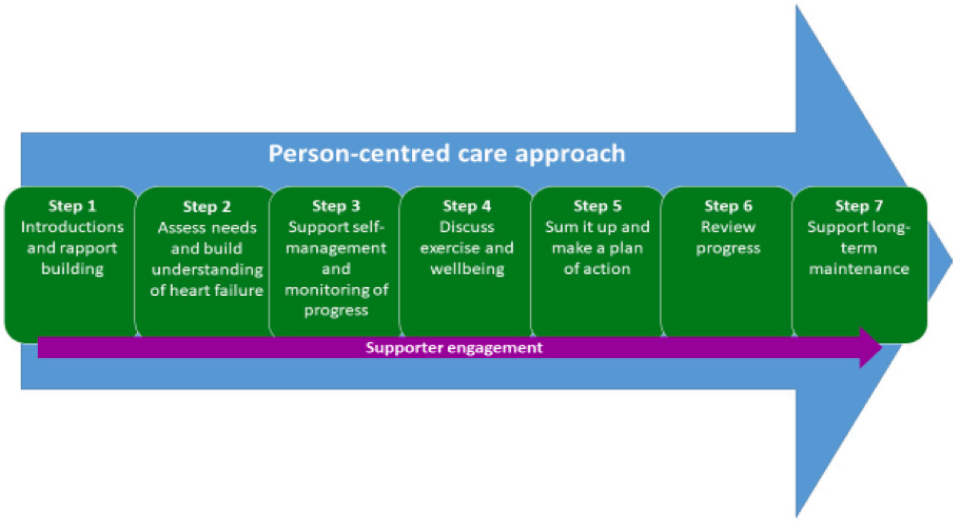
- The heart failure manual for the patient provides information about, and strategies for managing, the condition (i.e., lifestyle risk management, managing depression and anxiety, and getting support from others).
- A choice of two exercise training programmes; a chair-based programme (available on DVD and online) and a walking programme. In addition to general physical activity, patients are recommended to engage in exercise three times per week.
- A stress management programme (with relaxation techniques provided in the manual and in audio format) to help cope with anxiety and depression.
- A progress tracker designed for the patient to facilitate learning from experience through self-monitoring of behaviour and symptoms (prompting help-seeking, where necessary).
- A family and friends resource to increase caregiver understanding of the condition, to enable them to support the patient in their self-care and to help them address their wellbeing.
- Face-to-face and telephone facilitation over 12 weeks by a health professional trained to deliver the REACH-HF programme.

Facilitator training

Three health professionals with cardiac rehabilitation and/or heart failure experience from each Beacon Site will attend a three-day training course delivered by the HMD in Edinburgh. This training course will focus on the 7-steps of successful facilitation of REACH-HF (Figure 4)

and include sessions on psychology, behaviour change, physical activity and exercise, engaging the caregiver, and further content/interaction designed to bring all of the components together.

Figure 4 The 7-steps of successful REACH-HF facilitation (from Greaves et al., 2016)



The Beacon Sites will determine which members of the cardiac rehabilitation team will attend the REACH-HF training. The main requirement for the healthcare professional is experience of delivering cardiac rehabilitation and/or of working with patients with heart failure. The facilitators will likely be heart failure/cardiac specialist nurses or physiotherapists/exercise specialists with qualifications and/or experience in the delivery of exercise-based cardiac rehabilitation programmes.

It is expected that site identification, training and set up will take approximately six months. Following the set up period, each Beacon Site will have 12 months to deliver REACH-HF to 50

patients. During that time qualitative interviews, focus groups and audio recordings of REACH-HF sessions for selected patients will take place. At the end of the Beacon Site activity, a quantitative data download will be requested from the NACR and an interim download will be requested 9 months from the end of the study to allow piloting of data-cleaning and processing procedures (stopping short of analysis).

Measures and procedures

Qualitative methods

In-depth semi-structured interviews and focus groups with NHS staff. NHS staff will include REACH-HF practitioners (cardiac rehabilitation nurses and/or physiotherapists with experience in delivering centre-based cardiac rehabilitation who had been trained to deliver the REACH-HF programme in a three-day training course), service managers, clinical leads and commissioners. Interviews will take place at each Beacon Site using the interview topic guide (Appendix 2). Each identified staff member will, if possible, be interviewed twice (at the beginning and end of the data collection window) and one focus group will be held in each locality with identified study participants (at the midpoint of the data collection window). Interviews will be either face-to-face or by phone. The development of topic guides for qualitative interviews and focus groups was based on four constructs and 16 sub-domains from the NPT framework (Table 1). The topic guides content may be amended depending on feedback from stakeholders and the first few interviews.

Two video-conferencing peer supervision sessions will be available to all REACH-HF trained facilitators. These will be provided as part of the REACH-HF training package and delivered by the HMD staff. The researchers will observe and take notes from each of these sessions.

Table 1 Qualitative questions and their origins in the NPT construct and components

NPT construct	Construct's components	Interview questions
Coherence (sense-making)	Differentiation	Can you describe REACH-HF intervention and how it differs from your usual way of working?
	Communal specification	What is your colleagues understanding of the purpose of REACH-HF intervention?
	Individual specification	How does the intervention affect the nature of your work?
	Internalisation	In your opinion, what it the value of REACH-HF intervention? To you? To your patients?
Cognitive participation (relational work)	Initiation	Who are the individuals (you can include yourself) that drive REACH-HF forward and get others involved? What are their roles? What are they doing to support the project?
	Enrolment	How did the team need to change in order to introduce REACH-HF?
	Legitimation	How do you feel about being involved in the REACH-HF project?
	Activation	What is the future of REACH-HF in your service? What factors can enable the integration of REACH-HF into a cardiac rehabilitation service?
Collective action (operational work)	Interactional workability	How easy or difficult has it been to integrate REACH-HF into your existing work?

	Relational integration	How has implementing REACH-HF affected working relationships within the team?
	Skills and workability	How do the skills of the staff delivering REACH-HF match the needs of the programme?
	Contextual integration	Was REACH-HF training sufficient to allow for successful implementation? If not, what other topics or skills could have been included? Are there enough resources available to support the REACH-HF programme? Are there any other barriers to delivering REACH-HF on your patch?
Reflexive monitoring (appraisal work)	Systematisation	Are you in any way evaluating effectiveness, usefulness or impact of REACH-HF on the service?
	Communal appraisal	Do your colleagues consider the intervention worthwhile?
	Individual appraisal	Do you consider it worthwhile?
	Reconfiguration	Can REACH-HF intervention be easily modified and improved to suit your way of working? If yes, in what way?

Fidelity data

All REACH-HF cardiac rehabilitation treatment sessions (4-6 contacts), both face-to-face and phone-based, of approximately 48 consenting patients (12 per site) will be audio recorded by the healthcare professionals delivering the programme. Each REACH-HF facilitator will be requested to audio record all treatment sessions for four patients with heart failure. The selection of which patients to include will be guided by the researchers using a quasi-random process. Five months after the REACH-HF training, facilitators will be asked to invite all subsequent patients to take part in the study until two willing patients with heart failure agree to have their treatment sessions recorded. Approximately ten months after the REACH-HF training, an e-mail will be sent to repeat the invitation and audio recording process for the next two consenting patients.

The quality of delivery (intervention fidelity) of the recorded treatments will be assessed by the researcher, Paulina Daw (PD), using the same fidelity checklist used in the original REACH-HF research study [146]. This will allow comparison with fidelity scores achieved in the clinical trial. The recordings for the first six patients will also be double scored and two researchers (PD and Colin J Greaves) will discuss any differences in their scores to agree and 'anchor' the scoring process and minimise coder bias. If an agreement cannot be reached, a third reviewer, Jet JCS Veldhuijzen van Zanten, will be appointed for arbitration.

The fidelity checklist is a 12-item checklist focussed on identifying key delivery processes such as the use of a patient-centred communication style, making a plan of action and encouraging self-monitoring of progress (particularly with the exercise programme). The checklist uses the

Dreyfus scale of clinical skills acquisition [264] to rate clinical skills on a scale of 0-6 and is anchored such that a score of three or more represents adequate delivery quality for each item. Coding instructions are provided in Appendix 3.

REACH-HF facilitators will be asked to complete a brief self-rated fidelity checklist after each session they have recorded. This comprises questions about the same 12 main components of the treatment and allows the facilitators to rate the occurrences of each feature (absence, minimal, some, sufficient, good, very good, excellent) (Appendix 4). The main reason for including a self-rated fidelity checklist is that an independent observer-rating is time-consuming/labour intensive, whereas a self-rating assessment might provide a pragmatic, lower-cost alternative for checking delivery quality for use in real-world clinical practice. Lastly, for each patient opting into the study, age, sex, time since diagnosis and severity of symptoms will be recorded by the healthcare professionals delivering the REACH-HF intervention.

Quantitative methods

At the end of the Beacon Site project period, a report will be requested from the NACR team based at the University of York on:

- number of referrals made to the Beacon Sites during the study period,
- number of patients with heart failure enrolled on the REACH-HF programme (attending at least one session),
- cardiac rehabilitation attendance (average number of face-to-face and telephone sessions per patient),

- number of patients completing the REACH-HF programme (in the clinical trial, 'patient adherence to the intervention was defined as attendance at the first face-to-face contact with the facilitator and at least two facilitator contacts thereafter – at least one of which must have been face to face' [146]).

Summary data on key pre- and post-programme measures will also be requested to enable comparison with changes in the intervention group observed in the clinical trial. These include health-related quality of life – determined using the MLHFQ and exercise capacity – determined using the ISWT. The MLHFQ consist of 21 questions that rate on a scale of 0-5 (where 0 is not at all, 1 is very little and 5 is very much) how different heart failure symptoms (e.g., swelling of ankles and legs, shortness of breath and tiredness/fatigue/poor energy levels) prevent the patient from living as they would have wanted to during the four-week period prior to the first cardiac rehabilitation session.

The ISWT is an externally paced exercise capacity test that can be administered in the field with minimal equipment and without medical supervision. The test has good test-retest reliability and it is an acceptable alternative to (widely used to assess physical fitness and functional capacity of cardiac patients) exercise test with electrocardiogram monitoring or the cardiopulmonary exercise test [265]. A recent study confirmed that a single ISWT is a valid, low resource, assessment of an estimate for physical fitness and functional capacity for cardiac rehabilitation patients [266].

Data analysis

Qualitative data

Digital recordings of interviews and focus groups will be transcribed verbatim and any potentially identifiable information, such as individual or location names, will be redacted. The transcripts (Word documents) will be uploaded into NVivo software to help organise the data for analysis [267]. Illustrative quotes, which may be used in future presentations or publications, will be presented alongside pseudonyms to protect anonymity.

The transcripts will be analysed according to the principles of framework analysis outlined by Ritchie and Spencer [268] and using the four over-arching constructs of NPT (coherence, cognitive participation, collective action and reflexive monitoring) as an initial framework for coding the data [269]. NPT suggests general mechanisms that are associated with successful implementation. These include service providers' understanding of the new intervention and how it differs from standard practice, their motivation and attitude towards the healthcare innovation, and the work they do to deliver and evaluate the intervention. NPT will provide a framework for generating questions for interviews and focus groups and analysing gathered data. See Table 1 on page 38 for more details on the application of NPT to the data collection.

Fidelity assessment

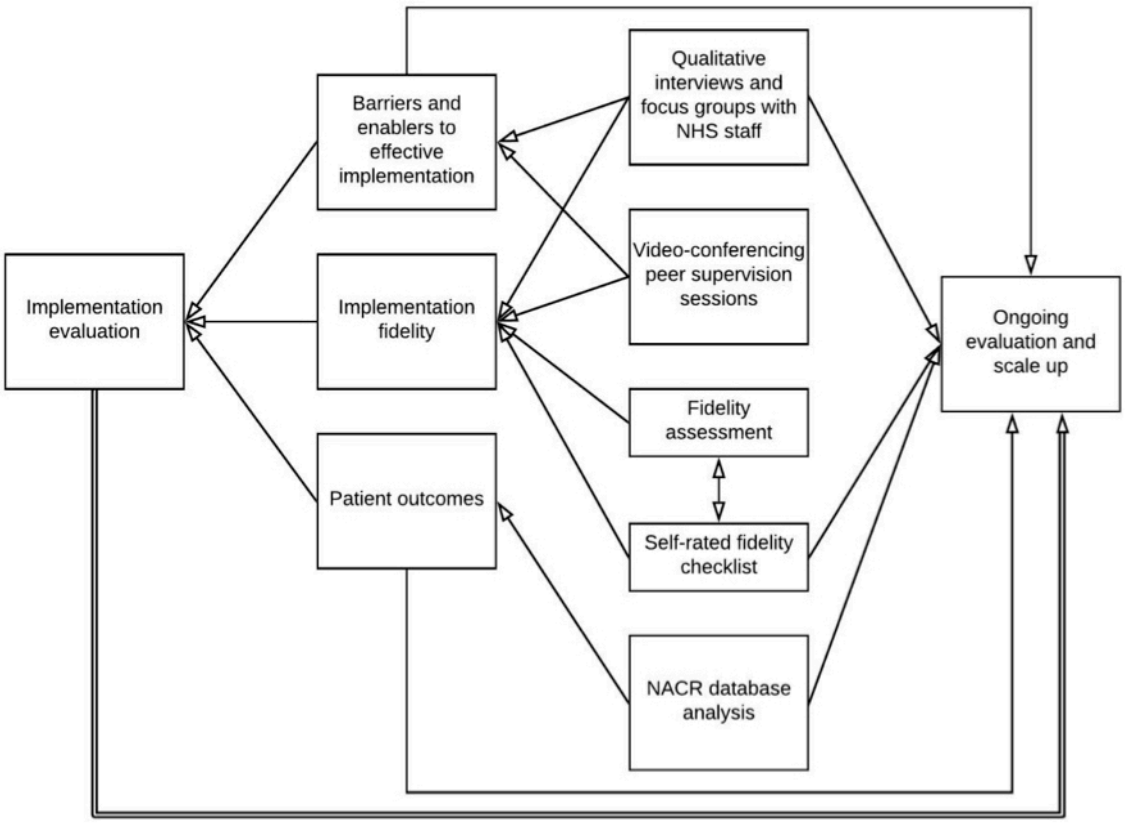
Implementation fidelity scores from the fidelity checklist will be collated at the level of the facilitator, the site and the total sample; these will be presented using descriptive statistics (means, ranges) using the same analytic approach as the original REACH-HF trial [146]. Numerical data (0-6) from the Dreyfus scale of clinical skills acquisition will be converted into categorical (yes/no) data reflecting whether the session reached the adequate level of

delivery (score three or above). Observer-rated treatment fidelity will be compared with self-rated fidelity from the post-session fidelity questionnaires completed by the REACH-HF facilitators at the end of each recorded session. The analytic approach to compare the two rating scales will be Pearson's correlation for continuous scores [270] and Gwet's first-order agreement coefficient (the AC1 statistic) for categorical ratings [271]. The fidelity assessment data sample reflects the sample size used to assess fidelity in the original REACH-HF clinical trial. The fidelity assessment requires a minimum of four patient recordings per facilitator to be able to assess variations in performance between staff and between NHS sites.

Quantitative outcomes

Changes from pre- to post-treatment in outcome data (MLHFQ and ISWT) will be reported as mean scores with 95% confidence intervals within each Beacon Site. Mean change scores for patients receiving REACH-HF will be compared across Beacon Sites and also with the changes found in the REACH-HF trial. This comparison will take account of potential differences in patient characteristic and take due attention to the confidence intervals. Similarly, change scores for patients receiving REACH-HF will be compared with an aggregate change score from the NACR database for those who receive other forms of cardiac rehabilitation (primarily centre-based or digital cardiac rehabilitation). Sub-group analyses will be conducted by the NACR team to determine variations in uptake and outcomes within the REACH-HF cohort by site, sex, and other characteristics of interest (e.g., area deprivation index, rurality). Data on the number of patients treated, uptake and completion rates, and session attendance will be presented using descriptive statistics. Figure 5 illustrates interactions between the study's aims and methods, and how they link with the process of ongoing evaluation and scale-up.

Figure 5 Beacon Site evaluation and embedded processes for ongoing monitoring



Patient and public involvement

Patient preference and acceptability have been addressed extensively during the REACH-HF clinical trials [146, 248]. Six patients with heart failure and four caregivers have been consulted and informed the design of the REACH-HF programme. Patient and public involvement in the proposed study has included involving a member of the public to read and comment on the content of the study invite letter, participant information sheet and the consent form designed for the study. Additionally, members of all cardiac rehabilitation teams involved in the study were consulted during the process of setting up the Beacon Sites on

issues such as the feasibility of the study, selected outcome measures and the burden of participation in the study. At the end of the study, the final report will be shared with NHS staff at the participating Beacon Sites, allowing them to use it for service evaluation, future service planning and sharing of good practice.

Discussion

The research-to-practice translation gap is well-documented. It is common that evidence-based interventions are not adopted into clinical settings and do not become routine practice. To narrow the translation gap, more insight is needed into mechanisms that allow for successful implementation of effective and cost-effective interventions. To advance the field, implementation theories and mechanisms need to be tested in real-world clinical settings. The REACH-HF Beacon Site project is a multi-faceted and interactive approach to a phased roll-out that aims to disseminate the multi-centre trial findings, increase awareness of the REACH-HF intervention and to explore replicability of the intervention in new contexts. At the time of writing this protocol, a further four Beacon Sites in Scotland have been established and will also contribute data on the implementation of REACH-HF [272].

In line with earlier recommendations for implementation research, this study will open a channel of feedback between researchers and implementers (NHS staff), with a common goal of improved service delivery for patients with heart failure. This study will provide an insight into the translation of the REACH-HF clinical trial findings into real-world practice and an in-depth understanding of the implementation process in the context of current NHS provision. These findings will inform the future, larger-scale implementation of REACH-HF, offer

guidance to policymakers, planners and commissioners of cardiac rehabilitation services, inform adaptations to the REACH-HF training package and intervention, and facilitate adoption and spread of home-based cardiac rehabilitation for patients with heart failure in the UK.

Authors' contributions

All authors contributed to the idea for the study. Paulina Daw and Samantha B van Beurden drafted the manuscript. Samantha B van Beurden lead the set up and recruitment of Beacon Sites. Sinéad T J McDonagh is overseeing the day-to-day management of the Beacon Site project. Paulina Daw secured all relevant ethical approvals for the project and prepared all study documentation. Colin J Greaves, Jet JCS Veldhuijzen van Zanten, Hasnain Dalal and Rod S Taylor are providing project supervision and oversight. Patrick J Doherty and Alexander Harrison will coordinate access to the NACR data. Alexander Harrison will provide statistical analysis advice. Paulina Daw will acquire and analyse the data for the study. All authors provided critical revision of the manuscript for important intellectual content and approved the final draft of the protocol for submission.

Reflection

Conducting research in the context of the NHS is not without its challenges. One of the main hurdles is the need to secure ethical approval at various levels (i.e., sponsor, central application system, lead research site and local research sites). Due to varied procedures and different governing structures, these can be particularly time-consuming and onerous when involving NHS sites in different nations [273]. This was the case in the conducted study, with three Beacon Sites based in England and one in Northern Ireland. Therefore, it took a considerable time to secure all relevant permissions for the overall study, and subsequently for each Beacon Site. Unfortunately, long delays and mixed messages from the research coordinator in Northern Ireland resulted in delays that made it impossible to obtain ethical approval for fidelity assessment to be conducted at this site. An official complaint was submitted to the Trust Research and Development Director and Deputy Medical Director. The complaint was upheld and used to introduce measures to manage more efficiently the issues that the management of the project had raised.

The additional challenge of conducting a low-cost implementation research project in the NHS is a reliance on staff from the participating sites to perform research activities and gather high-quality data without being be paid for doing so. In large well-funded research projects, most often randomised controlled trials, services are paid to backfill the time of staff who will be taking part in such projects, which means the staff have the capacity to deliver the treatment *and* collect the relevant outcomes. In the case of the conducted study, the available funds were limited and only sufficient to cover the REACH-HF training and intervention-provision resources. However, hypothetically, even if additional funds had been

available and used to employ research staff this may have changed the implementation context at a fundamental level and would go against the study's commitment to understanding the implementation process during *real-world* service delivery. Yet, by not employing research nurses, I observed hesitation from some staff to engage in the suggested research activities. For example, Beacon Sites did not generate any audio recordings for the fidelity assessment. However, this was also linked with the impact of the COVID-19 pandemic, so it is hard to clearly attribute the cause of this phenomenon. The potential impact of not paying NHS staff to gather and enter research data on the data quality and completeness of the final quantitative data set will be explored further in Chapter 5.

Deviations from the protocol

Protocol deviations (i.e., non-serious divergence from the protocol, for example, recruiting more study participants than intended) are relatively common occurrences in randomised controlled trials compared to more severe protocol violations (i.e., substantial divergence from the protocol, for example, failure to report serious adverse event) [274]. Hence, reporting guidelines for randomised controlled trials, such as the CONSORT Statement, request authors to report any protocol deviations and violations [275]. However, this phenomenon is largely omitted from the key guidelines and methodological papers on mixed methods research design. Instead, concepts of complexity, uncertainty, flexibility and adaptation are considered as a way of responding to challenges of conducting complex research projects in the real-world and a way of preserving the validity of the generated research findings [235, 276, 277].

The submitted PhD project was largely conducted during the COVID-19 pandemic. Many pandemic-related disruptions affected the delivery of healthcare during the data collection period. These included redeployment of NHS staff working in cardiac rehabilitation teams to the frontline of the COVID-19 response, temporary suspension of cardiac rehabilitation programmes, or, where such programmes continued to be delivered, a patient's inability (or unwillingness) to attend such programmes due to shielding (government advice to stay at home and have no, or minimal essential, contact with others) or self-isolating recommendations. Due to clinical vulnerability, the studied patient population was specifically deemed to be at high risk of complications following COVID-19 infection and, therefore, more likely to be in the shielding category or shielding by choice.

For the above reasons, I was unable to conduct some of the research activities outlined in the attached protocol paper, including the assessment of the treatment fidelity, repeating qualitative interviews and conducting focus groups. However, to compensate for the lost data, I introduced an additional research activity with a larger sample of healthcare professionals (i.e., an online survey). The results of the survey will be presented in Chapter 4.

On reflection, despite the difficulties in delivering this research project, the mixed methods design was still the most suitable research design. The pragmatism, which is at the heart of this research approach, accepts the uncertainty and human element of knowledge-generating endeavours (e.g., that data that one hoped to generate at the beginning of the study might not become available) as well as stays 'flexible and open to the emergence of unexpected data' [235]. In practice, the methodological choice allowed me to be responsive to the

context the research project was conducted in, most markedly the COVID-19 pandemic, for example, by adding an additional cohort of participants (i.e., healthcare professionals trained remotely during the pandemic) and a less intrusive method of data collection (i.e., online survey). The pragmatic paradigm of mixed methods research uncovered rich, yet practical, data pertaining to complex intrapersonal, interpersonal and organisational processes as well as having given voice to healthcare professionals working at the frontline of cardiac rehabilitation delivery. The emergent/qualitative knowledge was anchored in 'hard data' and built around an existing theory – NPT. Additionally, during interactions between implementation stakeholders, namely, the NHS staff working at the Beacon Sites, the REACH-HF research team and the REACH-HF trainers, new knowledge and practices emerged. This led to adaptations to the intervention and the REACH-HF training (i.e., digitalisation of the REACH-HF programme and training).

Personal reflection

Qualitative research reporting guidelines, such as the Consolidated Criteria for Reporting Qualitative Research checklist [278] or the Standards for Reporting Qualitative Research checklist [279], mandate a statement capturing the process of reflexivity on the conducted research study. Reflexivity is a practice, mostly relevant (but not exclusively) to qualitative investigations, during which researchers consider their contribution to the investigation (i.e., their background and experiences, level of expertise, and their opinions and biases) as well as the research process itself, for example, the personal connection with the phenomenon under investigation or the relationship with the study participants [280]. By engaging in the

reflexive process, the researcher can increase the integrity and trustworthiness of research findings [281]. Reflexivity is also a hallmark of ethical qualitative research [282].

Reflecting on my contributions to the conducted research study, I believe some of my personal characteristics and experiences had a positive impact on the research process, whereas others might have potentially a negative impact. I am a female researcher, originally from Poland, but I have lived in England for almost 20 years. English is my second language and I speak with a recognisable accent. Prior to this project, my research experience included conducting a systematic review as part of my Master's degree. Before commencing my PhD, I worked mainly in the NHS delivering and managing mental health services for over a decade. Indeed, I believe that my professional experience of delivering evidence-based treatment and feeling very passionate about improving the delivery of healthcare services in general was what drew me to this research project in the first place. During the design stages, those experiences and attitudes translated into a commitment to making this research study as pragmatic and useful to the end-user (i.e., healthcare professionals) as I possibly could. I appreciate that in my quest to change/improve healthcare, the process of knowledge creation for the sake of knowledge creation might have been secondary. Additionally, when reflecting on the amount and quality of data produced during this research project, I have wondered whether my first-hand experience of being part of a busy NHS team, made me less demanding/assertive in my liaisons with the Beacon Site staff, for example, around the importance of timely and accurate data entry.

I believe my extensive experience of delivering psychotherapy (having important conversations with people from different backgrounds) allowed me to quickly build rapport with the study participants and conduct meaningful interviews. On the other hand, my lack of knowledge of cardiac rehabilitation and/or heart failure were shortcomings – my interviewees might not have been able to be as technical when sharing their knowledge and experiences with me as they might have liked. Also, due to English being my second language, some of the subtler meanings might have been lost either at the stage of data collection (e.g., interviewing) or interpretation.

My preference for qualitative research influenced the qualitative/quantitative balance of the mixed methods design in favour of the former. Also, the fact that I was a complete novice in the area of implementation science at the beginning of this project, led to me relying on the chosen implementation theory throughout the project – this gave me somewhat of a starting point. On the other hand, my limited experience of implementation science also meant that I had a fresh and critical view of the chosen theory, which was not influenced by previous experience of other theories.

The data from the mixed methods studies will be presented in Chapters 4 and 5. Prior to that, I will present the methods and results from a systematic review conducted to identify provider- and system-level barriers and enablers affecting the delivery of cardiac rehabilitation for patients with heart failure.

CHAPTER 3 – SYSTEMATIC REVIEW

An overview of systematic reviews

Systematic reviews (especially meta-analyses) are considered to be the most robust sources of evidence and placed at the top of the hierarchy of evidence pyramid [283]. An overall goal of a systematic review is to increase the reliability and trustworthiness of research findings on the chosen topic by synthesising data from different research studies, which meet the predefined inclusion/exclusion criteria [284]. When conducting a systematic review, each comparative step (i.e., deciding inclusion/exclusion criteria, search strategies, study selection and appraisal, and synthesis of data) needs to be documented to ensure transparency and replicability [285]. By levelling out methodological shortcomings and biases of individual studies, systematic reviews can increase the likelihood of research findings being valid and credible. Therefore, the results of systematic reviews are often used to inform clinicians about the safety and efficacy of interventions and healthcare planners and commissioners about which interventions to include in routine service delivery [286]. For example, the Cochrane Collaboration is an international not-for-profit organisation at the forefront of synthesising evidence on health interventions and healthcare systems as well as providing guidance on the process of conducting systematic reviews [287, 288]. Another established authority in the realm of scientific reviews is an Australia-based research organisation providing training, tools and resources for conducting different types of reviews – the Joanna Briggs Institute [289].

Different types of reviews and 'empty reviews'

There are different types of reviews depending on study design (e.g., clinical effectiveness, diagnostic or prognostic reviews) and methodology (e.g., rapid reviews, reviews of reviews, qualitative metasynthesis or scoping reviews). Clinical effectiveness reviews using a meta-analytic approach tend to dominate peer reviewed journals [290]. However, advances in review methodology have led to an increased use of systematic reviewing principles to answer non-efficacy questions such as in methodological systematic reviews or economic evaluation reviews [291]. Just as in primary research, the choice of a systematic review question is the most important step when deciding the scope of such a review [292]. A systematic review question will inform the most appropriate review type and the most effective tools for data analysis and synthesis. For example, an expert opinion systematic review can confirm current best practice, whereas a psychometric review can identify the best psychometric tool to use [291].

Some systematic reviews do not identify any articles that are eligible for inclusion. These are called 'empty reviews' [293]. A 2012 study confirmed that nearly 9% of active Cochrane reviews at a specific point in time in 2010 had not identified any studies [294]. Despite this, empty reviews still have the potential to establish gaps in the current knowledge and shape and streamline future research efforts [295]. However, many do not get published often due to journal editors' perceptions of their lack of impact potential [296]. There is, therefore, a need for better guidance on reporting empty reviews [294].

‘Garbage in, garbage out’

An important step when conducting a systematic review is to consider the methodological quality of the identified primary sources. It is important to avoid the ‘garbage in, garbage out’ phenomenon, in which a synthesis of low quality primary research studies results in a low quality systematic review with recommendations that are not robust [297]. To avoid this, reviewers can use study design-specific quality assessment tools, such as the Critical Appraisal Skills Programme checklists [298] and the MeaSurement Tool to Assess Systematic Reviews 2 [299] or reporting guidelines, for example, the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement [300]. Potential biases that can negatively affect the quality of selected primary studies, and consequently reduce the validity of the systematic review findings, include selection bias, performance bias, attrition bias and detection bias [301].

When during systematic searches randomised controlled trials are identified a risk of bias assessment should be conducted. This can help to identify sources that are of lower quality and, therefore, contextualise the overall review findings within the available evidence-base. Different errors during the conduct of randomised controlled trials can lead to the occurrence of biases. For example, selection bias (systematic differences between treatment and control groups) can occur due to incomplete randomisation, performance bias (systematic differences in the care received between treatment and control groups) due to a lack of blinding, attrition bias (systematic exclusion of randomised participants) due to not applying the intention-to-treat principle, or detection bias (systematic differences in assessment of outcomes between treatment and control groups) due to non-blinded assessment protocol

[288]. Presence of the above biases can impact negatively on the interpretation of randomised controlled trial findings and inadvertently on meta-analysis of such trials. Different tools can be used to conduct a thorough risk of bias assessment, one of them is the revised tool for assessing the risk of bias in randomised trials – RoB 2 [302], as recommended in the Cochrane Handbook for Systematic Reviews of Interventions [288].

Observational studies can also be negatively impacted by biases [303]. For example, poor selection of study participants can lead to a lack of representativeness between study sample and target population (selection bias). Information bias (errors during data collection and/or data recording) can be further divided into measurement error or misclassification (inaccurate measurement or recording), recall bias (misremembering past events) or interviewer bias (systematic differences during data collection between different cohorts). Information bias, in the form of missing data, might mean that exclusion of specific study participants took place, for example, if certain groups of people are more likely to have missing data (e.g., when elderly patients or people without access to technology are not able to complete an online survey). Interviewer bias might be linked with the interviewer ability to build rapport with participants and elicit personally sensitive information.

No randomised controlled trials were identified during the conducted systematic review. A thorough quality assessment was conducted for each observational and survey study included in the systematic review, using design-appropriate quality assessment tools (details in Table 4 on page 76).

The use of theory in systematic reviews

Just as primary research studies (e.g., intervention design or efficacy trials) can greatly benefit from comprehensive theoretical foundations, systematic reviews of implementation studies can use implementation theories or an intervention's theory of change to design and refine the review's methods and/or as a framework for data analysis and interpretation [304]. Certain scientific reviews, most notably realist syntheses, focus overtly on understanding an intervention's causal mechanisms (i.e., how the intervention works, in what circumstances and for whom), which can lead to development or refinement of the intervention's theory of change [305]. Systematic reviews investigating processes of implementation have used different implementation theories, models and frameworks, for example, the Consolidated Framework for Implementation Research, the Theoretical Domains Framework or Normalisation Process Theory [269, 306-309].

Using a theoretical scaffolding was also considered for the conducted systematic review. However, this was rejected due to the paucity of implementation research on the chosen topic. An advantage of operationalising an existing implementation theory would have been in potentially creating a conceptual starting point and a lens for the systematic review. On the other hand, conducting a systematic review underpinned by a theoretical model would narrow the inclusion criteria, which could lead to an exclusion of studies or not detecting barriers and enablers outside of the theoretical frame. The exploratory (scoping) character of the review will be considered further in the reflection section at the end of this chapter.

Groundwork/prior reading informing the design of the current systematic review

The research-to-practice gap (i.e., the low uptake of cardiac rehabilitation in patients with heart failure) identified in Chapter 1 was the starting point for conducting the systematic review. To specify and refine the research question, existing literature on the topic was considered. The perusal of the existing literature confirmed the presence of a substantial body of evidence exploring patient-level barriers leading to the healthcare disparity affecting patients with heart failure. This contrasted with a lack of systematic reviews and a relative lack of empirical studies exploring non-patient (i.e., provider- and system-level) factors that can influence the provision of cardiac rehabilitation in this clinical population. Hence, the aim of the review was to identify provider- and system-level barriers and enablers affecting the delivery of cardiac rehabilitation for patients with heart failure, with a view that increasing the understanding of a wider set of influences (and suggesting ways to mitigate some of these non-patient barriers) can lead to improved patient care.

The scope

Initially, when deciding the scope for the systematic review I considered including grey literature, for example, clinical guidance, expert consensus documents, narrative reviews and opinion pieces. Following the preliminary searches, it became clear that, if included, grey literature would have substantially outweighed the available empirical evidence. In light of this, a decision was made to exclude grey literature from the current review. The main advantage of excluding non-empirical studies from the review was preserving the

methodological quality of the included primary research sources and increasing the rigour of the current review findings. However, by synthesising data from empirical studies only, some of the more subtle discourses present in the field of cardiac rehabilitation for heart failure were potentially excluded. For example, numerous illustrations of good practice outlined by healthcare professionals who come into contact with patients with heart failure as well as any potentially unhelpful narratives present within the healthcare community (e.g., that patients with heart failure are too frail to safely engage in cardiac rehabilitation). Both of these examples could have been useful to the reader of the report as they capture the current *status quo* positively and negatively affecting the delivery of cardiac rehabilitation for patients with heart failure. The decision to exclude grey literature was made on the basis that this was the first systematic review on this topic and, therefore, it was more important to preserve the methodological quality of the included empirical studies rather than to cast the net very wide. Studies in languages other than English were also excluded. This was due to limited time and funding for translating such studies.

Analytic approach

The extent, type and quality of the articles that met the scope for the systematic review were an important consideration when deciding the analytical approach to data synthesis. Two synthesis methods were considered for the systematic review: narrative synthesis and meta-ethnography. The main advantage of using meta-ethnography would have been to examine interactions between different studies (i.e., reciprocity, refutation and line of argument) and to 'translate' findings from multiple sources into each other, resulting in more nuanced integrated findings (i.e., a picture that is more than the sum of its parts) [310]. However, due

to the paucity of rich conceptual data on the chosen topic, it was decided that a robust meta-ethnographic approach was not possible.

On the other hand, meta-ethnography is a highly interpretive method that requires substantial qualitative research expertise and considerable immersion in the qualitative data. This would have been difficult due to the lack of rich input data and would have, therefore, not yielded much more depth of analysis than a less in-depth narrative synthesis. Given the low number of qualifying studies and the quality of available empirical data (a lack of rich conceptual output) a descriptive narrative synthesis was considered to be the most appropriate analytical approach. A very important advantage of the narrative synthesis over meta-ethnography is that it tends to produce research outputs that are accessible to a wider audience (i.e., academics, policymakers, practitioner and commissioners), whereas meta-ethnography outputs are considered to be more targeted towards an academic audience [311]. Lastly, to enrich the synthesis of the data and include some consideration of the interaction between sources (a key element lost by rejecting meta-ethnography), a triangulation protocol [312], resembling some of the meta-ethnographic translation steps, was included in the data analysis.

The systematic review paper

Below is a systematic review paper titled ‘A systematic review of provider-and system-level factors influencing the delivery of cardiac rehabilitation for heart failure’. A version of this manuscript was published in BMC Health Services Research (DOI https://doi.org/10.1186/s12913-021-07174-w).

Abstract

Background

There is a longstanding research-to-practice gap in the delivery of cardiac rehabilitation for patients with heart failure. Despite adequate evidence confirming that comprehensive cardiac rehabilitation can improve quality of life and decrease morbidity and mortality in patients with heart failure, only a fraction of eligible patients receive it. Many studies and reviews have identified patient-level barriers that might contribute to this disparity, yet little is known about provider- and system-level influences.

Methods

A systematic review using narrative synthesis. The aims of the systematic review were to a) determine provider- and system-level barriers and enablers that affect the delivery of cardiac rehabilitation for heart failure and b) juxtapose identified barriers with possible solutions reported in the literature. A comprehensive search strategy was applied to the MEDLINE, Embase, PsycINFO, CINAHL Plus, EThoS and ProQuest databases. Articles were included if they were empirical, peer reviewed, conducted in any setting, using any study design and describing factors influencing the delivery of cardiac rehabilitation for patients with heart failure. Data were analysed using inductive thematic analysis and a triangulation protocol to identify convergence/contradiction between different data sources.

Results

Seven eligible studies were identified. Thematic analysis identified nine overarching categories of barriers and enablers, which were classified into 24 and 26 themes, respectively. The most prevalent categories were 'the organisation of healthcare system', 'the organisation of cardiac rehabilitation programmes', 'healthcare professional' factors and 'guidelines'. The most frequent themes included 'lack of resources: time, staff, facilities and equipment' and 'insufficient knowledge, and poor awareness and attitude of healthcare professional'.

Conclusions

The systematic review identified a wide range of provider- and system-level barriers impacting the delivery of cardiac rehabilitation for heart failure, along with a range of potential solutions. This information may be useful for healthcare professionals to deliver, plan or commission cardiac rehabilitation services as well as future research.

Background

Heart failure is a debilitating and progressive clinical syndrome that, due to increasing life expectancy and more widespread adoption of a Western lifestyle, has seen a steady increase in prevalence across the globe [13]. The cost of treating patients with heart failure by the National Health Service (NHS) is estimated at two billion pounds per year, with most of the cost associated with hospital admissions [313]. There is also a substantial human cost to heart failure as many patients experience a diminished quality of life related to their illness [314]. Improving health-related quality of life is a fundamental aim of heart failure management [315].

Key strategies for improving health-related quality of life include self-management of symptoms and psychological consequences of heart failure, and exercise-based rehabilitation of physical functioning, all of which are part of comprehensive cardiac rehabilitation programmes. Several trials and systematic reviews have confirmed the safety and effectiveness (reduction in hospital admissions and improvement in health-related quality of life) of cardiac rehabilitation for heart failure [74, 108, 109]. Thus, cardiac rehabilitation programmes are an effective and cost-effective strategy for improving health-related quality of life in patients with heart failure [110, 146].

Despite the strong evidence for effectiveness, according to a recent global survey, cardiac rehabilitation is available in only half the countries of the world [85]. Furthermore, even in countries that do offer cardiac rehabilitation services, coverage is low. Globally only 30% of eligible patients access cardiac rehabilitation [316] and there

are large regional variations in the content of cardiac rehabilitation programmes [86]. The European Cardiac Rehabilitation Inventory Survey 2010 [112] also highlighted that less than 20% of patients with heart failure receive cardiac rehabilitation.

The low proportion of eligible patients receiving cardiac rehabilitation may reflect a lack of service availability or it may reflect low uptake by patients of services. For example, in the United Kingdom (UK) uptake of cardiac rehabilitation is estimated to be around 50% on average, with lower uptake in women, ethnic minorities, and people living in rural areas and areas of high deprivation [317]. There is a large body of evidence exploring patient-level factors impacting cardiac rehabilitation enrolment/attendance, compliance/adherence, completion and drop-out rates amongst general cardiac population [118, 318-324]. Patient-level factors include distance required to travel, financial constraints and work obligations [128]. However, to the best of my knowledge, there have not been any systematic reviews of non-patient level factors (i.e., provider- and system-level barriers affecting the delivery of cardiac rehabilitation for patients with heart failure).

The current systematic review, therefore, aimed to answer the following research question: 'What are the factors influencing the offer, referral, delivery, implementation, and provision of cardiac rehabilitation for heart failure?'. The purpose of the study was to identify and qualitatively describe barriers and enablers affecting the delivery of cardiac rehabilitation for patients with heart failure.

Methods

The systematic review has been registered with PROSPERO (CRD42019153247) and reported in concordance with PRISMA guidance [300]. During the conduct of the review, I also consulted the Guidance on the Conduct of Narrative Synthesis in Systematic Reviews for issues specific to reviews focusing on implementation [303].

Inclusion and exclusion criteria

The scope for the systematic review is illustrated in Table 2.

Table 2 PICOS search strategy

PICOS	Definition
Population	Services and professionals working with patients with heart failure
Intervention	'A coordinated and structured programme designed to remove or reduce the underlying causes of cardiovascular disease' [325] to 'include a range of interventions with health education, lifestyle advice, stress management and physical exercise components' [325-328].
Comparison	
Outcome	Barriers and enablers
Study type	Any empirical

Search strategies

The full search strategy is provided in Appendix 5. The following databases were searched using a combination of free-text search terms and controlled vocabulary (Medical Subject Headings): MEDLINE (OVID interface), Embase (OVID interface), PsycINFO (OVID interface), CINAHL Plus, and EThoS and ProQuest libraries. The only

exclusion criterion applied to the search strategies was for studies in languages other than the English language.

Study selection

Paulina Daw (PD) conducted all searches and the initial screening of all titles and abstracts; Colin J Greaves (CJG) and Thomas Withers (TW) screened 20% each of the total titles and abstracts. Following the initial screening, PD read the full-text of all potentially eligible articles. CJG and TW reviewed 50% each of the total of full-length articles against the eligibility criteria. To ensure saturation in sources, extensive backward and forward citation tracking was applied to reference lists of relevant articles and key texts. Any discrepancies in selection were discussed between the reviewers and a fourth reviewer Jet JCS Veldhuijzen van Zanten was available for arbitration if needed. No additional information had to be sought from study authors to inform eligibility decisions. The review authors were not blind to the journal titles, study authors or institutions of the full-text articles.

Study appraisal

The systematic review used four different quality assessment tools for different study designs in line with the National Institute for Health and Care Excellence (NICE) manual on developing guidelines [329]. The chosen study appraisal tools are listed in Table 4 on page 76. Using the most suitable quality assessment tool, a total numerical score obtained for each study was re-calculated into percentages and assigned into the following categories of quality: low (below 20%), low-to-medium (20% - 44%), medium

(45% - 69%), medium-to-high (70% - 89%) and high (above 90%). The quality assessment was conducted by PD and TW who independently scored all of the included studies.

Data extraction

PD extracted study characteristics and all relevant data on factors influencing delivery of cardiac rehabilitation from the included studies using a data extraction template. Data extraction for all included studies was verified by CJG and TW. The extracted study characteristics included author, year, study design/methods of data collection, country/setting, sample size, study/report aim and healthcare professional population. Extraction of the data pertaining to provider- and system-level barriers and enablers associated with the delivery of cardiac rehabilitation for heart failure included first-order constructs (data from the original study participants) and second-order constructs (assumptions and observations made by researchers). The review team only included reported data (i.e., the lack of a barrier was not entered as an enabler unless the article clearly identified it as such). Passages of text describing barriers and enablers were inputted and organised in the NVivo software [330] and summarised into a table of provider- and system-level barriers and enablers identified in the literature (Table 3).

Table 3 Provider- and system-level barriers and enablers identified in the literature

	Barriers and enablers identified in the literature
Non-patient barriers	Tradition of resting patients with heart failure, lack of a mortality benefit with cardiac rehabilitation among patients with heart failure, lack of evidence for alternatives to centre-based cardiac rehabilitation, a large variety of complex guidelines and position statements, guidelines providing no specific implementation details, cardiac rehabilitation not included in the local guidelines, poor healthcare professional education, organisational constraints (e.g., lack of facilities and time), high costs of cardiac rehabilitation, lack of equipment, high cost and shortage of multidisciplinary teams, exclusion from local commissioning agreements, lack of inclusion in the contract with the referring institutions, other people (e.g., heart failure specialist nurses) providing a similar service, lack of healthcare integration, governance split among several entities, nonalignment of payment incentives and/or information systems between organisations, lack of local patient pathways, lack of medical insurance cover, lack of integration of clinical algorithms into the Information and Communication Technology systems, professional isolation between departments, lack of minimal standards and consistency in heart failure management, lack of well-defined effective strategies for implementing cardiac rehabilitation, lack of referrals from healthcare professionals, lack of alternatives to centre-based cardiac rehabilitation, reduced number of operating centres, limited eligibility criteria, difficult to decide which programme patients should be referred to (where several programmes are available), extensive and confusing referral tests, professional's lack of knowledge, awareness, familiarity and attitude, ignorance among physicians with regard to the benefits of cardiac rehabilitation, overemphasis on procedural solutions, safety concerns, perception that patients with heart failure are too ill for exercise, lack of knowledge on the benefits and safety of cardiac rehabilitation programmes, inefficient referral

	processes, poor flow of patient care from acute hospitals to outpatient and community follow-up, lack of strategies to improve healthcare professional's condition-specific health literacy and referral processes, lack of flexibility in programme delivery.
Non-patient enablers	Data in favour of the beneficial effects and safety of cardiac rehabilitation in patients with heart failure, better tailoring of guidelines, inclusion of cardiac rehabilitation for the management of heart failure in contemporary clinical guidelines, combining and translating guidelines into clinical algorithms, development of cross-institutional guidelines, better implementation of the existing guidelines, education programmes for healthcare professionals, establishing inter-professional collaboration forums (e.g., working groups), creating possibilities for collective education (e.g., knowledge-sharing meetings), better strategies to improve physicians' perceived benefits of cardiac rehabilitation, initiatives influencing awareness of the importance of cardiac rehabilitation (e.g., the Cardiac Rehabilitation Network of Ontario), improved insurance coverage or reimbursement, healthcare authorities to increase financial resources, refining multidisciplinary team responsibilities, providing integrated healthcare, collaboration with healthcare authorities, systematic inpatient referral, automatic referral by institutions, large-scale implementation of clinical algorithms, utilisation of the EXPERT tool (interactive decision-support), developing collaborative relationships between health professionals looking after patients with heart failure, adding cardiac rehabilitation programmes to usual care programmes, incorporating cardiac rehabilitation into hospital performance measures, targeting non-referred populations, the rate of inpatient cardiac rehabilitation referral as a performance measure for the institution, choice between hospital-based rehabilitation and home-based individual programmes, innovative strategies and new delivery systems such as telemedicine, broadened eligibility, changing professionals' attitudes regarding integration of care, encouragement of reluctant referrers, advertisement opportunities of rehabilitation programmes to healthcare professionals, flexibility within the cardiac rehabilitation programme delivery.

Data synthesis

In developing the analytic approach for the systematic review, I followed guidance on the selection of qualitative evidence synthesis methods for health technology assessments of complex interventions [311] and the seven-domain RETREAT framework [331]. The following components of the framework were considered: the type of review question, the review's purpose and the targeted audience, the time frame, the availability of resources and expertise, and the type of available data. Consequently, I conducted a narrative review of the qualitative data using thematic analysis. Categories identified during the thematic analysis were further analysed using concept triangulation. Following my initial analysis, to help to structure the findings and to relate them to an existing theoretical framework, the themes were categorised according to their level of influence according to the social ecological model [312, 332]. This model was chosen as it provides a good fit with the data and allows the presentation of influencing factors at multiple levels of social organisation (from intra-individual to societal/cultural).

Thematic analysis

All data relevant to the research question were entered into the NVivo software. The verbatim text of first- and second-order constructs representing barriers and enablers was organised thematically using thematic coding procedures and reflexive thematic analysis principles described by Braun and Clarke in their 2006 and 2019 papers [333, 334]. First- and second-order constructs were given the same weight in the final analysis. The coding scheme emerged inductively following reading and rereading of the original data sources and discussions between the core review team (PD and CJG). The final coding scheme consisted of

a small number of overarching categories and a larger set of more granular themes within each category. The identified themes were further analysed in terms of their frequency and prominence (identifying the most common themes across the data set and their spread).

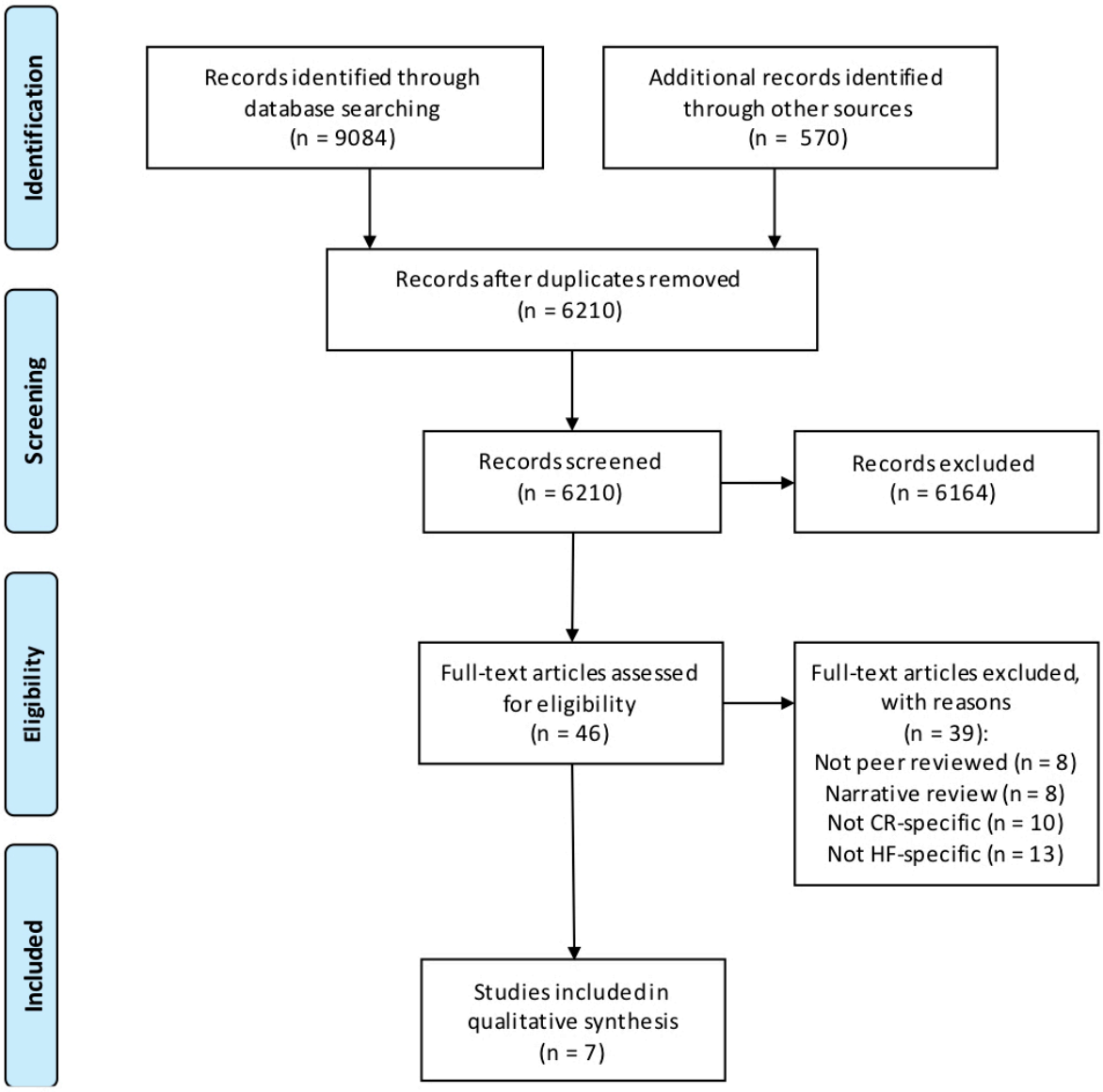
Triangulation protocol

A triangulation protocol was used to summarise similarities and differences between different data sources [312]. Each theme was considered in each data source and categorised as being in agreement, partial agreement or dissonance. An additional category (isolation) was created for themes that were neither confirmatory nor contradictory, as they simply added a concept that was not identified in other studies. In case of disagreement between data sources, further data within the articles (e.g., year of publication, differences in populations or methods used) were considered as potential explanations of such discrepancies.

Results

All searches were conducted in October 2019 by PD and updated in March 2021. The searches identified 9654 articles, of which 3444 were duplicates. Following the screening of titles and abstracts of 6210 articles, 46 full-text articles were obtained, and seven articles were included for analysis [87, 123, 124, 126, 127, 335, 336]. The full search results are presented in Figure 6.

Figure 6 Flow diagram by PRISMA of included studies



Study characteristics

The characteristics of the included studies and the quality assessment tools/scores are presented in Table 4. There was little demarcation between studies in terms of setting (centre-based cardiac rehabilitation programmes taking place in hospitals or community settings), healthcare professionals involved in the study (members of multidisciplinary teams that ordinarily care for patients with heart failure), methods of data collection (mostly qualitative methods utilising document analysis, survey questionnaires, interviews, focus groups and observations) or evidence quality (medium to medium-to-high). The included studies were published between 2010 and 2020 and represented mostly European healthcare systems (i.e., Denmark, Netherlands, the UK and the European Society of Cardiology affiliated countries) or Western healthcare systems (i.e., Australia, Canada and the United States of America). Five studies were rated as being of medium quality and two were rated as medium-to-high quality.

Table 4 Characteristics of included studies and quality assessment tools/scores

Study details					Population	Quality assessment
Author (year)	Study design/method(s) of data collection	Country/setting	Sample size	Study/report aim(s)	Healthcare professional(s)	Tool (score)
Achttien et al. (2015)	Guideline review Document analysis (Dutch and European cardiac rehabilitation guidelines and position statements), systematic review and expert panel	Cardiac rehabilitation centres in Netherlands offering exercise-based cardiac rehabilitation	Not reported	To develop evidence-based clinical algorithms that can serve as best practice standards for prescription and evaluation of exercise-based cardiac rehabilitation in patients with coronary artery	Multidisciplinary expert panel (cardiologists, physiotherapists, sports physicians, occupational physicians, rehabilitation physician, human movement scientist and health informatician)	AACODS checklist [337] (medium-to-high)

				disease and chronic heart failure		
Dalal et al. (2012)	Cross-sectional survey Two-stage, postal questionnaire-based national survey (the stage 1 questionnaire responses were 224 out of 277 and 17 out of 24 for stage 2)	Cardiac rehabilitation programmes in England, Wales and Northern Ireland	n=224 at stage 1 and n=17 at stage 2	To determine why so few patients with chronic heart failure in England, Wales and Northern Ireland take part in cardiac rehabilitation	Service managers and other heartcare professionals responsible for the cardiac rehabilitation service/team	Centre for Evidence-Based Management survey questionnaire study checklist [338] (medium)
Frolich et al. (2010)	Observational, non-comparative case study Surveys, before and after patient performance measurements, semi-	Quality improvement project set up in Denmark (Bispbjerg University Hospital, the City of Copenhagen	n=44 GPs answered the mailed questionnaire	To describe the process and results of a project that led to the development of new management practices and improvement of existing ones to	Two specialists (in geriatrics and internal medicine), specialist physiotherapist, nurse specialist, project leaders, hospital management, department leadership, leadership of the healthcare centre,	National Heart, Lung, and Blood Institute Quality Assessment Tool for Before-After (Pre-Post) Studies With

	structured interviews and observations (with key informants, including the leadership of the hospital and healthcare centres, a leading representative for the GPs, the project leaders, health professionals in the hospital and in the healthcare centre, and GPs)	and the GPs in Copenhagen)		support integrated care between three healthcare organisations	representatives of the GPs, 'a steering committee' and four working groups	No Control Group [339] (medium)
Golwala et al. (2015)	Observational, prospective Get With The Guidelines–Heart Failure registry and	Various institutions representing community hospitals and	n=338	To assess proportional use, temporal trends and factors associated with cardiac	Hospital staff ordinarily looking after patients with heart failure	National Heart, Lung, and Blood Institute Quality Assessment

	quality improvement programme Used the Get With The Guidelines–Heart Failure database to determine the contemporary proportional use, temporal trends and major factors associated with referral for cardiac rehabilitation at discharge among eligible patients with heart failure	tertiary-care referral centres from all United States of America geographic regions		rehabilitation referral at discharge among patients admitted with decompensated heart failure		Tool for Before-After (Pre-Post) Studies With No Control Group [339] (medium)

Nguyen et al. (2013)	Observational, retrospective cohort study Database analysis (multivariate logistic regression to examine patient characteristics, in-hospital diagnosis, clinical events and investigations associated with cardiac rehabilitation referral)	Hospitals in Ontario, Canada	n=11	To assess cardiac rehabilitation referral rates during index hospitalisation (report the frequency and temporal trends of cardiac rehabilitation referral rates in Ontario, describe the factors associated with cardiac rehabilitation referral and examine the use of evidence-based medical therapies and their relationship with cardiac rehabilitation	Hospital staff from 11 Canadian sites reporting to the Global Registry of Acute Coronary Events database	Critical Appraisal Skills Programme Cohort Study Checklist [340] (medium-to-high)

				referral before hospital discharge)		
Palmer et al. (2020)	National online cross-sectional survey (365 registered programmes were contacted and 165 healthcare professionals completed the survey)	Cardiac rehabilitation programmes in Australia taking place in community settings and accepting patients with heart failure Programmes were excluded if their rehabilitation programme was conducted within	n=165 healthcare professionals completed the survey	The primary aim of the study was to identify clinician perceived barriers to engagement in rehabilitation for patients with heart failure	Participants were clinicians such as registered nurses or physiotherapists working as the programme coordinators	Centre for Evidence-Based Management survey questionnaire study checklist [338] (medium)

		an inpatient hospital setting				
Piepoli et al. (2019)	Survey questionnaire study Sub-analysis of the web-based Exercise Training in Heart Failure survey	Cardiac centres from the European Society of Cardiology affiliated countries	n=172	To investigate the regional variations in the implementation and prioritisation of exercise training programmes; to identify specific/local barriers to implementation	Cardiologists, nurses, psychologists, exercise physiologists/therapists, dieticians and physiotherapists	Centre for Evidence-Based Management survey questionnaire study checklist [338] (medium)

Thematic analysis

During the process of thematic analysis, the identified barriers were organised into nine categories and 24 themes. The same categories, save for one – 'the origins of cardiac rehabilitation and previous practices', emerged in the thematic analysis of reported enablers; the enablers were further divided into 26 themes. Table 5 contains a summary of the thematic analysis – the main analysis used to analyse the available data. This table lists the identified categories and themes, highlights each theme frequency and coverage, and, where possible, matches a theme related to a barrier with a counteracting enabler.

Table 5 Barriers and enablers to delivering cardiac rehabilitation to patients with heart failure identified during the thematic analysis

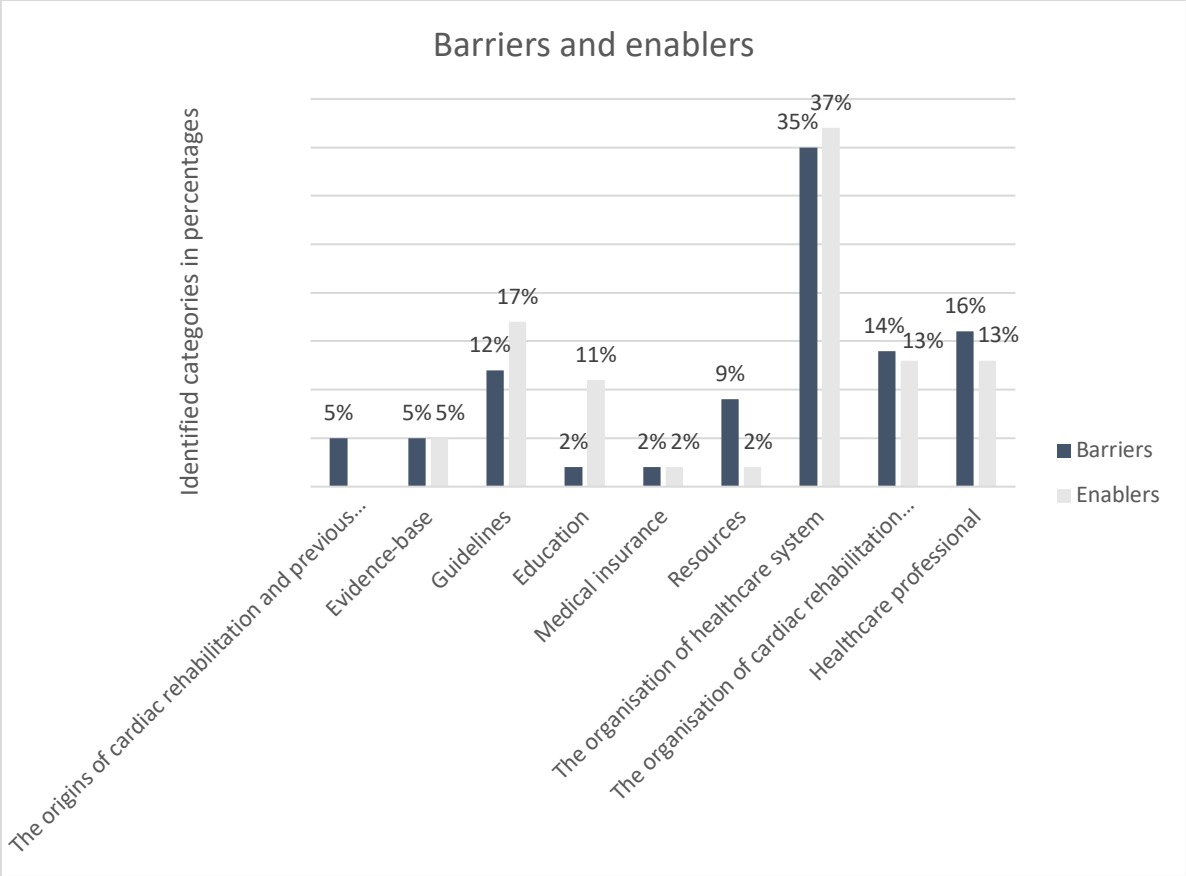
Overarching categories	Barriers/factors preventing delivery of cardiac rehabilitation (theme frequency/coverage)	Enablers/factors promoting delivery of cardiac rehabilitation (theme frequency/coverage)
The origins of cardiac rehabilitation and previous practices	The outdated practise of bed rest [87, 123]	
Evidence-base	Poor evidence-base supporting cardiac rehabilitation for heart failure [124, 126]	Sufficient evidence-base supporting cardiac rehabilitation for heart failure [123, 124]
Guidelines	Guidelines not tailored to the end-user [126, 127]	Better tailoring of guidelines [126, 127]
	Volume and complexity of guidelines [87, 127]	Translating guidelines into clinical algorithms [127]
	Lack of inclusion of cardiac rehabilitation in local guidelines [87]	Guideline endorsement [123, 124]
		Cross-institutional guidelines [335]
		Guideline implementation [87]
Education	Lack of formal education on exercise training [87]	Education programmes on the importance of exercise training [87]
		Knowledge sharing opportunities [124, 335]

		Awareness-raising [123, 336]
Medical insurance	Lack of medical insurance cover [124]	Medical insurance eligibility criteria and sufficient cover [124]
Resources	Lack of resources: time, staff, facilities and equipment [87, 126, 127, 336]	Adequate resources: time, staff, facilities and equipment [87]
The organisation of healthcare system	Lack of commissioning [87, 126]	Sufficient commissioning [87, 124]
	Blurred professional roles [87, 126]	Clear professional roles and responsibilities [87, 124]
	Lack of integration between organisations [87, 335]	Better integration between organisations [87, 335]
	Lack of patient pathways [87, 126, 336]	Referral system [123]
	Inadequate IT systems [127]	Adequate IT systems [87, 127]
	Lack of integration between departments [335]	Better integration between departments [87, 335]
	Lack of care standardisation [87]	Care standardisation [335]
	Lack of implementation strategies [124]	
	Lack of referrals [126, 336]	
		Healthcare legislation [124]
		Performance and target measures [123]
		Use of clinical algorithms [127]

The organisation of cardiac rehabilitation programmes	Lack of different modes of delivery [126, 336]	Availability of different modes of delivery [124, 126, 336]
	Lack of programmes [87]	Availability of programmes (specialised and community-based) [87]
	Limiting eligibility criteria [124]	Broadened eligibility [87]
	Difficult to choose a suitable programme [335]	
	Confusing referral procedures [335]	
Healthcare professional	Insufficient knowledge, and poor awareness and attitude of healthcare professional [123, 124, 127, 336]	Sufficient knowledge and awareness, and positive attitude of healthcare professional [123, 124, 335, 336]
	Safety concerns [123, 124, 336]	
		Improving the doctor-patient relationship [87]

‘The organisation of healthcare system’ was the most frequent category for both barriers (15 instances) and enablers (15 instances) and this category was mentioned at least once in all of the included articles. The other most frequent categories related to barriers were ‘the organisation of cardiac rehabilitation programmes’, ‘healthcare professional’ factors and ‘guidelines’. The same categories were the most frequent categories describing enablers. Themes pertaining to barriers that were quoted most frequently in the included studies were ‘lack of resources: time, staff, facilities and equipment’ and ‘insufficient knowledge, and poor awareness and attitude of healthcare professional’’. The latter was also the most frequently identified enabler. Figure 7 apportions the identified categories relating to barriers and enablers.

Figure 7 Identified categories of barriers and enablers in percentages



Triangulation of themes across the data sources

Convergence analysis (Table 6) revealed that 50% (n=12) of themes related to barriers and 53% (n=14) of themes related to enablers appeared as isolated concepts. There was agreement or partial agreement for 50% (n=12) of the identified barriers and dissonance was identified for 8% (n=2): 'insufficient knowledge, and poor awareness and attitude of healthcare professional' and 'safety concerns' – themes that showed the most complex convergence relationship (agreement, partial agreement and dissonance).

Piepoli et al. concluded that 'perceived lack of importance (…), safety concerns, and uncertainties about the usefulness (…) all played a marginal role' [87]. Similarly, Dalal et al. found that 'more than half (54%) of the centres expressed confidence in the skill mix and knowledge of their staff to provide cardiac rehabilitation in heart failure' [126] as well as that 'a lack of evidence on safety or clinical benefit was not a factor that influenced most centres' ability to offer cardiac rehabilitation' [126].

Thus, Piepoli et al. and Dalal et al. were in agreement about a marginal influence of 'insufficient knowledge, and poor awareness and attitude of healthcare professional' and 'safety concerns', that was at odds with the remaining data sources, which recognised those as substantial barriers. Additionally, Piepoli et al. concluded that 'lack of resources: time, staff, facilities and equipment' was a barrier affecting non-Western regions of the European Society of Cardiology affiliated countries only. This partial agreement with two other studies might be linked with Piepoli et al. considering in their analysis several distinct geographical areas and, therefore, capturing a more nuanced picture in the results.

Fifty-seven percent (n=4) of sources were aligned regarding the top potential factor positively impacting the delivery of cardiac rehabilitation for heart failure (i.e., 'sufficient knowledge and awareness, and positive attitude of healthcare professional'). Twelve (46%) enabler themes were classified as being in agreement with at least one additional data source. Only one (4%) dissonant relationship was identified amongst themes related to enablers and this theme was linked to 'guideline endorsement'. Piepoli et al. highlighted that barriers to the delivery of cardiac rehabilitation 'cannot be overcome by the development of different

guidelines for the different geographical areas (Southern/Northern/Western/Eastern/extra-EUR), but by a better implementation of the existing ones' [87]. This was in conflict with two other studies, which reported further guideline endorsement as a potentially enabling factor.

Table 6 Triangulation of reported barriers and enablers across the data sources

	Triangulation of themes related to barriers						
Evidence quality	M-H	M	M	M	M-H	M	M
Author	Achttien et al.	Dalal et al.	Frolich et al.	Golwala et al.	Nguyen et al.	Palmer et al.	Piepoli et al.
Insufficient knowledge, and poor awareness and attitude of healthcare professional	✓	✗		✓	✓	✓	✗
Safety concerns		✗		✓	✓	✓	✗
Lack of resources: time, staff, facilities and equipment	✓	✓				✓	✓
Blurred professional roles		✓					✓
Guidelines not tailored to the end-user	✓	✓					
Lack of commissioning		✓					✓
Lack of integration between organisations			✓				✓
Lack of patient pathways		✓				✓	✓

The outdated practise of bed rest					✓		✓
Poor evidence-base supporting cardiac rehabilitation for heart failure		✓		✓			
Lack of different modes of delivery		✓				✓	
Lack of referrals		✓				✓	
Volume and complexity of guidelines							
Inadequate IT systems							
Confusing referral procedures							
Difficult to choose a suitable programme							
Lack of integration between departments							
Lack of implementation strategies							
Lack of medical insurance cover							
Limiting eligibility criteria							
Lack of care standardisation							

Lack of formal education on exercise training							💡
Lack of inclusion of cardiac rehabilitation in local guidelines							💡
Lack of programmes							💡
	Triangulation of themes related to enablers						
Evidence quality	M-H	M	M	M	M-H	M	M
Author	Achttien et al.	Dalal et al.	Frolich et al.	Golwala et al.	Nguyen et al.	Palmer et al.	Piepoli et al.
Sufficient knowledge and awareness, and positive attitude of healthcare professional			✓	✓	✓	✓	
Guideline endorsement				✓	✓		✗
Clear professional roles and responsibilities				✓			✓
Better integration between departments			✓				✓

Better integration between organisations			✓				✓
Adequate IT systems	✓						✓
Sufficient evidence-base supporting cardiac rehabilitation for heart failure				✓	✓		
Availability of different modes of delivery		✓		✓		✓	
Knowledge sharing opportunities			✓	✓			
Sufficient commissioning				✓			✓
Better tailoring of guidelines	✓	✓					
Awareness-raising					✓	✓	
Translating guidelines into clinical algorithms	💡						
Use of clinical algorithms	💡						
Care standardisation			💡				
Cross-institutional guidelines			💡				
Healthcare legislation				💡			

Medical insurance eligibility criteria and sufficient cover				💡			
Performance and target measures					💡		
Referral system					💡		
Adequate resources: time, staff, facilities and equipment							💡
Availability of programmes (specialised and community- based)							💡
Broadened eligibility							💡
Education programmes on the importance of exercise training							💡
Guideline implementation							💡
Improving the doctor-patient relationship							💡

M-H = Medium-to-high, M = Medium, ✓ = Agreement, ✓ = Partial agreement, ✗ = Dissonance, An empty field = Silence, 💡 = Isolated idea

Discussion

The systematic review identified a wide range of provider- and system-level barriers and enablers affecting the delivery of cardiac rehabilitation for heart failure and linked the identified barriers with possible solutions. The broad array of factors identified may reflect the complexity of the phenomenon or it may reflect the range of healthcare systems and implementation contexts studied. Encouragingly, most of the identified barriers were matched with potential 'enablers' or solutions.

The most prevalent barriers were 'insufficient knowledge, and poor awareness and attitude of healthcare professional', 'lack of resources: time, staff, facilities and equipment' and 'safety concerns'. These can have significant clinical implications, for example, they can lead to a systematic exclusion of patients with heart failure from cardiac rehabilitation programmes and consequently, a diminished quality of care. Interestingly, the most prevalent themes also showed some dissonance, with one of the most recent studies [87] presenting a more nuanced and updated picture relating to those factors. Namely, that a lack of resources might not be as much of a barrier in Western regions of the European Society of Cardiology affiliated countries as opposed to more poorly-resourced areas, and that professionals' knowledge and safety concerns may no longer be as prevalent as previously reported [341]. The latter dissonance might be linked with changing attitudes of healthcare professionals as a result of a gradually improving evidence-base for offering cardiac rehabilitation to patients with heart failure [69].

The majority of identified barriers were consistent with literature outlining more generic barriers to implementation of healthcare services. Examples of this are the system, staff and intervention-level barriers affecting implementation of novel interventions identified by Geerligs et al. [342] or barriers to change identified by the NICE guide (e.g., staff awareness, knowledge, workforce skills, resources and political environments) [343]. A barrier identified in the review that might be particularly pertinent to the delivery of cardiac rehabilitation for patients with heart failure that has not been considered extensively in other literature is 'the origins of cardiac rehabilitation'. The awareness of healthcare staff of the benefits of cardiac rehabilitation (as opposed to the outdated practice of bed rest) is a strong predictor of cardiac rehabilitation referral [344].

The identified categories of barriers and potential solutions fit well with the social ecological model, which has previously been used to identify influences impacting healthcare delivery at several different levels (Table 7). These include the macrosystem encompassing widely shared cultural/social values, beliefs, customs and laws (e.g., public policies, enabling environments), the exosystem capturing the indirect environment (e.g., economic system, political system, educational system, governmental system, community-level influences), the microsystem describing the interpersonal environment (e.g., a small group of professionals who work together on a regular basis) and the mesosystem capturing the interactions between microsystem and exosystem (e.g., organisation-level influences). The most granular level of influence is the individual level, in this case understood as an intrapersonal environment (e.g., a healthcare professional providing care to individual patients).

Table 7 Social ecological model

Level of influence	Barriers	Potential solutions
Individual	Healthcare professional	• Offering education to healthcare professionals on the benefits of cardiac rehabilitation in patients with heart failure' • Establishing inter-professional collaboration forums (e.g., working groups, knowledge-sharing meetings) • Developing collaborative relationships between health professionals looking after patients with heart failure
Microsystem	The organisation of cardiac rehabilitation programmes	• Using new delivery systems such as telemedicine • Providing choice between hospital-based group rehabilitation and home-based individual programmes • Providing feedback to programmes regarding the management of their patients with heart failure
Mesosystem	The organisation of healthcare system	• Providing integrated healthcare • Developing local patient pathways • Using automatic referral systems

Exosystem	Education	• Education programmes for healthcare professionals on the importance of exercise training
	Medical insurance	• Better collaboration with healthcare authorities • Increasing insurance coverage
	Resources	• Inclusion of cardiac rehabilitation for heart failure in local commissioning contracts • Changes to healthcare systems that improve access to cardiac rehabilitation by removing some of the financial constraints (e.g., accountable care organisations under the new Affordable Care Act in the United States)
Macrosystem	The origins of cardiac rehabilitation and previous practices	• Initiatives influencing awareness of the importance of cardiac rehabilitation (e.g., the Cardiac Rehabilitation Network of Ontario)
	Evidence-base	• Increasing the evidence-base confirming the benefits and safety of cardiac rehabilitation in patients with heart failure (especially heart failure with preserved ejection fraction)
	Guidelines	• Development of cross-institutional guidelines • Combining and translating guidelines into clinical algorithms (to reduce practice variation and increase guideline adherence) • Better implementation of existing guidelines

Barriers to the delivery of cardiac rehabilitation for patients with heart failure are varied and multi-levelled and overcoming them will involve changes at different levels. This reflects the suggested 're-engineering of healthcare system' and 'progressive policy' in the recently published Journal of the American College of Cardiology expert panel report [345]. In recent years, healthcare systems have been described as complex and adaptive [346]. A change in one part of the system can lead to changes to other components, for example, offering education to healthcare professionals on the benefits of cardiac rehabilitation in patients with heart failure may lead to development of inter-professional collaborations or inspire service providers to use novel delivery systems.

Individual and microsystem-level initiatives include creating inter-professional knowledge-sharing opportunities or in-house monitoring and evaluation of the management of patients with heart failure. These solutions can be implemented by individual cardiac rehabilitation teams. An example of a practical solution from the mesosystem of influence is introducing an automated referral system to mitigate barriers linked with poor clinical knowledge. Such organisational level solutions may also facilitate the development of local patient pathways (which in turn may lead to the provision of more integrated healthcare). Exosystem and macrosystem-level solutions related to the availability of resources and the creation of further evidence require collaborations between many different stakeholders and rely on policy-level changes and improvements (e.g., development of cross-institutional guidelines or increasing insurance cover).

Strengths and limitations

To the best of my knowledge, this is the first systematic review investigating provider- and system-level factors affecting the delivery of cardiac rehabilitation for heart failure. The review applied robust methods, that is, systematic search strategy, second coding of study selection and study quality procedures, and use of comprehensive narrative synthesis techniques, which included thematic analysis and triangulation of identified themes to maximise depth and robustness of the findings. Additionally, the included studies used different methodologies leading to triangulation of available data and increasing rigour of the systematic review findings.

Despite applying a very inclusive search strategy the review identified only seven studies meeting the inclusion criteria. The paucity of empirical studies and/or relatively poor quality of empirical data limits the findings and increases the possibility of a publication bias being present in the final synthesis. Additionally, although including second-order constructs increased the overall amount of data, the origins and robustness of the second-order constructs were difficult to establish.

Due to limitations of the data reported in the reviewed literature, it was not possible to consider how representative the sample was of professionals involved in the delivery of cardiac rehabilitation for heart failure. However, the systematic review sample was restricted to European and Western healthcare systems. Therefore, the generalisability of the identified barriers and enablers is limited to this context. Furthermore, the literature reviewed did not report characteristics of the patient populations served or consider how barriers might vary

depending on patient characteristics (e.g., some healthcare professionals may be less willing to invite more frail patients for cardiac rehabilitation).

Future research

Further research is needed to identify barriers in other healthcare systems and in a wider more clearly defined range of healthcare professionals. Future implementation studies could also seek to identify any barriers and enablers that apply differently to different patient groups. Further research is also needed to qualitatively investigate barriers that are unique to the heart failure population (e.g., the origins of cardiac rehabilitation) and barriers that showed divergent relationships between sources included in the review (e.g., the impact of professional's knowledge, guidelines, safety concerns and lack of resources).

The gaps in the literature, uncovered by the systematic review, confirmed a continuing dearth of implementation studies on the topic of cardiac rehabilitation for heart failure and an ongoing need for further high-quality research that goes beyond patient-level factors affecting the delivery of cardiac rehabilitation for heart failure. Such research is acutely needed in the light of initiatives to improve access to and uptake of cardiac rehabilitation for heart failure, such as the NHS Long Term Plan that aims to increase the proportion of eligible patients with heart failure accessing cardiac rehabilitation from less than 10% to 33% by 2028 [105, 347].

Conclusions

The systematic review identified a broad range of provider- and service-level factors affecting the delivery of cardiac rehabilitation for heart failure. The identified barriers and enablers operate on multiple levels of influence from the knowledge and views of individual healthcare professionals to the organisation of cardiac rehabilitation teams and the wider healthcare system. Consequently, efforts to increase the delivery of cardiac rehabilitation for patients with heart failure will likely require interventions at all these levels. Strategies for improving delivery of cardiac rehabilitation for heart failure may include increasing inter-professional collaboration, providing choice between hospital and home-based rehabilitation programmes, inclusion of cardiac rehabilitation for heart failure in local commissioning contracts, and staff-education initiatives to raise awareness of the importance of cardiac rehabilitation and of the evidence-base on the benefits and safety of cardiac rehabilitation in patients with heart failure.

Authors' contributions

Paulina Daw, Colin J Greaves, Jet JCS Veldhuijzen van Zanten contributed to the concept and the design of the systematic review. Colin J Greaves and Thomas Withers were involved in data selection and quality assessment. Paulina Daw acquired, analysed and interpreted the data. Paulina Daw drafted the manuscript. Alexander Harrison contributed important intellectual content. All authors revised the manuscript critically and approved the version to be published.

Reflection

In the beginning stages of conducting the systematic review the research question, search strategies and approach to synthesis were adjusted iteratively based on the scope, quantity and quality of the available data. A different review team might have made different choices, for example, by including grey literature or choosing a different analytical approach for data analysis and synthesis, and, therefore, might have obtained slightly different results. Nevertheless, the conducted systematic review substantially captured and synthesised the current body of information on non-patient factors impacting the delivery of cardiac rehabilitation to patients with heart failure.

The published systematic review underwent two rounds of peer review, as the initial reviewers were not available to re-review the revised version of the manuscript. Interestingly, one of the initial reviewer's requests was to specify which 'strategy is more effective based on the evidence'. This comment captures the ongoing domination of efficacy reviews and even perhaps a desire present amongst academics and clinicians for definitive, black-and-white answers. In contrast, the systematic review captured the complexities of delivering a complex intervention within a complex system of healthcare provision. In this context, the 'best' strategy may depend on numerous contextual factors (e.g., resources available, healthcare professionals' knowledge or existing care pathways), rather than being a single one-size-fits-all solution. In this sense, the findings of the systematic review are more nuanced than simply pointing to the 'best way' to implement cardiac rehabilitation for patients with heart failure. By identifying the factors influencing implementation, the systematic review was able to

provide recommendations on ways to increase implementation across a range of different contexts.

Deviation from the recommended procedure

The Cochrane Handbook for Systematic Reviews of Interventions recommends (this step is desirable, but not mandatory) that two reviewers independently screen all identified titles and abstracts and consider which full-text articles meet the inclusion criteria [288]. This is to ensure detection of all relevant primary sources [348] and a reduction of researcher bias [349]. A study comparing systematic reviews where initial screening was conducted by a single researcher with those screened by two researchers, confirmed that substantially more relevant articles were missed in the case of the former [350]. The 2019 study also concluded that inexperienced (professional) reviewers were more likely to miss relevant studies. However, the error rate was unknown for student reviewers, as these were excluded from the study. Methodological shortcuts, including single reviewer protocols, have been considered as potentially suitable alternatives when conducing rapid reviews [350, 351].

In the conducted systematic review, 40% of the identified titles and abstracts were independently screened by two reviewers. However, as the main reviewer, who screened 100% of the titles and abstract, I followed a very inclusive selection strategy (i.e., often allowing full-text consideration rather than rejecting an article at title and abstract screening stage). Therefore, I am confident that no relevant studies were missed. My thoroughness combined with a high agreement between reviewers for the 40% of the articles which were double-screened justified not double screening 100% of the identified titles and abstracts.

Furthermore, if during discussions it had come to light that there were significant differences between coders we would have then screened 100% of the titles and abstracts.

Suitability of a scoping review

On reflection, as the main aim of the conducted systematic review was *not* to make explicit recommendations for clinical practice (i.e., confirming efficacy or safety) and as the review encountered a combination of a lack of relevant research studies and a significant heterogeneity in the identified primary research, a systematic scoping review would have been an alternative viable option to answer the study's aim. Scoping reviews are 'exploratory projects that systematically map the literature available on a topic, identifying key concepts, theories, sources of evidence and gaps in the research' [352]. Such reviews can lead to developing a better understanding of the available evidence or, in fact, the knowledge gaps present in the literature, which, in turn, can direct future research efforts. Scoping reviews are particularly suitable when there is a lack of a comprehensive literature overview on the chosen topic and/or where there is a great heterogeneity within the evidence-base [353]; both of which were encountered in the conducted study.

In 2005, Arskey and O'Malley suggested specific reasons for conducting scoping reviews. Below is a current and extended list of the possible objectives for conducting such reviews:

- 'to identify the types of available evidence in a given field,
- to clarify key concepts/definitions in the literature,
- to examine how research is conducted on a certain topic or field,
- to identify key characteristics or factors related to a concept,

- as a precursor to a systematic review,
- to identify and analyse knowledge gaps' [355].

Therefore, the choice of a scoping review instead of a systematic review could have been justified by highlighting the relevance of the chosen aim (i.e., uncovering factors influencing the offer, referral, delivery, implementation, and provision of cardiac rehabilitation for heart failure) to one of the indicators for a scoping review (i.e., identifying key characteristics or factors related to a concept).

Although the choice of a scoping review instead of a systematic review would most likely result in identical (or very similar findings), the advantage of the former would lie in reducing the tension between the precision of a systematic review protocol and a large heterogeneity in primary research sources. On the other hand, the omission of quality assessment (a permissible step when conducting a scoping review) would have somewhat undermined the interpretation and credibility of the current review's results. On balance, I believe that the original choice of methodology was appropriate.

Building on the systematic review/next steps

The review has the potential to help with informing implementation of cardiac rehabilitation to patients with heart failure by suggesting possible solutions to the uncovered provider- and system-level barriers. Alongside the identified barriers and enablers, the systematic review also highlighted the scarcity of implementation studies exploring non-patient influences contributing to the suboptimal quality of care received by the heart failure population. Therefore, to expand the current understanding of this research-to-practice gap, I conducted

a qualitative study using interviews and an online survey with healthcare providers to understand barriers and facilitators to the implementation of a home-based cardiac rehabilitation programme for patients with heart failure – the Rehabilitation EnAblement in CHronic Heart Failure programme. The results of the qualitative study will be described in the next chapter.

CHAPTER 4 – QUALITATIVE STUDY

Research-to-practice gap

The research-to-practice gap, also called the second translational gap, relates to 'a gap in the translation of new medical interventions into everyday practice' [250]. This disconnect is particularly evident when considering the implementation of complex interventions [356] and when innovations are introduced in primary care and community settings [357, 358]. Both of these conditions applied during the Rehabilitation EnAblement in CHronic Heart Failure (REACH-HF) Beacon Site implementation project. Ensuring the consistent and successful uptake (i.e., replicability at scale) of evidence-based interventions across healthcare systems, including the National Health Service (NHS), is a significant challenge for clinicians, service providers and commissioners. Different factors can impact the implementation of innovations. Broadly, these include the intervention itself (e.g., whether it has been sufficiently described by designers or how easy it is to adapt to different settings), the implementers (e.g., the appetite for a new intervention amongst healthcare professionals who will be delivering it) and the implementation context (e.g., the availability of resources and systems necessary for effective adoption) [163]. A relative lack of funding for implementation research, in contrast to innovation and efficacy research, is an important contributor towards the ongoing research-to-practice gap [359]. One problem in trying to close the research-to-practice gap is the lack of a consistent implementation science taxonomy (described in Chapter 1). For example, there is a lack of consensus on what successful implementation actually means [163, 360].

Defining successful implementation

The concept of *successful* implementation has been extensively debated by implementation scientists worldwide. Measuring implementation success can involve assessing patient outcomes (e.g., a reduction in risk factors) or improvements in patient care (e.g., decreased waiting times) as well as monitoring the required/desired behaviours of healthcare professionals delivering the service (e.g., following a new handwashing procedure) or the quality of the intervention delivery (e.g., adherence to the intervention's protocol). Although confirmation of an intervention's efficacy is an important step towards widespread adoption, often, in itself, it is not a guarantee of successful implementation [361]. Proctor et al. described successful implementation as a dynamic interaction between an intervention's effectiveness and implementation outcomes, which are different from service outcomes (e.g., efficiency, safety) and clinical outcomes (e.g., symptom improvement, patient satisfaction) [360]. The eight implementation outcomes suggested by Proctor et al. are: acceptability, adoption, appropriateness, feasibility, fidelity, implementation cost, penetration and sustainability; these can be qualitatively classified as low, medium and high.

Selection of the most appropriate implementation framework for the study

As described in the Methods chapter, framework analysis was the chosen analytic approach for the study [268]. To select an appropriate theoretical framework for the project, I consulted the Theory Comparison and Selection Tool [362] and the Implementation Science Research Development tool [363].

Theory Comparison and Selection Tool

The Theory Comparison and Selection Tool was designed following an international survey study conducted with 223 implementation scientists from 12 countries [193]. The tool supports implementation researchers to decide which theory, model or framework to choose for their next project by considering and comparing the potential options according to the following four domains – usability, testability, applicability and acceptability [362]. Assessment of the usability domain considers the fit between the implementation model and the implementation project, for instance, how easily the chosen model's constructs will be understood by the key stakeholders involved in the project and the recipients of the final report (e.g., commissioners). Testability assesses the theory underpinning the selected implementation model or framework. High scores in the applicability domain will be given to models that provide a good fit with the selected project implementation outcomes (e.g., fidelity, acceptability), the chosen research method (e.g., interviews, surveys) or the desired analytic level (e.g., individual, organisational, community). Assessment of the acceptability relates to the fit between the potential theory, model or framework and the particular discipline (e.g., healthcare research, education research).

The Implementation Science Research Development tool

The Implementation Science Research Development tool designed by King's Improvement Science Centre in 2018 is made up of 10 domains that explore the core principles and methods currently available in the field of implementation science [363]. The tool can help

implementation researchers design and conduct high-quality implementation projects. The tool is a step-by-step guide that can help in the selection of the most appropriate implementation theory, model or framework, aid understanding of common barriers and facilitators to the implementation process, guide development of implementation strategies to improve implementation and ongoing adoption, identify matching implementation outcomes as well as help researchers work effectively with stakeholders, and consider the inadvertent impact of implementation projects.

Strengths, Weaknesses, Opportunity, Threats analysis

The above tools (i.e., the Theory Comparison and Selection Tool and the Implementation Science Research Development tool) helped me to narrow down and consider the nuances of the available theories, models and frameworks, for example, the focus, the brevity or the expertise required to meaningfully engage with a selected implementation frame. I also considered the match between the available theories, models and frameworks and the chosen study methodology (i.e., mixed methods evaluation) and aims (i.e., identification of barriers to implementation, facilitators of implementation, and development and refinement of an implementation manual).

The initial selection process identified eight well-known empirically tested and reviewed theories, models and frameworks as potentially suited to the project. These included four determinant frameworks, two evaluation frameworks and two implementation theories (as described in Chapter 1). Namely:

- Promoting Action on Research Implementation in Health Services [201-205],

- Consolidated Framework for Implementation Research [206],
- Theoretical Domains Framework [188, 207-209],
- Conceptual Model for Considering the Determinants of Diffusion, Dissemination, and Implementation of Innovations in Health Service Delivery [161],
- Organization Reach, Effectiveness, Adoption, Implementation, and Maintenance framework [221],
- Predisposing, Reinforcing, and Enabling Constructs in Educational Diagnosis and Evaluation – for Policy, Regulatory, and Organizational Constructs in Educational and Environmental Development [222, 223],
- Capability, Opportunity, and Motivation Model of Behaviour Change model [213],
- Normalisation Process Theory (NPT) [214-220].

To examine the suitability of these alternatives to be the implementation framework for the qualitative study, I considered each tool using the Strengths, Weaknesses, Opportunity, Threats (SWOT) analysis [364]. The most pertinent aspects of the potential theories, models and frameworks gathered during the selection process, using the two implementation selection tools, are outlined in Table 8 using the SWOT format.

Table 8 Comparison of selected theories, models and frameworks using the SWOT analysis (adapted from Tabak et al., 2012)

Framework and year	Strengths	Weaknesses	Opportunities	Threats
Promoting Action on Research Implementation in Health Services – 1998 and Integrated Promoting Action on Research Implementation in Health Services – 2015	Well-known and widely used. Specific to healthcare settings. Accounts for multiple dimensions, the complex nature of healthcare system and the influence of context. Focusses on the implementation process. Designed to explain and predict implementation process and outcomes. Critiqued, evaluated and revised. Addresses individual, community and organisational level influences. The revised version takes into account systems (e.g., healthcare system) and policy level	Eclectic theoretical underpinnings (potentially introducing high levels of theoretical complexity). Criticism of the original framework – a lack of clarity between elements and sub-elements, no definition of successful implementation, omission of the role of healthcare professionals and the wider social, political and legal context.	Testing and appraising the revised framework.	A relative lack of evaluation of the revised version. Minimal practical tools for evaluation designed by the framework developers.

	influences. 3 out of 5 on the construct flexibility scale*.			
Conceptual Model for Considering the Determinants of Diffusion, Dissemination, and Implementation of Innovations in Health Service Delivery and Organization – 2004	Well-received and frequently quoted as a comprehensive catalogue of factors affecting an implementation process. Emphasis on communities and organisation. 4 out of 5 on the construct flexibility scale.	Unclear theoretical underpinnings. Focusses on dissemination over implementation. Poor evidence of use during the evaluation of implementation process.	Using a well-formulated, comprehensive framework.	A lack of practical tools for evaluation designed by the framework developers.
Consolidated Framework for Implementation Research – 2009	Well-operationalised and multi-level model that derived from theory. Usefulness confirmed in a systematic review (n=26). Provides a comprehensive overview of factors impacting implementation and can be applied to a range of interventions, settings and	Some concepts too broad to capture the intricacies of the implementation process – can lack depth leading to oversight of dimensions. Due to a large number of constructs might not be able to address them all. Institution-centric – individuals	A wide range of tools and templates to assist creation of interview guides based on the model.	Potential to neglect the influence of key stakeholders on an individual level. Time consuming and workload heavy.

	research designs. Useful tool for creating interview guides. Focusses on the implementation process. Addresses community and organisational level influences. Coherent terminology and language. Some constructs well-defined and easy to identify and measure. Can complement process evaluation. 4 out of 5 on the construct flexibility scale.	only considered on the periphery.		
Theoretical Domains Framework – 2005, revised in 2012	Well-operationalised, multi-level framework. Derived from theory. Addresses individual level influences. Can be used with the Capability, Opportunity, and Motivation Model of Behaviour	More suited for individual level change evaluations. Lacks appreciation of wider dynamics affecting implementation (e.g., social, emotional and contextual influences). Lacks	Originally developed to monitor behaviour change of healthcare professionals. Would offer an in-depth	A lack of consideration for the complexity of modern healthcare could lead to a one dimensional (linear,

	Change as an evaluative tool of an implementation process.	consideration for the dynamics of change.	exploration of that phenomenon.	overly reductionist) analysis.
The Capability, Opportunity, and Motivation Model of Behaviour Change – 2011	Originally a theoretical model of behaviour change. In recent years, adapted to facilitate evaluation of an implementation process. Can be used in conjunction with the Theoretical Domains Framework to examine the process of implementation.	Initially designed to be used in conjunction with the Behaviour Change Wheel – a method for designing behaviour change interventions. If applied on its own lacks depth and consideration for many complexities of a modern healthcare system. Little consideration for the dynamics of change.	Due to the simplicity of the model it can be easily used in conjunction with other frameworks.	If used on its own it might produce a limited insight. A lack of practical tools for evaluation designed by the framework developers.
Normalisation Process Theory – 2007	Focusses on the implementation process. 3 out of 5 on the construct flexibility scale. Addresses individual, community, organisational and system level influences.	Out of the four constructs that make up the framework, Collective Action has been utilised the most – leading to underutilisation of the complete framework.	A number of practical tools designed by the framework developers. A well-	Widely used to evaluate implementation in the field of e-health and telehealth.

	Consistent framework, originally developed to assist in trial design of complex interventions. Usefulness of application confirmed in a systematic review (n=29). Can assist to make recommendations for future implementation and scale-up.		defined middle-range theory.	
Reach, Effectiveness, Adoption, Implementation, and Maintenance framework – 1999	Focusses equally on dissemination and implementation. Addresses individual, community and organisational level influences. 4 out of 5 on the construct flexibility scale. Usefulness of application confirmed in a systematic review (n=71).	Most studies do not report all 34 criteria and five dimensions that make up the framework – leading to underutilisation of the complete framework.	Using a well-established framework.	Qualitative methods rarely used.
Predisposing, Reinforcing, and Enabling	Focusses equally on dissemination and	Theory application is not mandatory. Working backwards	Widely applied and easy-to-follow.	Heavily data-driven and rigid in structure.

Constructs in Educational Diagnosis and Evaluation – Policy, Regulatory, and Organizational Constructs in Educational and Environmental Development – 1980	implementation. Addresses individual, community and organisational level influences. 5 out of 5 on the construct flexibility scale. A well-established planning model (a blueprint for building and improving intervention programmes). Ecological approach to health promotion. Evaluation is a macro-function of planning models. Provides guidance for the selection and use of theory.	from the end goal. Labour-intensive.		

*Construct flexibility scale: 1 = broad (loosely outlined and defined constructs that allow greater flexibility to apply the model to a wide array of implementation activities and contexts), 5 = operational (detailed step-by-step actions for evaluation of dissemination and/or implementation research processes)

The SWOT analysis of the potential theories, models and frameworks highlighted some common weaknesses that could be applied to any tool. For example, confusing definitions of constructs, some overlap between constructs and a possibility of data falling outside of the available constructs. Additionally, most theories, models and frameworks give equal weight to the included constructs, and in order to engage with the tool in a meaningful way often the broad scope of each tool requires tailoring to the local implementation context. As these limitations could apply to any theory, model or framework, to make the final choice I instead concentrated on applying a set of pre-defined criteria for the most suitable frame. These were developed through discussions between my supervisors and I to consider the suitability for delivering the aims of the thesis. The criteria included: focus on implementation (rather than, for example, dissemination or scale-up), moderate construct flexibility (that will allow tailoring to the specific implementation context), availability of practical tools created by the designers (e.g., to help generate interview questions) and attention to as many levels of influence as possible (i.e., individual, community, healthcare system). It was decided that NPT was the most suitable theory for the study, as it fulfilled most of the above requirements.

Normalisation Process Theory

NPT is a well-established and extensively reviewed implementation framework [214-220]. It suggests general mechanisms that are associated with successful implementation of innovations in health service settings. These include service providers' understanding of the new intervention and how it differs from standard practice, their motivation and attitude towards the healthcare innovation, and their perceptions of and reactions to the work they do to deliver and evaluate the intervention.

NPT has been described as a sociological middle-range theory [217] 'that focuses on what people – both individuals and groups – do rather than what they believe or intend' [269]. The concept of the middle-range theory was first introduced by a sociologist, Robert Merton, to guide empirical inquiry by bridging a gap between general theories and empirical evidence [365]. In 1949, he proposed that middle-range theories 'lie between the minor but necessary working hypotheses that evolve in abundance during day-to-day research and the all-inclusive systematic efforts to develop a unified theory that will explain all the observed uniformities of social behaviour, social organization, and social change' [365]. NPT outlines four particular mechanisms that influence the implementation process, namely, coherence, cognitive participation, collective action and reflexive monitoring [218]. Each overarching construct is further divided into four more granular components (Table 9).

Table 9 Normalisation Process Theory – constructs, components and definitions (based on the NPT Online Toolkit at www.normalizationprocess.org)

Constructs	Definition	Components	Definition
Coherence (the sense-making work)	During implementation there is a need for all actors involved to understand the new intervention and how it differs from the standard practice and to conceptualise and make sense of the work that the new intervention requires.	Differentiation	Whether the intervention is easy to describe to service providers and whether healthcare professionals can appreciate how it differs or is clearly distinct from current ways of working.
		Communal specification	Whether healthcare professionals have or are able to build a shared understanding of the aims, objectives and expected outcomes of the proposed intervention.
		Individual specification	Whether individual staff have or are able to make sense of the work – specific tasks and responsibilities the proposed intervention would create for them.

		Internalisation	Whether healthcare professionals have or are able to easily grasp the potential value, benefits and importance of the intervention.
Cognitive participation (the relational work)	During implementation the new intervention needs to become a legitimate entity with support from individuals and teams.	Initiation	Whether or not key healthcare professionals are able and willing to get others involved in the new practice.
		Enrolment	The capacity and willingness of healthcare professionals to organise themselves in order to collectively contribute to the work involved in the new practice.
		Legitimation	Whether or not healthcare professionals believe it is right for them to be involved and that they can make a contribution to the implementation work.
		Activation	The capacity and willingness of healthcare professionals to collectively define the actions and procedures needed to keep the new practice going.

Collective action (the operational work)	Emphasises organisational resources, such as training and divisions of labour as well as the confidence and expertise to deliver the new intervention and whether the intervention is a good fit with the current service provision.	Interactional workability	Whether healthcare professionals are able to enact the intervention and operationalise its components in practice.
		Relational integration	Whether healthcare professionals maintain trust in the intervention and in each other.
		Skill-set workability	Whether the work required by the intervention is appropriately allocated to healthcare professionals with the right mix of skills and training to do it.
		Contextual integration	Whether the intervention is supported by the host organisation, management and other stakeholders, protocols, policies, and procedures.
Reflexive monitoring (the appraisal work)	During implementation there is a need for ongoing appraisal and monitoring of the implementation work.	Systematisation	Whether healthcare professionals can determine how effective and useful the intervention is from the use of formal and/or informal evaluation methods.
		Communal appraisal	Whether, as a result of formal monitoring, healthcare professionals collectively agree

			about the worth of the effects of the intervention.
		Individual appraisal	Whether individuals involved with the intervention (healthcare professionals), or affected by the intervention (patients), think it is worthwhile.
		Reconfiguration	Whether healthcare professionals or services using the intervention can make changes as a result of individual and communal appraisal.

NPT in its current form is the result of an extensive iterative process which spanned more than a decade and involved three iterative phases. Early research confirmed that NPT has 'face validity in (i) assessing the potential for complex interventions to become routinely embedded in everyday clinical work, and (ii) evaluating the factors that promote or inhibit their success and failure in practice' [215]. The model pays particular attention to the interaction between different healthcare professionals involved in the delivery of interventions as well as the interaction between healthcare professionals and different components of interventions [216].

The first systematic review of NPT – 'A qualitative systematic review of studies using the normalization process theory to research implementation processes' from 2014 reported that NPT has been received positively by the research community and that there was a 'strong endorsement from researchers for the theory across a range of disciplines' [306]. Most often NPT is used to qualitatively assess the process of implementation of complex interventions in a diverse range of healthcare settings. The advantages of using NPT have been linked with its ability to provide 'a useful framework for understanding the processes that affect the implementation, embedding, and integration of new technologies into healthcare systems' [366]. The framework can capture barriers and facilitators to the implementation process on an individual as well as organisational levels [122] and it can be used to inform and make recommendations for future implementation projects or further scale-up [306]. Grol et al. [256] and Murray et al. [214], confirmed that there is scope for NPT to be used during the

planning stages of implementation projects to explore the real-world context in which the work will take place.

The main criticism of NPT pointed out in the 2014 review was the framework's, somewhat, complicated terminology/taxonomy, which can impact negatively on the process of operationalisation of its constructs [306]. Some studies reported a small number of concepts falling outside of the NPT's constructs and some researchers have observed an apparent overlap between constructs leading to difficulties in allocating codes that could fall into more than one category. The 2014 review called for implementation researchers using NPT to clearly justify the choice of the theory, more prospective use of NPT and involvement of a variety of stakeholders in the process of identifying implementation mechanisms.

A recent development of NPT focussed on the saliency of implementation contexts and how they can shape and influence the implementation processes [219]. The resulting Extended NPT introduced 'an ecological model of the ways that participants in implementation and health improvement processes interact with contexts' [220]. There is growing evidence of the usefulness of NPT outside of implementation research; NPT has been used to augment the process of design of novel interventions [367] and during randomised controlled trials of such interventions, for example, to evaluate intervention delivery processes [368].

To conclude, NPT is a sociological framework that advocates the whole-system approach to implementation research and can aid the process of understanding of how new interventions and procedures become adopted, implemented and embedded or 'normalised' in everyday

healthcare practices. The application of NPT can, therefore, contribute towards bridging the translational gap between research and practice [306].

Proctor et al.'s implementation outcomes (described earlier in the chapter) map well onto the four NPT constructs:

- coherence = acceptability (i.e., the perception of healthcare staff about the usefulness of the programme),
- collective action = adoption (i.e., intention to use the programme),
- cognitive participation = appropriateness (i.e., the perception of healthcare staff about the fit between the programme and the service and between the programme and patients/their health condition),
- reflexive monitoring = feasibility (i.e., the ability to offer the programme on an ongoing basis) [360].

The above implementation success criteria will be discussed further in Chapter 6 – the Overall discussion chapter.

The study manuscript

Below is a manuscript titled ‘Barriers and facilitators to implementation of a home-based cardiac rehabilitation programme for patients with heart failure in the NHS: a mixed methods study’. A version of this manuscript is currently undergoing peer review with BMJ Open.

Abstract

Objectives

This study aimed to identify barriers to, and facilitators of, implementation of the REACH-HF programme within existing cardiac rehabilitation services, and develop and refine the REACH-HF Service Delivery Guide (an implementation guide co-created with healthcare professionals). REACH-HF is an effective and cost-effective 12-week home-based cardiac rehabilitation programme for patients with heart failure.

Settings/participants

In 2019, four early adopter 'Beacon Sites' were set up to deliver REACH-HF to 200 patients. In 2020, five online REACH-HF training events were attended by 85 healthcare professionals from 45 NHS teams across the United Kingdom (UK) and Republic of Ireland.

Design

The mixed methods study used in-depth semi-structured interviews and an online survey. Interviews were conducted with staff trained specifically for the Beacon Site project, identified by opportunity and snowball sampling. The online survey was later offered to subsequent NHS staff who took part in the online REACH-HF training. NPT was used as a theoretical framework to guide data collection/analysis.

Results

Seventeen healthcare professionals working at the Beacon Sites were interviewed and 17 survey responses were received (20% response rate). The identified barriers and enablers included, amongst many, a lack of resources/commissioning, having interest in heart failure and working closely with the clinical heart failure team. Different implementation contexts (urban/rural), timing (during the COVID-19 pandemic) and factors outside the healthcare team/system (quality of the REACH-HF training) were observed to negatively or positively impact the implementation process.

Conclusions

The findings are highly relevant to healthcare professionals involved in planning, delivering and commissioning of cardiac rehabilitation for patients with heart failure. The study's main output, a refined version of the REACH-HF Service Delivery Guide, can guide the implementation process (e.g., designing new care pathways) and provide practical solutions to overcoming common implementation barriers (e.g., through early identification of implementation champions).

Strengths and limitations of this study

- The mixed methods used (i.e., interviews and survey) allowed triangulation of data, increasing the robustness of the study findings.
- The combination of sampling methods (i.e., opportunity sampling and snowball sampling) improved representativeness of the study sample.

- A validated theoretical framework, NPT, was used to guide data collection and interpretation.
- The framework analysis procedure used both inductive and deductive analysis, preventing the forcing of emerging concepts into the themes of NPT.
- The findings may be transferable to other UK home-based cardiac rehabilitation programmes, but may not transfer well to healthcare services outside the UK.

Background

Heart failure and cardiac rehabilitation

Heart failure is a complex, debilitating syndrome with significant health consequences that, due to an ageing population, advances in device and pharmacotherapy, and more widespread adoption of Western lifestyle, is on the rise globally [13]. There are approximately 64.3 million people living with heart failure in the world [12] and one million in the UK [142]. Heart failure is associated with high healthcare costs (stemming particularly from hospitalisations [109]) and is a significant global healthcare challenge [13]. Cardiac rehabilitation participation is an important part of heart failure management, as it has been shown to increase exercise capacity and health-related quality of life, and reduce the risk of hospital admission in patients with heart failure [109]. However, cardiac rehabilitation is greatly underutilised globally [85]. In Europe, less than 50% of eligible patients receive cardiac rehabilitation; the uptake is particularly low in patients with heart failure (with only 14% receiving it) [112]. Offering alternative models of delivery, such as home-based programmes, can potentially improve the uptake of cardiac rehabilitation amongst this clinical population by reducing some of the patient-level barriers (e.g., dislike of group sessions) and making it more accessible, for example, for patients who are housebound [124, 126].

The REACH-HF programme

REACH-HF is a novel cardiac rehabilitation programme for patients with heart failure and their caregivers, designed to be delivered in the patient's home [248, 262, 369, 370]. The 12-week programme was co-developed by researchers with patients, caregivers and service providers [145]; its clinical effectiveness (for improving heart failure-related quality of life) was

demonstrated in a multicentre UK clinical trial and a decision model-based analysis confirmed its cost-effectiveness [100, 146, 263]. The multi-component intervention consists of a heart failure manual, a choice of two exercise training programmes (chair-based and walking), a stress management programme, a progress tracker, and a family and friends resource. The programme requires facilitation over a 12-week period from a healthcare professional (most often a cardiac rehabilitation nurse or physiotherapist) trained to deliver REACH-HF.

Beacon Sites

In January 2019, the research team appointed four cardiac rehabilitation services to become early adopter sites (the REACH-HF Beacon Sites) and deliver the REACH-HF programme to a target total of 200 patients between June 2019 and June 2020. The Beacon Site criteria, recruitment and set up processes are described in detail in the published study protocol (included in Chapter 2) [371] . Briefly, the Beacon Sites consisted of four well-established cardiac rehabilitation teams from diverse geographical areas (urban and rural) in England and Northern Ireland. Three healthcare professionals from each team attended a three-day, in-person REACH-HF training course. Prior to their involvement with REACH-HF, the Beacon Sites mainly offered group, centre-based cardiac rehabilitation and one service excluded patients with a primary diagnosis of heart failure.

REACH-HF remote training

During the recent COVID-19 crisis, most group, centre-based cardiac rehabilitation programmes (the prevailing mode of delivery prior to the pandemic [93]) were suspended [101]. The challenges to service provision caused by staff redeployment and social distancing

and shielding guidance led to a sharp demand for alternative models of delivery [102], including home-based programmes [372]. To facilitate this, members of the REACH-HF research team adapted the three-day face-to-face REACH-HF training into a two-day remotely delivered format and offered it free-of-charge to interested cardiac rehabilitation teams. A total of 85 healthcare professionals from 45 NHS organisations and four centres in the Republic of Ireland attended the REACH-HF remote training between May 2020 and September 2020.

Normalisation Process Theory

A lack of theoretical underpinning can lead to a failure in developing a comprehensive understanding of the implementation process [192] as well as a failure of introducing evidence-based interventions into clinical practice [373]. The use of implementation models, theories and frameworks in published implementation research studies has increased in the last decade [196]. The current study used NPT to help understand the mechanisms of successful implementation . NPT can be used to describe and evaluate different aspects of the implementation process, including barriers to, and facilitators of, implementation. The theory uses four main constructs (coherence, cognitive participation, collective action and reflexive monitoring) and 16 components to capture the work that healthcare professionals do to implement (or 'normalise') a new set of practices. The framework is sensitive to influences at the individual-, community-, organisational- and system-levels [195].

Study aims

This study is part of a larger mixed methods pragmatic implementation evaluation project [371]. The first aim of the current study was to identify barriers to, and facilitators of, implementation of the REACH-HF programme using two different cohorts of healthcare professionals. The second aim was to develop and refine an implementation manual to inform the future implementation of REACH-HF.

Methods and analysis

Study design and participants

The study used in-depth semi-structured interviews and an online survey. To recruit participants for the interviews, opportunity sampling was used – inviting all trained REACH-HF Beacon Site practitioners (n=12) to participate, followed by snowball sampling – the initial interviewees were asked to identify other key staff involved in, or impacting, the implementation process. Participant recruitment continued until saturation in the identified themes was reached. The online survey invitation was sent to all healthcare professionals (n=85) who took part in the REACH-HF remote training.

Data collection and analysis

Paulina Daw (PD) and Colin J Greaves (CJG) generated the interview topic guide (Appendix 2) using all 16 concepts from NPT. All interviews were conducted by PD (mainly, prior to the COVID-19 pandemic) via the telephone or face-to-face. Each participant was interviewed once (mainly, at the beginning of the implementation process) and it was not possible to repeat interviews or conduct focus groups, as stated in the protocol, due to lockdown restrictions

and temporary redeployment of rehabilitation staff to support pandemic-related healthcare service delivery [371]. Audio recordings of the interviews were transcribed verbatim. The transcripts were redacted to remove any identifiable information and entered into NVivo (version 12) programme for analysis [330]. The online survey (Appendix 6) was based on the interview topic guide with additional questions about the REACH-HF Service Delivery Guide and consisted of a mixture of closed-response and open (qualitative) questions. The survey was conducted using the LimeSurvey online platform [374]. Qualitative data from the survey were entered into NVivo for analysis alongside the interview data. This process of integration of the two databases used was integration through methods, and more specifically through merging (i.e., two sets of results are brought together for analysis) [241].

Data analysis was conducted by PD, Grace Emily Rachel Wood (GERW) and CJG following the procedures for framework analysis outlined by Ritchie and Spencer [268]. These included identification of a theoretical framework suitable for the study (i.e., NPT), familiarisation with the data, indexing, charting, mapping and interpretation of themes. The analysis initially consisted of two rounds of independent coding of two transcripts by PD and GERW and in-depth discussions of emerging themes, moderated by CJG, between the rounds of coding. The resulting framework was then used to code the remaining data, with variations and extensions of the thematic framework added as new ideas emerged. To avoid forcing themes into a framework, the coding procedure allowed identification of emergent themes that were outside of NPT; these were included in the study and were given the same weight of evidence in the final interpretation.

An implementation manual, the REACH-HF Service Delivery Guide (Appendix 1), was developed following the initial qualitative interviews with NHS staff from the Beacon Sites (n=9). The draft guide was then circulated amongst one of the healthcare teams for comments and further development and refined following the consecutive interviews with the participating sites. The latest iteration of the Service Delivery Guide also incorporated data from the survey.

Research ethics approval

The study (IRAS 261723) has received ethics approval from the South Central (Hampshire B) Research Ethics Committee (19/SC/0304) and used the Standards for Reporting Qualitative Research checklist to report the qualitative findings (Appendix 7) [279].

Patient and public involvement

The REACH-HF intervention was co-designed with patients, caregivers and healthcare professionals, as detailed in the intervention development paper [145]. The focus of the current study was on implementation into routine service delivery, therefore, the research team worked closely with healthcare staff working at the Beacon Sites to discuss the feasibility of the study, selected outcome measures and the burden of participation. Additionally, the first draft of the REACH-HF Service Delivery Guide was shared with staff from one of the Beacon Sites to comment on its content, layout and completeness. All amendments and suggestions made by the staff (during interviews and when completing the survey) were implemented into the subsequent version of the guide.

Results

Qualitative interviews were conducted between September 2019 and February 2021 with 17 healthcare professionals working at the Beacon Sites (Site 1 – six interviewees, Site 2 – six interviewees, Site 3 – four interviewees and Site 4 – one interviewee). Although, the protocol target of recruiting 24 healthcare professionals was not reached, careful consideration of the saturation in themes confirmed that interviews with 17 participants generated enough rich conceptual data and that further interviews would most likely not add greatly to the coding framework. All except two of the interviews were conducted before the COVID-19 pandemic. Six cardiac rehabilitation nurses, five physiotherapists/exercise physiologists/exercise instructors, three clinical leads/projects managers, two heart failure nurses and one consultant cardiologist were interviewed. The survey invitation was sent to 85 participants on 25th February 2021. The survey was active until 8th April 2021 and the response rate was 20% (15 participants fully completed the survey and two partially completed it). Out of the 17 healthcare professionals who took part in the survey study, seven were physiotherapists, six cardiac rehabilitation nurses and four heart failure nurses. To preserve the anonymity of both participants and study sites, no other demographic or identifiable information were collected.

Barriers and facilitators to implementation

The study uncovered a wide range of general influences and a smaller number of site-specific factors positively and negatively affecting the implementation of REACH-HF (Table 10 and Table 11). Most of the identified barriers and facilitators mapped onto the existing NPT constructs. Factors that fell outside of the NPT framework are listed in the 'Non-NPT barriers

and facilitators' sections of each table. Appendices 8 and 9 contain extended versions of Tables 10 and 11, which include quotes relating to each construct.

Table 10 Barriers to implementation of REACH-HF across the Beacon Sites

NPT construct	Barriers
Differentiation	
Communal specification	Confusion about patient criteria
Individual specification	Initial trial-and-error with operationalising the intervention
Internalisation	
Initiation	Lack of implementation plan
	Lack of champions
Enrolment	Routine of delivering group centre-based programmes
	Practitioners being away from core cardiac rehabilitation duties/team being stretched
	Low team morale and lack of enthusiasm for REACH-HF
	Challenging personal circumstances
	Poor communication with heart failure team
Legitimation	Initial hesitation about being part of project
Activation	Perception of REACH-HF in its current format as not implementable

Interactional workability	Additional time
	Additional cost
	Additional admin
Relational integration	Higher opinion of centre-based provision
	Negative opinion of REACH-HF resources (DVDs are outdated, technical problems, written resources are too lengthy)
Skill set workability (including REACH-HF practitioner's training)	Disinclination for lone working
	Disjointed working between cardiac rehabilitation and heart failure teams
	REACH-HF training not well-pitched to audience
Contextual integration	Lack of time allocation
	Lack of staff
	Staff redeployment due to COVID-19
	Commissioning structure (lack of commissioning of cardiac rehabilitation for patients with heart failure)
Systematisation	Time required for evaluation
	Task of evaluation lies with management

Communal appraisal	
Individual appraisal	
Reconfiguration	
Non-NPT barriers	
Patient-level factors	Multimorbidity patients (frequent hospitalisations, not stable to exercise, additional time)
	Engaging with technology (lack of DVD players or internet, not being technologically savvy)
	Apparent lack of improvement following REACH-HF
	Expectations and preferences (lack of motivation, preference for group centre-based programmes, dislike of home visits)
Geographical factors	Size and type of patch (large catchment area, transport issues)

Table 11 Facilitators of implementation of REACH-HF across the Beacon Sites

NPT construct	Facilitators
Differentiation	Good grasp of difference between REACH-HF and usual service delivery
Communal specification	Good grasp of purpose of REACH-HF

	Agreement that REACH-HF adds value to service
	Initial dissemination of purpose and structure of REACH-HF
	Awareness of service gap
	Clear vision for REACH-HF
Individual specification	Clear procedures and increased efficiency
Internalisation	Good grasp of value of intervention to heart failure population
Initiation	Availability of champions (whole team, organisation, three REACH-HF practitioners, single REACH-HF practitioner)
	Identification of potential referrers/referral streams
Enrolment	Strong endorsement for REACH-HF
	Interest in heart failure
	Effective communication (within cardiac rehabilitation team, between cardiac rehabilitation and heart failure teams)
Legitimation	Feeling positive about involvement
	Feeling positive about challenge of introducing REACH-HF

	Being part of innovative team
Activation	REACH-HF part of service going forward
	Watchful waiting
	Implementing REACH-HF post COVID-19
Interactional workability	Gaining balanced perspective of time involved in delivery of REACH-HF
	COVID-19 led to changes in service provision
	Good fit with service and with patient
Relational integration	More objective opinion of centre-based programmes
	Positive opinion of REACH-HF resources (written resources are just right, being able to use friends and family resource)
	Trust in intervention and each other
	REACH-HF practitioner's peer support
	Preference for home-visits
	Close working with heart failure team

Skill set workability (including REACH-HF practitioner's training)	Choice of REACH-HF practitioners (self-selection, personal attributes, training more than one individual, experiences of working with multimorbidity patients)
	Skills combination (cardiac rehabilitation, physiotherapy/exercise physiology and heart failure)
	Improvements to REACH-HF training (making it more practical, more emphasis on exercise component, input from previous implementers, shorter modular online training, having more in-depth pre-training reading around self-management approach, recommending pre-training course – the British Association for Cardiovascular Prevention and Rehabilitation heart failure exercise or activity training course
Contextual integration	Protected time
	Management team is proactive (securing additional funding, redesigning service, offering flexible rehabilitation)
	Commissioning structure (being block contractor)
	Support from management
Systematisation	Planned, formal evaluation (by management)
	Reflective, informal evaluation (by REACH-HF practitioners)
Communal appraisal	Developing more balanced view of intervention and implementation process
Individual appraisal	Job satisfaction
	Continuous professional development

	Positive feedback from patients
Reconfiguration	Fully home-based programme
	Fully remote delivery during COVID-19 pandemic
	Smoother enrolment onto programme
	Reduced home visits
	Home/centre hybrid
	Group centre-based programme
	Inspiration for better service delivery in general
	Amendments to REACH-HF resources (careful wording, simplified version of exercises, online resources)
Non-NPT facilitators	
Patient-level factors	Simplified version of exercises
	Overcoming technological issues
	Expectations and preferences (preference for, and motivation to, take part in home-based programme, being housebound)
Geographical factors	Size and type of patch (small catchment area, availability of transport)

Barriers and facilitators related to Normalisation Process Theory

Coherence – the sense-making work

There was agreement between participants and across all sites about the purpose and value of the REACH-HF intervention. An initial process of trial-and-error at the beginning of the implementation process linked with operationalising the intervention, for example, developing delivery and/or administrative procedures, and some minor confusion about patient criteria/eligibility were present at all sites. Site 1 was the only site that had a very clear vision for the intervention from the outset; the targeted delivery of the programme at this site involved offering it to patients who would not otherwise have been able to attend traditional/centre-based cardiac rehabilitation. Effective dissemination of the purpose and value of the REACH-HF programme amongst the wider team was an important part of the sense-making work at all Beacon Sites and a task of REACH-HF practitioners following the initial training.

Cognitive participation – the relational work

There were significant differences between the sites in terms of what or who was driving the implementation process forward. The identified champions included the organisation itself (Site 2), a single practitioner (Site 4), all trained REACH-HF practitioners (Site 3) and the whole team (Site 1). Participants were unanimous that an early identification of potential referrers, most often heart failure nurses, was an important pre-requisite for programme delivery – this was achieved easily at Site 1 due to a close proximity between the cardiac rehabilitation and heart failure teams. A strategy for improving the relational work, highlighted by all

participants, was effective communication within the cardiac rehabilitation team and between the cardiac rehabilitation team and the heart failure team.

Low team morale (also exacerbated by challenging personal circumstances) and a lack of enthusiasm for the intervention were identified at Sites 2 and 4. On the other hand, participants at Sites 1 and 3 expressed feeling positive about their involvement in the implementation of REACH-HF. Being part of an innovative team and enjoying the implementation challenges were particularly evident at Site 1.

Another noteworthy difference between the sites was how NHS staff perceived the future of the REACH-HF intervention in their service. At Site 1, there was a strong hope that REACH-HF would be part of the service going forward. At Site 3, a pattern of watchful waiting was observed (a process of working out if REACH-HF can fit within the service delivery and whether it is sustainable). At Site 2, there was a strong perception of the intervention in its current format not being implementable (mainly, linked with a large catchment area served by this service). Staff at Site 4, were looking forward to re-engaging with the innovation post-COVID-19.

Collective action – the operational work

Interviewees were in agreement that operationalising REACH-HF into a service required additional time (e.g., travelling and with patients) and additional cost (e.g., the REACH-HF manuals and travel fares). Additional administrative tasks were identified at Site 2 only; these

were specific to the unique way staff working at Site 2 were enrolling patients onto the programme, which included posting out the REACH-HF manual prior to the initial assessment.

Collective action can be positively or negatively influenced by the healthcare professionals' opinions of the innovation. No specific patterns in the data or site-level differences relating to the REACH-HF resources were discovered; on occasions, what one person suggested as a negative, was a positive for another person. For example, some healthcare professionals enjoyed using the progress tracker and believed it allowed them to engage in a more meaningful way in goal setting and goal tracking during treatment, whereas others found the progress tracker to be a surplus part of the treatment. The strongest collective endorsement for the intervention was identified at Site 1. A practical way of improving collective action (increasing the trust in the intervention and in each other) was to introduce regular (most often monthly) REACH-HF peer support/supervision sessions – these were spontaneously introduced and implemented by staff working at Sites 1 and 3 and involved discussing implementation and/or clinical challenges linked with introducing REACH-HF programme into routine service delivery.

Two operational barriers relating to the availability of resources were consistent between the sites – a lack of sufficient time to implement REACH-HF and being understaffed. A lack of commissioning structure for cardiac rehabilitation for patients with heart failure (in general, not just for the REACH-HF programme) was a barrier particular to Site 2, whereas at Site 1 the specific type of commissioning arrangement (being a block contractor) was identified as a facilitator, as it allowed more flexibility in how the service is delivered. Managers can

positively impact barriers related to collective action by providing support to the implementers and being proactive – securing additional funding, redesigning the service and offering a flexible cardiac rehabilitation provision. The latter was done by adjusting the length of centre-based cardiac rehabilitation (typically 12 weeks) so it was tailored to patient needs and lifestyle (not all patients will require the full length of a set centre-based programme), which will free up REACH-HF practitioners to offer home-based rehabilitation to more complex patients with heart failure.

Reflexive monitoring – the appraisal work

Within each site, various evaluation procedures were used to conduct the appraisal work. These ranged from ad hoc informal reflection by REACH-HF practitioners to formal, planned approaches using both patient-level and service-level data. Individual and communal appraisal (two important aspects of reflexive monitoring) resulted in a more balanced view of the intervention and the implementation process. For example, an acknowledgement that the time required to deliver the programme was overestimated at the beginning of the implementation process (the reduction in time needed was also linked with increased efficiency in delivery) or that it will be possible to secure referral pathways through developing links with heart failure nurses. Positive feedback from patients and increased job satisfaction were frequently quoted by the REACH-HF practitioners when commenting on appraisal of the programme.

Different levels of reconfiguration of the REACH-HF programme were suggested by the interviewees. These ranged from a fully home-based programme (suggested by participants

at Site 1) to a home-based/centre-based hybrid (at Site 3) or adapting REACH-HF into a group centre-based programme (at Site 2). At Site 1, the programme was delivered fully remotely during the COVID-19 pandemic, using phone contacts and video consultations to facilitate the intervention. A more detailed overview of the barriers and facilitators relating to each of the 16 NPT components (which were subsumed within the four over-arching themes described above) can be found in Appendix 10.

Barriers and facilitators not related to Normalisation Process Theory

Patient-level factors

Patient-level factors related to multimorbidity, issues with technology, and patient expectations and preferences. Interviewees were in agreement that patients with multimorbidity sometimes struggled to engage with the intervention due to frequent hospitalisations and not being stable or well enough to exercise. The impact of multimorbidity on patients' abilities to complete the programme was particularly evident at Site 1, which targeted patients who were housebound and would not otherwise be able to engage in centre-based cardiac rehabilitation programmes. Many patients treated at this site were unable to attend baseline and end-of-treatment assessments at the clinic and/or had periods of no exercise. The availability of a smaller paper-based set of exercises was a suggested facilitator for managing more complex patients.

Some patients were unable to engage with the chair-based exercise programme due to not having access to a DVD player or the internet. Patients who were less technologically savvy (often, but not exclusively, older patients) needed additional support from staff to access the

chair-based exercises [375]. Managers and staff working at Site 1 took steps to overcome technological challenges by purchasing and lending DVD players to patients who did not have them. Staff also helped to address technical challenges by inputting the chair-based exercises weblink into patients' devices during assessments or follow-up appointments.

Patient expectations and preferences also played an important part in the implementation process as they could hinder it (e.g., a lack of motivation, dislike of home visits and preference for group-based programmes) or facilitate it (e.g., motivation to engage with home-based programmes and a preference for receiving the intervention at home).

Geographical factors

A large catchment area for a cardiac rehabilitation service (over a vast rural sprawl) was reported as a significant barrier to implementation by all interviewees at Site 2. Whereas at Site 1 a more contained catchment area (in a dense urban environment) with good transport links facilitated implementation. This additional non-NPT factor is somewhat related to the NPT component of 'contextual integration', but as it extends beyond the organisational focus of this construct's definition, it was placed outside of the framework.

Survey data

Following the REACH-HF remote training, and at the time of completing the survey (approximate median time – 34 weeks), six (35%) healthcare professionals had delivered the REACH-HF programme. The barriers to implementation identified in the survey data were mostly consistent with barriers identified in the interview data. These included commitment

to delivering traditional cardiac rehabilitation programmes (and a consequential lack of capacity to deliver alternative programmes), a lack of commissioning and funding/resources/capacity, and patients not taking up the offer or not having access to a DVD player/the internet to support the implementation of REACH-HF. Three additional barriers were identified in the survey: a lack of an implementation plan, lack of champions in the service and staff redeployment due to COVID-19. The survey also uncovered a more nuanced impact of the COVID-19 pandemic. The forced changes to the delivery of cardiac rehabilitation during the COVID-19 pandemic were seen as a facilitator – some services embraced new technologies to enable more remote ways of delivering cardiac rehabilitation. However, in some services the patient recruitment process was hindered by the redeployment of staff due to COVID-19. One participant also noted that the positive impact of COVID-19 on the team's capacity to offer alternative models of delivery was reversed as the service returned to its usual way of operating (i.e., offering mainly centre-based programmes). The facilitators to implementation identified in the survey were closely aligned to those identified in the interviews.

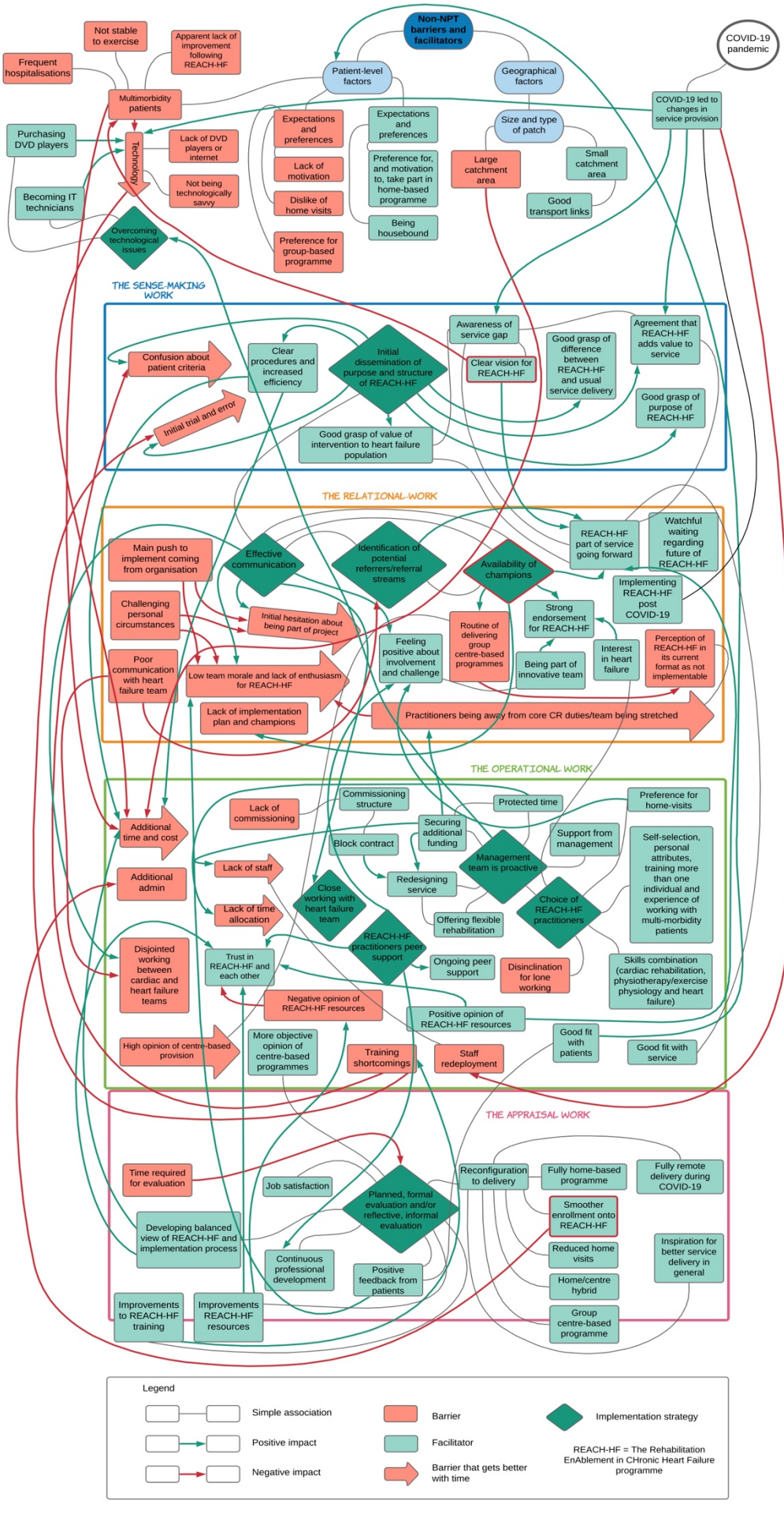
The majority of survey participants (n=14, 82%) had read the REACH-HF Service Delivery Guide, which was included with the survey invitation. Of these, eight (57%) strongly agreed that it would be useful to have access to this implementation manual at the beginning of setting up the REACH-HF programme. Seven (50%) participants agreed that the length of the guide was just right and the same number agreed that the guide was easy to use.

Data from the survey, the successive interviews and feedback from one Beacon Site were used to refine the latest version of the REACH-HF Service Delivery Guide (Appendix 1). The key changes included adapting phraseology throughout the document to suit the intended audience, improving/clarifying terminology used in the patient criteria and selection tool, adapting formatting of clinical pathways, and adding modifications required to deliver the programme remotely, for example, during the COVID-19 pandemic.

Dynamic interactions between different components

Analysis of the data identified numerous interactions between the barriers and facilitators described above (Figure 8). These interactions occurred both within and between NPT domains. The implementation process was also (positively or negatively) influenced by external factors beyond the healthcare team. These included the COVID-19 pandemic and the resulting restrictions on personal movement and interaction. Factors relating to the innovation itself (e.g., the REACH-HF resources) and to the REACH-HF training also played an important role in the implementation process.

Figure 8 Dynamic interactions between model's components



The study identified several distinct types of interaction between the model's components:

- simple associations (denoted by a plain line in the diagram),
- positive impact, when one component positively impacts another (green arrowed line),
- negative impact, when one component negatively impacts another (red arrowed line).

An example of a simple association was feeling positive about the challenge of implementing REACH-HF and being part of an innovative team. An example of a positive impact interaction was having an interest in heart failure, which led to a strong endorsement for REACH-HF. Another example was securing additional funding and thereby reducing the barrier of staff shortages. An example of a negative impact interaction was that shortcomings of the REACH-HF training led to a period of trial-and-error at the beginning of the implementation process.

Many of the interactions between different components followed a typical trajectory (i.e., they were in some sense expected/predictable), for example, effective communication between healthcare professionals strengthened multidisciplinary working and effective dissemination of the purpose/structure of REACH-HF dispelled confusion about patient criteria. However, there were also some unexpected interactions where an apparent facilitator also had a negative impact on implementation. One example of this was that having a clear recruitment target for the intervention at Site 1 (offering it to patients who would not otherwise be able to attend centre-based programmes) led to an increase in patient-level barriers – research suggests that some multimorbid patients can be less technologically literate compared to their younger counterparts [376]. Another example, was where a strong organisational push to implement the innovation (an organisation as the main champion)

resulted in the team's hesitation/resistance to roll out REACH-HF at Site 2. Lastly, a positive reconfiguration at Site 2 (posting out manuals before the assessment session) led to patients starting the programme in a timely manner, but also increased the amount of administrative cost and burden placed on the team.

It is important to note that most identified barriers reduced with time and practice. For example, initial trial-and-error was mostly replaced with new systems and efficiency. Other barriers subsided following evaluation when, for example, healthcare professionals developed a more realistic view of the time required to deliver REACH-HF and allocated resources accordingly. No weakening in the relevance of facilitating factors over time was observed.

Discussion

Principal findings

This is the first study to investigate the implementation of a home-based cardiac rehabilitation programme in a variety of contexts (pre and during the COVID-19 pandemic). The study identified a complex matrix of general and site-specific barriers and facilitators to implementation that interact and change over time. These influences occur on different levels: individual clinician (e.g., having an interest in heart failure, a lack of enthusiasm for the intervention), the community of practice (e.g., close working with the heart failure team), organisational (e.g., availability of resources, a good fit between the intervention and the service) and the wider systems (e.g., a lack of commissioning of cardiac rehabilitation for patients with heart failure). The most pronounced variations between the Beacon Sites included main drivers behind the innovation (i.e., who instigated and was driving the

implementation forward), varying levels of enthusiasm for delivering REACH-HF, perceived sustainability of delivery and the level of adaptation of the intervention.

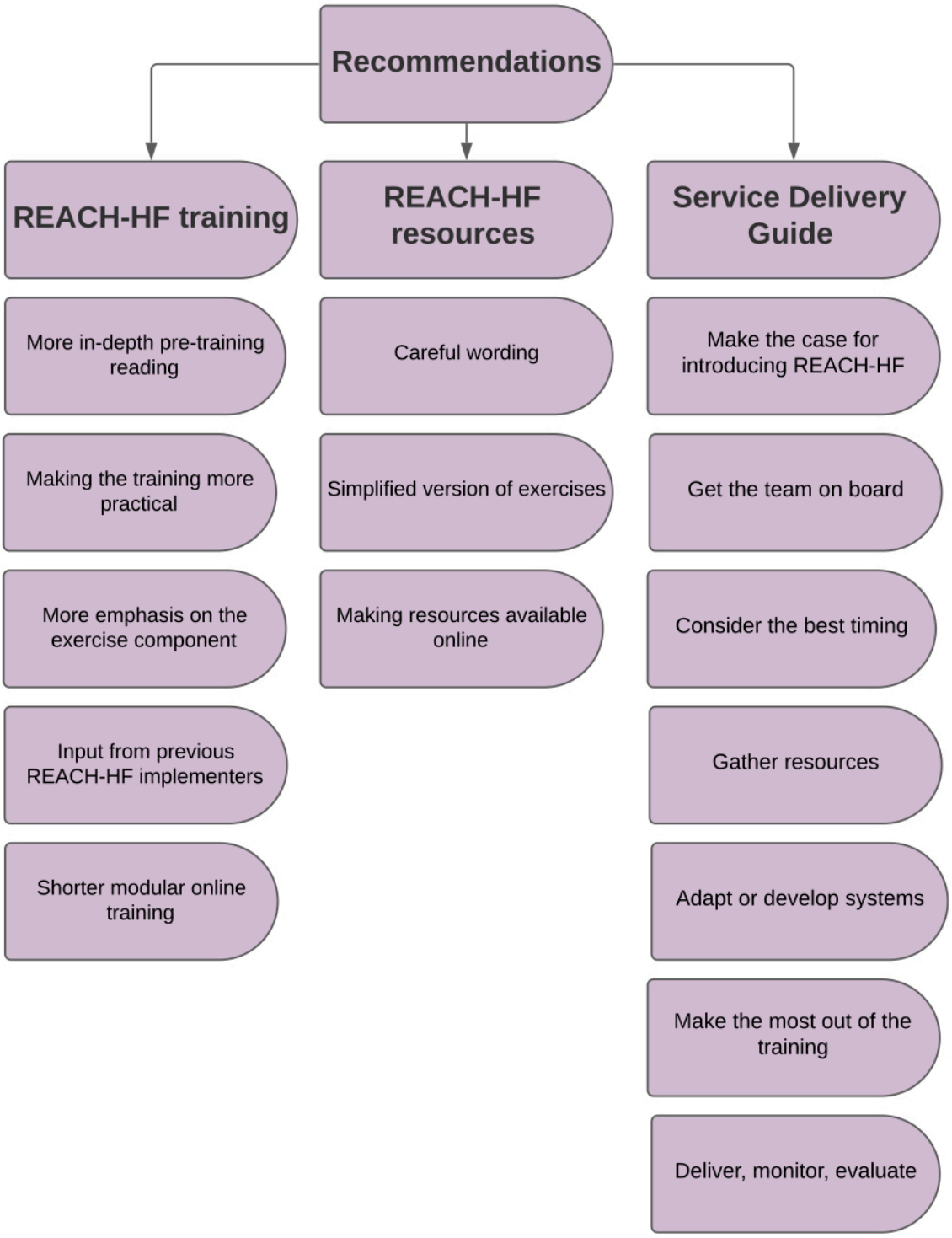
The majority of identified barriers and facilitators to implementation of the REACH-HF programme were consistent with the wider implementation science literature on generic factors that can positively or negatively affect the implementation of new innovations [342, 343]. The study provides a worked model of assessing implementation that can be used as an example in future implementation evaluation projects of different healthcare innovations.

The meaning of the study: possible explanations and implications for clinicians and policymakers

The complexity [377] and adaptability [378] of modern healthcare systems is well-documented and widely accepted within the realm of implementation science and the study undeniably captured the complex and dynamic nature of the implementation process. By understanding the backdrop of barriers and facilitators affecting implementation, the study made recommendations for future implementers and for further development of the intervention and its training course (Figure 9). For example, the study highlighted the importance of choosing the best timing when introducing REACH-HF into a service or of a careful selection of staff to train in the intervention delivery. Data gathered during the study were used to expand and refine the REACH-HF Service Delivery Guide, for example, by considering practicalities of introducing remote delivery. Some of the recommendations from the current study have been already put into action. For example, early adopters are now involved in delivering the REACH-HF training, and the REACH-HF research team is in the

process of digitising the healthcare professional training [379] and the intervention [380] as well as adapting it for use in Denmark [381]. The study is of high clinical relevance, as it can provide healthcare professionals responsible for planning, delivering and commissioning of cardiac rehabilitation services valuable insight into the implementation process as well as a pragmatic implementation manual. It is hoped that these tools/recommendations will guide the ongoing introduction of the REACH-HF programme into NHS and other healthcare settings as well as promoting its sustained delivery.

Figure 9 Recommendations for further intervention and training development, and future implementers



REACH-HF Service Delivery Guide

Following the initial interviews conducted for this study, and in collaboration with staff working at one Beacon Site, the REACH-HF Service Delivery Guide (Appendix 1) was created. This implementation manual is designed to support healthcare teams wishing to add the REACH-HF programme to their cardiac rehabilitation service. The 18-page guide describes pragmatic solutions to overcoming implementation challenges encountered at the Beacon Sites and is designed to be used in conjunction with the REACH-HF Facilitator Training Pack. The guide can be used to help 'make the case' for introducing REACH-HF into a service, which is an important part of the implementation process. It also outlines the necessary practical steps for adding REACH-HF into a service, such as equipment required, deciding the best timing for implementation, gathering resources and designing new care pathways. The guide highlights the importance of evaluation and lists some of the adaptations to delivery that took place at the Beacon Sites, including adaptations to fully remote delivery during the COVID-19 pandemic. The guide is publicly available through the National Institute for Health and Care Excellence Shared Learning Database [382].

Strengths and limitations of the study

The main strength of the study is that it goes beyond the identification of barriers and facilitators to implementation and provides practical guidance for cardiac rehabilitation teams interested in offering the REACH-HF programme to their patients. Additionally, using two methods of data collection, at different time points and with different cohorts of participants, allowed data triangulation and enriched the understanding of the implementation process in

different contexts and under different circumstances. Involving professionals from a large number of healthcare teams and using two sampling methods increased the representativeness of the study sample and relevance of the study's results. The study has sound theoretical underpinnings in the form of NPT, however, to avoid forcing emerging concepts into the pre-existing NPT components, a combined deductive/inductive analytic approach was used. There are two main limitations to the study. The first one is a deviation from the study protocol – due to the COVID-19 pandemic it was not possible to repeat the interviews later during the implementation process or to conduct focus groups. The second limitation of the study is its likely poor transferability/relevance outside of the UK healthcare system.

Unanswered questions and future research

The study was the first attempt to understand the process of implementation of the REACH-HF programme into routine service delivery. Further implementation data relating to different healthcare contexts are needed. In this regard, data are currently being gathered in the SCOT REACH-HF project involving six health boards in Scotland [272]. The growing knowledge of the implementation process in different contexts could be further expanded by exploring interactions between the innovation and the implementation context, for example, by investigating the 'plasticity of intervention components' (the adaptability of the intervention) and the 'elasticity of contexts' (rigidity/flexibility of the implementation environment) [220].

Conclusions

This study identified a wide range of barriers to, and facilitators of, implementation of the home-based REACH-HF cardiac rehabilitation programme across the UK. The study highlighted many interactions between different components of the model, including reductions in barriers over time as well as interactions with the intervention itself and the quality of training. The main output of the study is a pragmatic implementation guide – the REACH-HF Service Delivery Guide, which the study confirmed to be a useful tool for cardiac rehabilitation services wishing to include the REACH-HF programme in their service provision.

Authors' contributions

All authors (bar Grace Emily Rachel Wood) contributed to the idea for the study and protocol development. Hasnain Dalal was instrumental in setting up the Beacon Sites. Samantha B van Beurden led the set up and recruitment process. Sinéad T J McDonagh was overseeing the day-to-day management of the Beacon Sites. Paulina Daw secured all relevant ethical approvals for the project, prepared all study documentation and acquired the data. Paulina Daw, Grace Emily Rachel Wood and Colin J Greaves analysed the data. Colin J Greaves, Jet JCS Veldhuijzen van Zanten, Hasnain Dalal, Rod S Taylor, Patrick J Doherty and Alexander Harrison provided project supervision and oversight. PD drafted the manuscript. All authors provided critical revision of the manuscript for important intellectual content and approved the final draft for submission.

Reflection

Qualitative methods (the dominant mode of inquiry in the conducted study), often used during the early stages of the research cycle (Figure 10), are useful when investigating a new phenomenon, tackling under-researched areas and shining a light onto emerging fields. Qualitative methods have also been extensively used in healthcare research and implementation science [383, 384], evaluation research [385] and process evaluations of complex interventions [386]. Studies utilising qualitative methods 'can provide insight as to why program does not work as intended; [they] may also provide insight into unanticipated benefits or outcomes' [383].

Figure 10 Possible interactions between qualitative and quantitative research and how qualitative and quantitative studies can inform each other

The conducted study identified several reasons and contexts that may negatively impact the scale-up of the REACH-HF programme; these require tailored solutions to ensure ongoing implementation. For example, some interviewees acknowledged that a large geographical area is a significant barrier impacting a cardiac rehabilitation team's ability to deliver a home-based cardiac rehabilitation programme. This is as much of a barrier for the cardiac rehabilitation teams as it is a barrier for patients enrolled onto centre-based programmes. Therefore, geographical catchment area should not prevent services from offering home-based cardiac rehabilitation programmes. One notable suggestion to overcome this particular obstacle was to create a number of cardiac rehabilitation hubs, which would allow healthcare professionals to offer home-based visits to several patients who live in one particular area during a working day without the need to travel to the central cardiac rehabilitation team office. Also, there were a number of unintended benefits of the implementation of REACH-HF at the Beacon Sites illuminated during the study, such as an inspiration to improve the general service provision, for example, by conducting a functional capacity assessment on all patients receiving cardiac rehabilitation.

In the conducted study, as per the earlier recommendations to use implementation tools prospectively (described in Chapter 1 and at the beginning of Chapter 4), the chosen theoretical framework (i.e., NPT) was used to guide data collection (e.g., generating questions for interviews and the online survey) and the analysis and interpretation of the study's findings. The results of the study – empirical validated barriers and facilitators – were used to improve the REACH-HF training and the innovation as well as design and refine an

implementation manual to aid further implementation and scale-up initiatives. An additional advantage of using the NPT framework was that it is largely based on social theory and, as I had access to different healthcare teams, using a model which focusses on building an understanding of the interpersonal dimension of the implementation process was particularly appropriate. One disadvantage of using this particular implementation theory was that it lacked tools for assessment of the implementation context. However, as the study used four different implementation sites, a systematic context assessment prior to implementation would have been time-consuming and burdensome for participating sites. Instead, I used the Beacon Site application forms to gather pre-implementation data for the four sites. Further contextual factors were uncovered during qualitative interviews with the study participants.

On reflection, the chosen research methodology (i.e., mixed methods), analytical approach (i.e., framework analysis) and the implementation theory (i.e., NPT) were suitable for the project and led to the development of a thorough understanding of the implementation process at the Beacon Sites and beyond. Operationalising all four NPT constructs (consisting of 16 components) allowed a very comprehensive examination of the implementation process. However, including all available NPT components was also time-consuming and I found some overlap between different constructs. Due to the very large scope of this framework, several other prior empirical studies used only selected NPT dimensions to assess the process of implementation [306]. Such an approach was considered for this study. However, despite the additional time required during the data analysis and synthesis, using all available NPT components, on balance, was beneficial. As well as generating rich conceptual data, the study suggested ways to expand the initial implementation theory (as discussed in

the manuscript). The identified themes that were outside the scope of NPT (e.g., patient-level and geographical factors) can be tested in future qualitative and/or quantitative studies.

Qualitative methods and scientific rigour

To increase scientific rigour, empirical studies must demonstrate commitment to validity, reliability, generalisability and objectivity, or in qualitative terms – credibility, dependability, transferability and reflexivity [387, 388]. One way of increasing the validity of qualitative research is through achieving data saturation (i.e., a point during the data collection stage when no further data relating to the study's aims can be added to the data set to expand the coding frame). However, there is no agreed method for assessing/deciding the point of data saturation [389]. Furthermore, in practice, the end of data collection/analysis is often constrained by resource availability (research time) rather than considerations of data saturation. Additionally, it is problematic to think of data saturation as a categorical phenomenon (i.e., yes or no). In fact, the degree of saturation sits on a spectrum and different themes or concepts within the data set will be more saturated than others. A better question might be to consider whether the research questions/aims have been sufficiently addressed and whether further analysis will yield substantial changes to the results or interpretation. The conducted study relied on independent double-coding of a selected number of transcripts and frequent meetings between the members of the coding team to compare the developing framework and make a decision that no further participant recruitment was necessary.

Another technique for validating research findings and strengthening the rigour of qualitative studies is to invite the study participants to check whether researchers captured their experiences accurately. This is called member checking or participant/respondent validation and can increase the trustworthiness and credibility of the qualitative research findings [390]. However, member checking can also pose practical issues (e.g., tokenistic involvement, poor relevance and value within the study design or limited resources available to offer further analysis) and ethical considerations (e.g., distress to study participants) [391]. Member checking was considered as part of the protocol for the conducted study (i.e., inviting the interviewed healthcare professionals to review the themes elicited from the transcripts). The decision not to involve the interviewed stakeholders in the analysis stage was made based on the assumption that it would be difficult to conduct – due to the clinical workload of participants and a lack of time allocated to compensate for participation in the research. This could then lead to an additional research burden and increased workload for the participants; especially as the coding frame used an existing framework with a very specific taxonomy (i.e., NPT), which might have been difficult to understand by the interviewees.

A further technique for increasing the trustworthiness of qualitative research findings is the inclusion of deviant and non-confirmatory cases [392]. The combination of sampling strategies used in the study (i.e., opportunity and snowball) allowed the identification of various stakeholders at the Beacon Sites. Each conducted interview was transcribed and data extracted from each were included in the analysis. During the data synthesis, all uncovered divergent themes were included and reported in the final report. In fact, I paid particular attention to deviating cases/opinions as they might have been linked to specific

implementation contexts or specific attitudes from healthcare professionals implementing REACH-HF.

The process of interpretation of qualitative research findings is susceptible to coder bias. In order to mitigate such bias, a proportion of transcripts were double-coded and frequent meetings were held, including all members of the coding team, to discuss the coding strategy and data interpretation. Another way of mitigating coder bias was by adopting an a priori coding framework, in the case of the conducted study – NPT. Lastly, to further increase the scientific rigour of the study, I used reflexivity in the form of a reflective journal in which I made notes and observations throughout the whole of the study. Explicit reflexivity in qualitative research can help to identify and mitigate conscious and unconscious biases [280]. The notes I made were summarised in the Personal reflection section in Chapter 2.

Very often the lack of generalisability of qualitative research findings is reported as a limitation of a study. In the case of the conducted study, I assumed likely transferability of findings to the UK cardiac rehabilitation context when the REACH-HF programme is being delivered. Hence, the findings were used to design and refine the REACH-HF Service Delivery Guide. Transferability to a wider sets of implementation contexts, for example, when implementing different types of cardiac rehabilitation programmes or if the REACH-HF programme is implemented in non-UK setting, is limited. However, I agree with Palinkas that qualitative studies are 'designed for depth and not breadth of understanding, [and that] the generalizability of findings is of less importance' [383]. During the conduct of the study, a lot of effort has gone into ensuring that the rigour, significance and originality of the study were

guiding the process of data collection, data analysis/synthesis and write-up. This was also the case when conducting the systematic review (described in Chapter 3) and the quantitative study, results of which will be described in the next chapter (Chapter 5).

CHAPTER 5 – QUANTITATIVE STUDY

The multifactorial nature of implementation

Rogers in his book 'Diffusion of Innovations', a central text of implementation science, suggested that there are five broad types of implementers, categorised according to their speed of adoption/implementation and their attitude towards the new technology/intervention [157]. According to Rogers' classification:

- Innovators are the least common type of implementers (2.5%), they show the quickest rate of adoption, see themselves as being at the cutting edge of new technologies, and are pivotal in educating and inspiring peers.
- Early adopters (13.5%) follow closely behind the innovators, they are well-respected in the given field and have an appetite for setting new trends.
- Early majority (34%) are interested in increasing productivity with reliable technologies, they are happy with progress that is slow and steady.
- Late majority (34%) are very cautious in adopting new technologies, require tried-and-tested solutions, which they implement mostly to keep up with others working in their field.
- Laggards (16%) show the slowest rate of uptake and are frequently resistant to change. Laggards often see innovations as a hindrance to the established processes with which they are familiar.

Although Rogers' classification is very useful, it is also somewhat limited as the speed of implementation is not the only metric that matters and the drivers of innovation diffusion are

multifactorial. Using the first four categories from the above classification and considering only the uptake rate (i.e., the number of patients recruited at each Beacon Site to receive the Rehabilitation EnAblement in CHronic Heart Failure (REACH-HF) programme), Site 1 could be classified as innovators (61 patients started treatment), Site 2 as early adopters (35 patients), Site 3 as early majority (26 patients) and Site 4 as late majority (10 patients). However, as discussed in the previous chapter (Chapter 4) the phenomenon of a successful implementation is very complex and multifactorial, involving more than the rate of uptake. For example, the acceptability of the new programme to those delivering it, the intervention's reach/applicability (i.e., whether it is offered to and accepted by the target population) and a healthcare team's capacity to deliver the innovation. Fidelity of intervention delivery and its real-world effectiveness are also key drivers of implementation. Rogers' typology seems to confound innovation outcomes (speed) with key drivers of innovation (implementer attitudes), whilst ignoring many other key drivers. The conducted quantitative study attempted to explore some of these.

Building on the findings from Chapter 4, which considered healthcare professionals' attitudes towards the REACH-HF programme and their perceptions of barriers to, and facilitators of, implementation of the programme, the manuscript below reports on some of the additional characteristics of the successful implementation process. Firstly, I have evaluated the real-world implementation effectiveness of the REACH-HF programme (i.e., the effectiveness achieved during routine service delivery) by comparing patient-reported outcomes achieved at the Beacon Sites with those achieved during the REACH-HF randomised controlled trial. Secondly, I have examined the quality of delivery of the REACH-HF programme by comparing

the implementation patterns observed at the Beacon Sites and the intervention delivery protocol outlined by the intervention's developers (e.g., the number of sessions offered to patients enrolled onto the REACH-HF programme). Lastly, to examine the reach/applicability of the REACH-HF programme (as used at the Beacon Sites), I have compared the socio-demographic characteristics of patients who received REACH-HF at the Beacon Sites to those recruited into the trial and to the general heart failure population.

The study manuscript

Below is a manuscript titled ‘A pragmatic effectiveness-implementation study comparing trial evidence with routinely collected outcome data for patients receiving the REACH-HF home-based cardiac rehabilitation programme’. A version of this manuscript is currently undergoing peer review with BMC Cardiovascular Diseases and has been provisionally accepted by the journal, subject to addressing a second round of (very brief) reviewers’ comments.

Abstract

Background

Cardiac rehabilitation for heart failure continues to be greatly underused worldwide despite being a Class I recommendation in international clinical guidelines and uptake is low in women and patients with mental health comorbidities.

Methods

The REACH-HF programme was implemented in four United Kingdom (UK) National Health Service (NHS) early adopter sites ('Beacon Sites') between June 2019 and June 2020. Implementation and patient-reported outcome data were collected across sites as part of the National Audit of Cardiac Rehabilitation (NACR). The change in key outcomes before and after the supervised period of REACH-HF intervention across the Beacon Sites was assessed and compared to those of the intervention arm of the REACH-HF multicentre trial.

Results

Compared to the REACH-HF multicentre trial, patients treated at the Beacon Site were more likely to be female (33.8% vs 22.9%), older (75.6 vs 70.1), had a more severe classification of heart failure (26.5% vs 17.7%), had poorer baseline health-related quality of life (Minnesota Living with Heart Failure Questionnaire (MLHFQ) score 36.1 vs 31.4), were more depressed (Hospital Anxiety and Depression Scale (HADS) score 6.4 vs 4.1) and anxious (HADS score 7.2 vs 4.7), and had lower exercise capacity (Incremental Shuttle Walk Test (ISWT) distance 190m vs 274.7m).

There appeared to be a substantial heterogeneity in the implementation process across the four Beacon Sites as evidenced by the variation in levels of patient recruitment, operationalisation of the REACH-HF intervention and patient outcomes. Overall lower improvements in patient-reported outcomes at the Beacon Sites compared to the trial may reflect differences in the population studied (e.g., having higher morbidity at baseline) as well as the marked challenges in intervention delivery during the COVID-19 pandemic.

Conclusions

The results of this study illustrate the challenges in consistently implementing an intervention (shown to be clinically effective and cost-effective in a multicentre trial) into real-world practice, especially in the midst of a global pandemic. Further research is needed to establish the real-world effectiveness of the REACH-HF intervention in different populations.

Contributions to the literature

- Understanding the real-world implementation and impact on patient-reported outcomes of an evidence-based intervention for heart failure.
- REACH-HF may be a viable cardiac rehabilitation alternative for older patients and patients with mental health comorbidities and lead to an increase in the uptake of cardiac rehabilitation in these currently underserved populations.
- More effort is needed to offer the programme to a wider range of patients. This can be achieved by improving referral pathways and/or making the programme more accessible/appealing to different patients.

- The study is unique in utilising routine data to evaluate the real-world implementation of trial evidenced intervention; the findings can inform future studies employing similar methodologies.

Background

Cardiac rehabilitation for patients with heart failure

Cardiac rehabilitation for heart failure continues to be greatly underused worldwide despite being a Class I recommendation in international clinical guidelines. Less than 20% of eligible patients in Europe receive this intervention [112] and fewer still in the United States of America [124]. Patient-level factors associated with lower uptake rates include age, gender (women are much less likely to participate than men), ethnicity, being single, living in rural areas and areas of high deprivation, the distance required to travel, financial constraints, and work obligations [113, 118, 119]. Provider- and system-level barriers specific to the heart failure population include poor clinician's knowledge, awareness and attitude, a lack of resources, and safety concerns regarding cardiac rehabilitation [393].

The landscape of cardiac rehabilitation provision before the COVID-19 pandemic was dominated by group-based programmes delivered in hospitals and community cardiac rehabilitation centres [93]. Providing different modes of delivery, such as telemedicine or home-based programmes, are proposed alternatives that could help to increase the uptake of cardiac rehabilitation [96, 104, 124, 126, 336].

Intervention – the REACH-HF programme

The REACH-HF programme is a clinically effective and cost-effective, home-based, healthcare professional-facilitated cardiac rehabilitation programme for patients with heart [146]. The 12-week programme is delivered by existing cardiac rehabilitation staff

(who have undergone the REACH-HF facilitator training) using a mixture of home visits and telephone calls. The average contact time per patient in the REACH-HF effectiveness trial was 5.3 hours (made up of 4.5 hours of face-to-face contact and 0.8 hours of telephone facilitation) over an average of 6.5 sessions. The REACH-HF programme and the multicentre trial are described in more detail elsewhere [142, 145, 146, 263].

Research-to-practice gap

Moving research findings into routine clinical practice is a well-documented challenge [394, 395]. Once implemented, innovations often fail to replicate the effectiveness reported in clinical trials [162]. As many as 23 contextual factors can impact the implementation process leading to variations in the delivery of the same programme between centres/teams [396]. For example, patients treated in real-world clinical settings might be different to those recruited into the trial, staff implementing the innovation might lack the knowledge and skills required to deliver the intervention as it was intended, or a lack of resources might hinder effective implementation [254, 255].

Study aim

This low-resource pragmatic effectiveness-implementation study used routinely collected audit data from the NACR, which gathers data from England, Wales and Northern Ireland, to compare real-world changes in outcomes of patients receiving the REACH-HF programme to the prior clinical trial findings [146]. Audit data were also used to understand the implementation process by considering how the intervention was

delivered and the socio-demographic characteristics of patients treated. In the present study, the term 'Beacon Sites' is used to refer to four UK NHS early adopter sites offering the REACH-HF programme in real-world clinical settings.

The study aimed to answer the following research questions: a) 'What are the variations in the implementation process across the four Beacon Sites and how do such variations impact on patient outcomes?', b) 'Are the patients receiving the REACH-HF intervention at the Beacon Sites comparable to those recruited into the trial and to the general heart failure population?' and c) 'Are changes in outcomes of interest derived from routine data collected at the Beacon Sites for patients receiving the REACH-HF intervention comparable with the changes observed in the REACH-HF trial?'.

This study is part of a larger implementation project [371], the main output of this project is an implementation manual (the REACH-HF Service Delivery Guide – Appendix 1), which is available to healthcare teams interested in including REACH-HF in their service provision in the National Institute for Health and Care Excellence guidance [382]. The current paper will concentrate on patient-reported outcomes and quantitative implementation data.

Methods and analysis

Design

The current effectiveness-implementation study used a multi-centre prospective cohort design to evaluate the implementation process and compare trial evidence with

routinely collected pre-treatment and post-treatment healthcare data during the real-world implementation of the intervention at four Beacon Sites.

Setting up the Beacon Sites

The Beacon Sites selection process is described in detail in the published protocol [371]. Following the UK-wide two-stage recruitment process (application form and panel interview), four Beacon Sites were set up to deliver REACH-HF to 200 patients between June 2019 and June 2020. The Beacon Sites were required to administer two key outcome measures as were used in the clinical trial – MLHFQ and ISWT.

Characteristics of the Beacon Sites

The Beacon Sites were located in urban and rural geographical areas in England and Northern Ireland. Before becoming Beacon Sites, all four cardiac rehabilitation teams offered predominantly group-based programmes. Cardiac rehabilitation team characteristics and cardiac rehabilitation activity before each became a Beacon Site are summarised in Table 12.

Table 12 Cardiac rehabilitation team characteristics and cardiac rehabilitation activity before becoming Beacon Sites

	Site 1	Site 2	Site 3	Site 4
National Certification Programme for Cardiac Rehabilitation status*	Green	Amber	Green	Green
Average core rehabilitation programme length in weeks	12	6	10	14

Number of patients attending (starting) cardiac rehabilitation	635	726	295	500
Accepting patients with heart failure	Yes	No	Yes	Yes
Number of patients with heart failure who attended cardiac rehabilitation in the 12 months before the Beacon Site application	46	N/A	38	36
Offering supervised/facilitated home-based cardiac rehabilitation	Yes	Yes	Yes	No
Number of any cardiac patients who received supervised/facilitated home-based cardiac rehabilitation in the 12 months before the Beacon Site application	66	24	8	Not applicable
Approximate full-time equivalent staff in the multidisciplinary cardiac rehabilitation team	11	10	5	9

* unless stated otherwise, the included data are from the NACR 2016/2017 audit

Participants

Three cohorts of patients were compared in the study: patients with heart failure who received REACH-HF at the Beacon Sites, patients with heart failure who received REACH-HF within the multicentre randomised controlled trial and the general heart failure population – all patients with heart failure (except those receiving REACH-HF at the Beacon Sites) in the NACR database who received cardiac rehabilitation during the Beacon Site period (between June 2019 and June 2020).

Measures

NACR data

To capture the context of the Beacon Sites and the process of implementation, the following data were included: source of referral, number of patients enrolled on the programme, number of patients completing the programme, number of patients dropping out from the programme, reasons for not completing the programme, average programme duration in days and average number of clinical sessions received.

The socio-demographic and medical data of patients who received REACH-HF included: mean age in years, gender, ethnicity, marital status, employment status, rural/urban classification [397], index of multiple deprivation classification (quintile) [398], the severity of heart failure measured with the New York Heart Association Heart Failure Classification (NYHA) at baseline [399], and baseline recordings of mean diastolic and systolic blood pressure, prescribed drugs and comorbidities. An additional 'missing' category was created for measures when data were either not stated, not known, not available or not routinely recorded.

Pre-treatment and post-treatment measures for health-related quality of life, mental health status and exercise capacity were requested from the NACR database as follows: health-related quality of life ((MLHFQ) [400], Dartmouth Cooperative Functional Assessment (COOP) charts [401]), mental health status ((Patient Health Questionaire-9 (PHQ-9)[402], Generalised Anxiety Disorder Assessment-7 (GAD-7) [403], HADS [404]), and objective exercise capacity ((ISWT) [260], Six Minute Walk Test (6MWT) [405]). For outcome measures assessing the health-related quality of life and mental health status,

higher scores represent higher levels of impairment. The opposite is true for the exercise capacity measures, where higher scores represent higher physical fitness/functional capacity. The study's primary outcome measure of interest was the MLHFQ. Beyond that, all the other outcomes were secondary and all analysis performed was considered to be exploratory. A detailed description of all the outcome measures can be found in Appendix 11.

Data from the REACH-HF trial

107 participants were randomised into the intervention arm in the REACH-HF clinical trial [146]. The available trial outcome measures included MLHFQ, HADS and ISWT. The current study excluded 11/107 (10.3%) trial patients as they were missing the four-month follow-up data.

Data collection and analysis

All patient data used in the study were entered manually into the NACR database by the NHS staff working at the Beacon Sites. A download of the NACR data was conducted by the NACR data scientist (Alexander Harrison) in February 2021. The study focussed on the four-month trial follow-up time point, as it was the best match for the time period between pre-treatment and post-treatment assessments at the Beacon Sites (mean 125.2 days). Due to data governance requirements, analyses using individual patient-level data were conducted by the NACR staff.

Descriptive statistics were used to report the characteristics of the study sites and the patient sample. To explore whether the MLHFQ within-group change in the NACR data was different from the within-group change in the trial, a three-group (Beacon Sites vs trial treatment arm vs trial control arm) comparison (ANCOVA) was conducted with adjustment for the MLHFQ baseline score, age and gender. To understand the within-group differences at the Beacon Sites and the trial, a standardised mean difference approach was used to calculate effect sizes for primary and secondary outcome measures adjusted for the sample size (Hedges' *g*) [406-408]. Due to the NACR information governance arrangement, I was unable to have access to individual level data and, hence, I was unable to calculate *p* values using the t-test approach.

Results

Implementation process and sample characteristics

Implementation activity at the Beacon Sites is summarised in Table 13.

Table 13 REACH-HF Beacon Sites activity between June 2019 and June 2020

Started treatment n (%)		132
Completed treatment n (%)		96 (72.7)
Average sessions received mean (SD)		7.5 (3.9)
MIN/MAX sessions received n		1 (MIN), 24 (MAX)
Average treatment duration in days mean (SD)		125.3 (47.4)
MIN/MAX treatment duration in days n		70 (MIN), 299 (MAX)
Dropped out n (%)		36 (27.3)
Reason for not	Did not attend – unknown reason n (%)	6 (21.4)
	Left the area n (%)	1 (3.6)

	Planned/emergency intervention n (%)	1 (3.6)
	Too ill n (%)	7 (25)
	Died n (%)	3 (10.7)
	Hospital readmission n (%)	2 (7.1)
	Other n (%)	8 (28.6)
	Missing n (%)	8 (22.2)

Data for the individual sites can be found in Table 14.

Table 14 REACH-HF activity at individual Beacon Sites between June 2019 and June 2020

Site		Site 1	Site 2	Site 3	Site 4
Started treatment n (%)		61 (46.2%)	35 (26.5%)	26 (19.7%)	10 (7.6%)
Completed treatment n (%)		42 (68.9%)	28 (80%)	23 (88.5%)	3 (30%)
Average sessions received mean (SD)		9.2 (4.5)	6.3 (2.9)	6 (1.5)	4.7 (2.8)
Treatment duration in days mean (SD)		144.7 (53.4)	111.6 (26.7)	96.6 (24.1)	196 (64)
Dropped out n (%)		19 (31.1%)	7 (20%)	3 (11.5%)	7 (70%)
Reason for not completing n (%)	DNA unknown reason	1 (6.2%)	5 (83.3%)	-	-
	Left the area	1 (6.2%)	-	-	-
	Planned/emergency intervention	-	-	1 (33.3%)	-
	Too ill	5 (31.2%)	1 (16.7%)	1 (33.3%)	-
	Died	3 (18.7%)	-	-	-
	Hospital readmission	2 (12.5%)	-	-	-
	Other	4 (25%)	-	1 (33.3%)	3 (100%)

	Missing	3 (15.8%)	1 (14.3%)	-	4 (57.1%)

Across the four Beacon Sites, 132 patients with heart failure were enrolled on the REACH-HF programme between June 2019 and June 2020. Only one Beacon Site (Site 1) achieved the 50-patient target and the lowest enrolment site (Site 4) met only 1/5 of the goal.

Based on the data recorded by the cardiac rehabilitation providers, of the 132 patients enrolled, 96 (72.7%) completed the programme. The completion rate was calculated based on the patient having two valid assessments (baseline and end-of-treatment) or a 'completed' box being ticked for patients who were unable to attend their assessment appointments. The highest completion rate was achieved at Site 3 (88.5%) and the lowest at Site 4 (30%). Out of the 36 (27.3%) patients who did not complete the programme, reasons for non-completion were recorded for 28 (77.8%) patients and included being too ill to continue (25%), hospital admission (10.7%), death (10.7%) and leaving the area (3.6%).

On average, patients received 7.5 (SD 3.9) clinical sessions (a combination of centre-based assessments, home visits and telephone support) over 125.3 days (SD 47.4). There was a large variation in the number of sessions attended with a minimum of one and a maximum of 24 sessions. A similar variation was observed with treatment duration, 70 days was the minimum and 299 days the maximum.
The comparison of the three cohorts can be found in Table 15.

Table 15 Comparison of patients receiving the REACH-HF intervention at the Beacon Sites between June 2019 and June 2020, those recruited into the REACH-HF trial and the general heart failure population recorded in the NACR database between June 2019 and June 2020 (excluding Beacon Sites patients)

	Beacon Sites (n=132, unless specified otherwise)	Trial data – treatment arm (n=96*, unless specified otherwise)	Patients with heart failure recorded in the NACR for the same period (excluding Beacon Site patients) (n=5549)
Age in years – mean (SD)	75.6 (11.1)	70.1 (10.4)	68.8 (12.7)
Male sex – n (%**)	86 (66.2)	74 (77.1)	3860 (69.6)
Ethnic group – n (%)	White 81 (90)	White 91 (94.8)	White 3935 (83.5)
	Non-white 9 (10)	Other/Black/Asian ethnic group 5 (5.2)	Black, Asian and minority ethnic 780 (16.5)
Accommodation status/marital status – n (%)	Single 29 (35.8)	Living alone 25 (26.1)	Single 1081 (28.9)
	Married/living with a partner 52 (64.2)	Living with a partner and/or a family member 71 (73.9)	Married/living with a partner 2664 (71.1)
Employment status – n (%)	Employed 5 (7.8)	Employed 15 (15.6)	Employed 546 (16.3)
	Unemployed/retired 59 (92.2)	Unemployed/retired 81 (84.4)	Unemployed/retired 2798 (83.7)

Rural/urban indicator – n (%)	Rural town and fringe 12 (9.9)		
	Rural village and dispersed 9 (7.4)		
	Urban city and town 15 (12.4)		
	Urban major conurbation 85 (70.3)		
Index of multiple deprivation – n (%)	Lowest quintile 28 (23.1)		
	Second quintile 11 (9.1)		
	Third quintile 21 (17.4)		
	Fourth quintile 28 (23.1)		
	Fifth quintile 33 (27.3)		
Mean MLHFQ at baseline (SD, n)	36.1 (22.7, 50)	31.4 (22.8, 96)	
Mean HADS (depression) at baseline (SD, n)	6.4 (5, 23)	4.1 (3.3, 96)	5.5 (4, 2761)
Mean HADS (anxiety) at baseline (SD, n)	7.2 (5.2, 23)	4.7 (4.1, 96)	5.9 (4.5, 2762)

Mean ISWT at baseline (SD, n)	190 (119.4, 13)	274.7 (153.7, 90)		
Mean systolic blood pressure at baseline (SD, n)	117 (15.8, 43)	128.9 (19.2, 90)	122.3 (20.1, 4299)	
Mean diastolic blood pressure at baseline (SD, n)	65.1 (8.9, 43)	71.1 (10.2, 90)	71.7 (11.9, 4296)	
Heart failure status (NYHA) – n (%)				
Class I	2 (5.9)	22 (22.9)	217 (22.3)	
Class II	23 (67.6)	57 (59.4)	494 (50.7)	
Class III	9 (26.5)	17 (17.7)	211 (21.6)	
Class IV	-	-	53 (5.4)	
Comorbidities – n (%)				
Angina	-	18 (18.7)	475 (10.9)	
Arthritis (osteo or rheumatoid)	18 (13.6)	41 (42.7)	770 (17.7)	
Diabetes	10 (7.6)	25 (26)	1304 (30)	
Stroke	6 (4.5)	11 (11.4)	363 (8.3)	
Osteoporosis	3 (2.3)	6 (6.2)	95 (2.2)	
Hypertension	24 (18.2)	40 (41.7)	2038 (46.9)	
	5 (3.8)	9 (9.4)	Chronic bronchitis	267 (6.1)

Chronic obstructive pulmonary disease (Chronic bronchitis or Emphysema)			Emphysema	196 (4.5)
Asthma	4 (3)	9 (9.4)	421 (9.7)	
Chronic Back Problems	16 (12.1)	28 (29.2)	467 (10.7)	
Depression	7 (5.3)	21 (21.9)	380 (8.7)	
Key disease-modifying medicines – n (%)				
Angiotensin-converting enzyme (ACE) inhibitors	38 (28.8)	62 (64.6)	2223 (56)	
Angiotensin receptor blockers	21 (15.9)	26 (27.1)	918 (23.1)	
Beta blockers	72 (54.5)	82 (85.4)	3404 (85.8)	
Anticoagulant	42 (31.8)	42 (43.8)	1383 (34.8)	
Aldosterone receptor antagonist	23 (17.4)	52 (54.2)	1806 (45.5)	

* Baseline characteristics for 96 patients who had MLHFQ recorded at baseline and four-month follow-up, unless specified otherwise

** Valid percent values

Of the 132 patients enrolled on the programme, 86 (66.2%) were male and 44 (33.8%) were female. The mean age of patients treated at the four Beacon Sites was 75.6 (SD 11.1) years old; Beacon Site 1 patients were a mean of 10.5 years older than the remaining sites.

Patients treated at the Beacon Sites were mainly white Caucasian (n=81, 90%), 52 (64.2%) were married or living with a partner and the majority (n=85, 70.2%) were living in major urban conurbations. Beacon Sites recruited a similar proportion in each area deprivation quintile with 60 (49.6%) patients living in the three lowest quintiles (most deprived areas) and 61 (50.4%) in the two highest quintiles (least deprived areas). Table 16 includes socio-demographic characteristics of patients enrolled on the REACH-HF programme at individual Beacon Sites and missing data.

Table 16 Socio-demographic characteristics of patients enrolled onto the REACH-HF programme at individual Beacon Sites between June 2019 and June 2020 (including missing data)

Site (n)		Site 1 (61)	Site 2 (35)	Site 3 (26)	Site 4 (10)	Total (132)
Mean age in years (SD)		80.5 (8.6)	73.1 (10)	71.3 (12.4)	65.6 (12.1)	75.6 (11.1)
Gender n (%)	Male	39 (63.9%)	27 (81.8%)	13 (50%)	7 (70%)	86 (66.2%)
	Not specified	-	2 (5.7%)	-	-	2 (1.5%)
Ethnic group n (%)	White	52 (100%)	5 (100%)	15 (62.5%)	9 (100%)	81 (90%)
	Non-white	-	-	9 (37.5%)	-	9 (10%)
	Missing	9 (14.7%)	30 (85.7%)	2 (7.7%)	1 (10%)	42 (31.8%)
Marital Status n (%)	Single	16 (34.1%)	-	11 (52.4%)	2 (30%)	29 (35.8%) [of which 14 male]
	Married/living with a partner	31 (65.9%)	3 (100%)	10 (47.6%)	8 (70%)	52 (64.2%) [of which 35 male]
	Missing	14 (22.9%)	32 (91.4%)	5 (19.2%)	-	51 (38.6%)
Employment status n (%)	Employed	-	2 (100%)	2 (9.5%)	1 (12.5%)	5 (7.8%)
	Unemployed/retired	33 (100%)	-	19 (90.5%)	7 (87.5%)	59 (92.2%)

	Missing	28 (45.9%)	33 (94.3%)	5 (19.2%)	2 (20%)	68 (51.5%)
Rural/urban indicator n (%)	Rural town and fringe	-	12 (35.3%)	-	-	12 (9.9%)
	Rural village and dispersed	1 (1.6%)	8 (23.5%)	-	-	9 (7.4%)
	Urban city and town	1 (1.6%)	14 (41.2%)	-	-	15 (12.4%)
	Urban major conurbation	59 (96.7%)	-	26 (100%)	-	85 (70.2%)
	Missing	-	1 (2.8%)	-	10 (100%)	11 (8.3%)
Index of multiple deprivation n (%)	Lowest quintile	13 (21.3%)	2 (5.9%)	13 (50%)	-	28 (23.1%)
	Second quintile	4 (6.5%)	2 (5.9%)	5 (19.2%)	-	11 (9.1%)
	Third quintile	13 (21.3%)	5 (14.7%)	3 (11.5%)	-	21 (17.4%)
	Fourth quintile	11 (18%)	13 (38.2%)	4 (15.4%)	-	28 (23.1%)
	Fifth quintile	20 (32.8%)	12 (35.3%)	1 (3.8%)	-	33 (27.3%)
	Missing	-	1 (2.8%)	-	10 (100%)	11 (8.3%)
Heart failure status at baseline n (%)	NYHA Class 1	2 (8.3%)	-	-	-	2 (5.9%)
	NYHA Class 2	20 (83.3%)	-	2 (22.2%)	1 (100%)	23 (67.6%)
	NYHA Class 3	2 (8.3%)	-	7 (77.8%)	-	9 (26.5%)
	Missing	37 (60.6%)	35 (100%)	17 (65.4%)	9 (90%)	98 (74.2%)

Referral sources for patients treated at the Beacon Sites can be found in Table 17.

Table 17 Referral sources for patients enrolled on the REACH-HF programme at the Beacon Sites between June 2019 and June 2020

Total (n)		n=105
Source of referral n (%)	Consultant	5 (4.8)
	Cardiac nurse	96 (91.4)
	GP	1 (1)
	Primary care nurse	3 (2.9)
	Missing	27 (20.5)

Data for the individual sites and missing data are in Table 18.

Table 18 Referral sources for patients enrolled on the REACH-HF programme at individual Beacon Sites between June 2019 and June 2020 (including missing data)

Site (n)		Site 1 (60)	Site 2 (32)	Site 3 (12)	Site 4 (1)
Source of referral n (%)	Consultant	3 (5%)	-	2 (16.7%)	-
	Cardiac nurse	55 (91.7%)	32 (100%)	8 (66.7%)	1 (100%)
	GP	1 (1.7%)	-	-	-
	Primary care nurse	1 (1.7%)	-	2 (16.7%)	-
	Missing	1 (1.6%)	3 (8.6%)	14 (53.8%)	9 (90%)

Cardiac nurses were the main source of referrals with 96 (91.4%) patients enrolled on the programme following hospitalisation for heart failure. Only a fraction of referrals (n=4, 3.8%) came from primary care pathways (i.e., GPs, primary care nurses).

Patient outcomes

Table 19 compares primary and secondary outcomes achieved at the Beacon Sites with those from the trial. The ANCOVA analysis confirmed that the trial population did significantly better (Mean Difference -7.2: 95%CI -14.1 to -0.3) compared with the Beacon Site population in terms of improvement in health-related quality of life measured by the MLHFQ. Furthermore, the ANCOVA comparison (NACR data vs trial control group) confirmed that there was no significant difference in the improvement of the MLHFQ scores at the Beacon Sites (Mean Difference 1.9: 95%CI -5 to 8.9).

The pre-treatment and post-treatment effect sizes calculated at the Beacon Sites (Table 19) did not match the effect sizes calculated from the trial data for the health-related quality of life – MLHFQ (Mean Difference -0.09: 95%CI -0.49 to 0.30 vs -0.42: 95%CI -0.70 to -0.13), mental health measures – HADS depression (Mean Difference -0.15: 95%CI -0.73 to 0.43 vs -0.20: 95%CI -0.48 to 0.09) and exercise capacity measure – ISWT (Mean Difference 0.17: 95%CI -0.60 to 0.94 vs 0.27: 96%CI -0.03 to 0.58). The pre-treatment and post-treatment effect size for the HADS anxiety score recorded at the Beacon Sites exceeded the effect size calculated from the trial data (Mean Difference -0.14: 95%CI -0.72 to 0.44 vs -0.07: 95%CI -0.36 to 0.21).

Table 19 Comparison of the primary and secondary outcomes for patients who received the REACH-HF intervention at the Beacon Sites between June 2019 and June 2020 and those recruited into the REACH-HF trial

Measure	Pre			Post			Effect size
	N	Mean	SD	N	Mean	SD	Hedges' *g* (95% CI)
MLHFQ							
Beacon Sites	50	36.1	22.7	50	34.0	21.7	-0.09 (-0.49 to 0.30)
Trial	96	31.4	22.8	96	22.7	18.4	-0.42 (-0.70 to -0.13)
HADS (depression)							
Beacon Sites	23	6.4	5.0	23	5.7	4.2	-0.15 (-0.73 to 0.43)
Trial	95	4.2	3.3	95	3.6	2.7	-0.20 (-0.48 to 0.09)
HADS (anxiety)							
Beacon Sites	23	7.2	5.2	23	6.5	4.4	-0.14 (-0.72 to 0.44)
Trial	95	4.7	4.2	95	4.4	3.9	-0.07 (-0.36 to 0.21)
ISWT (m)							
Beacon Sites	13	190.0	119.4	13	211.5	122.9	0.17 (-0.60 to 0.94)
Trial	84	277.8	152.5	84	322.3	173.2	0.27 (-0.03 to 0.58)

The following pattern of variation in the magnitude of effect sizes (i.e., effect size below 0.2 is regarded as small, 0.5 as medium and 0.8 as large) at the individual Beacon Sites was observed. A deterioration in all outcome measures at Site 1, no change in the MLHFQ and a small positive change in the mental health measures at Site 2, a small positive change in all available outcome measures at Site 3 and a small, a medium and a large effect size at Site 4 for the MLHFQ, and the HADS depression and anxiety domains, respectively. Table 20 lists effect sizes for primary and secondary outcome measures at the individual Beacon Sites.

Table 20 Effect sizes for primary and secondary outcome measures at individual Beacon Sites for patients receiving REACH-HF programme between June 2019 and June 2020

		Site	Pre-treatment			Post-treatment			Effect size Hedges' *g* (95% CI)
			n	Mean	SD	n	Mean	SD	
Health-related quality of life	MLHFQ	S1	7	15.9	19.7	7	18.9	18.7	0.15 (-0.90, 1.20)
		S2	19	31.2	21.9	19	30.5	23.5	-0.03 (-0.67, 0.61)
		S3	22	43.3	18	22	38.6	16.7	-0.27 (-0.86, 0.33)
		S4	2	75	5.7	2	70	14.1	-0.27 (-2.74, 2.20)
	COOP	S1	3	17.4	7	3	21	7	0.41 (-1.24, 2.06)
		S2	-	-	-	-	-	-	-
		S3	1	21.9	14	1	18.7	14	Not estimable
		S4	-	-	-	-	-	-	-
Mental health	HADS (depression)	S1	7	2.9	3.1	7	5.1	4.7	0.52 (-0.55, 1.59)
		S2	-	-	-	-	-	-	-
		S3	14	6.9	4.4	14	5.7	4.2	-0.27 (-1.02, 0.47)
		S4	2	15	2.8	2	8	2.8	-1.43 (-9.75, 6.89)
	PHQ-9	S1	-	-	-	-	-	-	-
		S2	17	7.4	5.6	17	6.2	4.7	-0.23 (-0.90, 0.45)

		S3	-	-	-	-	-	-	-
		S4	-	-	-	-	-	-	-
	HADS (anxiety)	S1	7	4	4.8	7	4.7	4	0.15 (-0.90, 1.20)
		S2	-	-	-	-	-	-	-
		S3	14	7.4	3.8	14	6.3	3.8	-0.28 (-1.03, 0.46)
		S4	2	17	2.8	2	14	1	-0.82 (-5.83, 4.20)
	GAD-7	S1	-	-	-	-	-	-	-
		S2	17	4.1	3.3	17	3.3	3.3	-0.24 (-0.91, 0.44)
		S3	-	-	-	-	-	-	-
		S4	-	-	-	-	-	-	-
Objective exercise capacity	ISWT (m)	S1	2	160	56.6	2	135	7.1	-0.35 (-3.16, 2.45)
		S2	-	-	-	-	-	-	-
		S3	10	196	135.7	10	229	135.8	0.23 (-0.65, 1.11)
		S4	1	190	-	1	190	-	Not estimable
	6MWT (m)	S1	-	-	-	-	-	-	-
		S2	-	-	-	-	-	-	-
		S3	1	83	-	1	166	-	Not estimable
		S4	1	190	-	1	280	-	Not estimable

Discussion

The primary and secondary analysis confirmed that the results found in the REACH-HF trial intervention group were not replicated in the Beacon Site population. However, it was difficult to conclude definitively that the real-world implementation resulted in lower effectiveness, as there were substantial differences between the trial and the Beacon Sites in terms of the patient population and the level of implementation (treatment dose/duration). A small sample size and missing data encountered in the study introduced selection bias, further complicated by the lack of a non-treatment control group. The discrepancies in the implementation process and population characteristics observed in the study are consistent with other studies looking at the implementation of interventions that have been found to be effective in trials [409]. At the Beacon Sites the usual implementation challenges were exacerbated by severe service disruptions due to the COVID-19 pandemic.

Possible explanations of the data

Firstly, the COVID-19 pandemic led to substantial variations in the delivery of the programme across the Beacon Sites. The findings suggest that when delivered as part of a routine practice the programme was spread out over a longer time period (an additional 41 days). This was linked with scheduling delays, patient/staff sickness, staff redeployment and various service disruptions caused by the COVID-19 pandemic. There were large variations in the number of treatment sessions received and the length of treatment. This might suggest reduced treatment fidelity (leading to lower effectiveness). The inability to deliver the treatment as it was intended (face-to-face and in the patient's home) might have resulted in a diminished quality of care compared to the trial. For example, having to substitute face-to-face home

visits for phone sessions might have impacted the healthcare professional's ability to deliver the person-centred interactions that are at the core of the intervention [145].

Secondly, compared to the trial population, patients treated at the Beacon Sites were older, more depressed and anxious, had lower exercise capacity, and experienced more debilitating symptoms of heart failure. The 4.7-point difference in mean the MLHFQ between cohorts is close to the minimal clinically important difference of five points [410], which suggests that the health-related quality of life of patients treated at the Beacon Sites was lower than that of those recruited into the trial. In more clinically morbid populations with heart failure, the normal prognosis is for a worsening of the condition and an associated decline in quality of life over time [411]. Hence, in this population, a pattern of 'no decline' in symptoms over time may be a positive outcome. As we do not have data from a control group with the same baseline characteristics, we cannot be sure that this is the case here. However, the pattern of data between sites indicates that this is a plausible explanation. At Site 1, which treated the oldest/most frail patients of all the Beacon Sites, there was a consistent deterioration in all outcome measures (i.e., MLHFQ, COOP, HADS and ISWT), whereas across the other sites the trend was more positive (Table 20).

Historically, the uptake of cardiac rehabilitation in older patients with heart failure and in patients with mental health issues has been particularly low [113, 117]. Patients who received REACH-HF at the Beacon Sites, compared to those recorded in the wider NACR data set for the same period, were older (on average 6.8 years) and had more mental health morbidity (HADS (depression) score 6.4 vs 5.5 and HADS (anxiety) score 7.2 vs 5.9). It may be suggested

that the REACH-HF home-based cardiac rehabilitation programme might be a more acceptable form of rehabilitation to older/frailer patients and patients with mental health comorbidities compared with centre-based programmes (or at least that cardiac rehabilitation staff feel more comfortable recommending this rehabilitation option to these patients). In the real-word, only a limited range of patients accessed the programme, hence, the clinical implication of the study, irrespective of the cause of this pattern (patient preference or referral procedures), is a need to make the intervention accessible to a wider range of patients.

Strengths and limitations

Using routinely collected audit data was a low-cost and a low research-burden option that allowed me to conduct a rapid review of the implementation process and to compare REACH-HF trial outcomes with real-world implementation outcomes. The study is of high clinical relevance, as the initial results suggest that the REACH-HF programme may be a viable cardiac rehabilitation alternative for older patients and patients with mental health comorbidities, both often underrepresented in traditional centre-based programmes (or that healthcare professionals are more open to offering REACH-HF to such patients). However, steps need to be taken to make the programme more accessible to a wide range of patients. The study also provides good insight into conducting implementation research in challenging contexts and during unprecedented (for healthcare services, healthcare professionals and the general population) times.

The main limitations of the study were the substantial variations in implementation of the treatment, high levels of missing data, a limited sample size that may have introduced selection bias (all impacted by the COVID-19 pandemic), and the lack of a comparable patient group (the trial population selected for comparison was substantially different to the implementation sample).

Future research

More research, as is currently being conducted in the SCOT REACH-HF project (which is examining the real-world roll-out of REACH-HF across six health boards in Scotland [272]), is needed to understand the impact of REACH-HF (and other home-based rehabilitation treatments) on different populations and in relation to delivery characteristics (quantity and quality) and outside the context of global pandemic and lockdowns.

As the amount of NACR routinely collected data, from cardiac rehabilitation teams offering the REACH-HF intervention UK-wide, increase, more rigorous analysis of implementation effectiveness can be applied (i.e., patient-level analysis, further consideration of different implementation contexts, and correlation between the intervention (e.g., number of clinical sessions attended) and outcomes). However, steps should be taken to reduce the amount of missing follow-up data, particularly for key outcome measures such as health-related quality of life.

Conclusions

The gathered data suggest that changes in patient-reported outcomes seen in the REACH-HF randomised trial were not replicated in the real-world setting of this study. They also suggest that offering home-based cardiac rehabilitation may facilitate uptake amongst older patients and those with mental health comorbidities. However, the study's results need to be interpreted carefully given substantial differences in the populations treated and the context of the COVID-19 pandemic, which may have affected the intensity of treatment delivery.

Authors' contributions

All authors contributed to the idea for the study. Hasnain Dalal was instrumental in setting up the Beacon Sites. Samantha B van Beurden led the set up and recruitment of the Beacon Sites. Sinéad T J McDonagh was overseeing the day-to-day management of the Beacon Site project. Alexander Harrison coordinated access to the NACR data, conducted ANCOVA analysis and provided statistical analysis advice for the project. Rod S Taylor provided access to the relevant trial data. Paulina Daw secured all relevant ethical approvals for the project, conducted statistical analyses (apart from ANCOVA) and drafted the manuscript. Colin J Greaves, Jet JCS Veldhuijzen van Zanten, Alexander Harrison, Patrick J Doherty, Hasnain Dalal and Rod S Taylor provided project supervision and oversight. All authors provided critical revision of the manuscript for important intellectual content and approved the final draft of the manuscript for submission.

Reflection

There is a lack of research exploring implementation processes and real-world effectiveness of evidence-based interventions. Some of the known barriers impacting the adoption of evidence-based intervention into routine clinical practice include the innovation itself, the skills and attitudes of individuals implementing the innovation, and various organisational- and broader system-level influences [251]. Assessment of the implementation effectiveness relies on understanding the quality of delivery – 'negative results can occur if the program is not implemented sufficiently, or positive impact can be achieved through an innovation that, in practice, was very different from what was intended' [396]. The underperformance of efficacious interventions during the routine service delivery can be linked to a myriad of factors. For example, patients treated in real-world clinical settings might be different to those recruited into the trial, staff implementing the innovation might lack the knowledge and skills required to deliver the intervention as it was intended or a lack of resources might hinder effective implementation [254, 255]. Below is an extended discussion of some of these important issues.

Extended discussion

The main aim of the overall project was to investigate the real-world implementation of the programme. Therefore, practitioners and managers working at the Beacon Sites were given full autonomy about how to introduce and operationalise REACH-HF into their service according to their unique circumstances and needs. This resulted in significant variations in

patient recruitment, the level of implementation and programme effectiveness between the Beacon Sites.

The chosen Beacon Sites had been registered with the NACR from 2013 and three out of the four had been awarded the highest (green) NACR National Certification Programme for Cardiac Rehabilitation status (i.e., meaning they met all seven Key Performance Indicators outlined by the British Association for Cardiovascular Prevention and Rehabilitation and the NACR [258]). Despite being awarded high certification status which indicates that the sites report high-quality audit data to the NACR on a regular basis, this was not the case during the conducted study. The limited data set generated during the study could be due to challenges of delivering the programme during the COVID-19 pandemic or due to the fact that the Beacon Sites were asked to collect the same measures as in the REACH-HF trial (i.e., MLHFQ and ISWT) instead of the usually reported NACR measures (i.e., COOP and 6MWT). On reflection, if the latter was the reason for the missing data, then instead using familiar patient-reported outcome measures and exercise capacity assessment protocols, and established reporting procedures could be ways of improving the completeness of the final data set. Additionally, it should also be acknowledged that funded research projects, which cover the cost of data collection, might reduce the amount of missing data.

Intervention adherence achieved at the Beacon Sites was 72.7%; a higher intervention adherence (90%) was recorded in the trial. The difference could be attributed to the fact that patient adherence to the intervention in the trial was defined as 'attendance at the first face-to-face contact with the facilitator and at least two facilitator contacts thereafter – at least

one of which must have been face-to-face', whereas at the Beacon Sites intervention adherence meant completing the whole programme [146]. The most frequent known reason for dropping out from the programme was being too ill to continue, which is consistent with the fact that the Beacon Sites treated older, more morbid and more frail cohort of patients. Additionally, the self-isolating and shielding guidance, due to the COVID-19 pandemic, most likely played a role in the patient's ability to complete the treatment as well as impacted on the patient's receptivity to the intervention (e.g., the ability to engage with the exercise programme or pursue opportunities to better utilise the support network).

Effect size interpretation

The conducted study used 'a rule of thumb interpretation' to understand the magnitude of effect sizes (i.e., effect size below 0.2 is regarded as small, 0.5 as medium and 0.8 as large) [412]. The Publication Manual of the American Psychological Association recommends reporting standardised mean difference (i.e., effect size) alongside *p* values. Calculating effect size helps to understand the magnitude of difference between groups and it has become commonplace when conducting meta-analysis [413] and when reporting findings from quantitative studies in the field of social and health sciences [414]. The most common way of interpreting effect size is using the original index proposed by Cohen (i.e., small, medium, large), even though it was only recommended 'when no better basis for estimating the index is available' [412].

Indeed, 'a rule of thumb interpretation' is not without limitations [415, 416]. Recently, the widespread and uncritical use of the standardised mean difference when interpreting effect

size has been criticised for being ‘inappropriate and misleading’ [417]. To mitigate the bluntness of the ‘small, medium, large’ interpretation, researchers should consider the type of studies/groups that are compared and the context in which they were conducted as well as comparing the discovered effect size to those of previous studies conducted under similar conditions [418]. The complexities of the generated research findings are particularly evident when considering subjective exercise capacity assessment.

Subjective exercise capacity

When it was not possible to conduct an objective exercise capacity assessment (in the form of ISWT or 6MWT), for example, when the client was too frail to attend a centre-based exercise capacity assessment or when the programme was delivered entirely remotely during the COVID-19 pandemic, healthcare professionals could instead estimate exercise capacity by conducting a thorough interview with a patient. By eliciting from a patient his/her current level of activity, clinicians can approximate the corresponding Metabolic Equivalent of Task (MET) value (by using, for example, the Compendium of Physical Activities [419]) and translate it into a distance covered using the 6MWT Distance Conversion Table [420]. This method is not without limitations, especially as self-reported levels of physical activity are often exaggerated when compared with externally-measured physical activity levels [421-423]. In older adults this limitation was linked to inaccurate memory [424]. Additionally, in patients with heart failure, the perception of physical ability may be influenced by their emotional state and may not represent their actual physical activity levels (e.g., patients with lower emotional wellbeing may underreport their physical activity levels and vice versa in the case of patients with higher emotional wellbeing) [425]. This is particularly important, as

patients with heart failure are often depressed and experience diminished mental wellbeing, hence, the self-reported assessment of physical activity may be particularly unreliable in this clinical population. Furthermore, the subjective perception of the level of intensity during exercise can be also impacted by medication commonly prescribed to patients with heart failure, especially beta-blockers which reduce person's heart rate and blood pressure; these physiological changes can impact the person's ability to anchor and monitor their perceived exertion during exercise [426, 427].

Pre-treatment and post-treatment MET values were remotely estimated for 38 patients at Site 1 only. These were calculated for patients who were unable to attend their face-to-face pre-post treatment assessments or were unable to undergo ISWT. Although a pattern of decline in all objective outcome measures was observed at this site, that was not the case for the subjective outcome measures in the form of MET values. Interestingly, the pre-post standardised mean difference of the recorded MET values returned a very high effect size of 1.32 (95%CI 0.82 to 1.82).

This can be suggestive of several possibilities. The perceived exercise capacity of patients who received the REACH-HF programme at Site 1 increased greatly (despite them being the oldest and, most likely, the frailest patient cohort out of all of the Beacon Sites) or that the healthcare professionals working at Site 1 felt very positive about the programme and rated the exit MET values in accordance with how much they believed in the potency of REACH-HF. The latter is consistent with the findings described in the previous chapter (Chapter 4), which reported a particularly strong endorsement for the REACH-HF programme amongst staff

working at Site 1. The third option is 'social desirability' responding (i.e., the patient liked the healthcare professional who was treating them and so told them what they thought they wanted to hear).

The complexities of the implementation processes

The conducted quantitative study highlighted the many complexities of the implementation process. For example, patients treated in the highest recruiting site (Site 1) showed a consistent deterioration in all objective outcome measures, however, the opposite was true for the subjective exercise capacity outcome measure. There were large variations in the number of sessions conducted and the treatment duration at the participating sites. This could have been linked with the differences between the four cohorts of patients treated at the Beacon Sites or with varying levels of endorsement for the intervention from the healthcare professionals delivering it. The site which achieved the highest completion rate (Site 3) offered slightly fewer sessions compared to the trial (6 vs 6.5) and had the shortest treatment duration compared to the remaining sites (on average 54 days shorter). This reduction in the number of sessions offered might have been linked with transport issues affecting the delivery of REACH-HF at this particular location. Also, during the qualitative interviews, healthcare staff working at Site 3 highlighted developing efficient delivery systems, and so this could have led to the reduced treatment duration at this particular site.

Patients treated at Site 1 received on average 3.5 sessions more than patients at the remaining sites and 2.7 sessions more compared to the randomised controlled trial. This could have been linked with the socio-demographic and clinical profile of patients recruited

to receive REACH-HF at Site 1 (i.e., older, frailer, more advanced heart failure). This might mean that some of those patients needed the additional support, for example, at the beginning of the treatment (e.g., when setting up the technological components of REACH-HF) and during the treatment (e.g., ensuring correct exercise prescription). The extended treatment duration could have also been linked with healthcare professionals having a high opinion of the programme and enjoying delivering it. Indeed, positive attitudes from clinicians towards the intervention were corroborated during the qualitative interviews conducted at this site. However, it is not possible to definitely confirm whether the patients received more sessions because they needed them or because the healthcare professionals at the site enjoyed delivering them.

There were also substantial differences between the Beacon Sites in terms of the achieved intervention reach. Patients treated at Site 1 were particularly different to those recruited into the trial and the general heart failure population. This is consistent with the qualitative findings (i.e., Site 1 targeted patients who were not able to attend their centre-based provision). This selective recruitment strategy affected the comparability of the study's sample with the REACH-HF trial population, however, it also fulfilled a niche in the service provision for patients who would not otherwise have had any cardiac rehabilitation. The very prescribed use of the programme at Site 1 can be interpreted as a negative – as large swathes of patients were excluded from REACH-HF on the basis of them being able to access centre-based sessions or a positive – by fulfilling a shortfall in the service delivery, the team may be more likely to adopt the innovation long-term.

Findings from each part of the project (i.e., systematic review, qualitative study, quantitative study) will be considered together in the next chapter – Overall discussion.

CHAPTER 6 – OVERALL DISCUSSION

The thesis includes a linked mixed methods series of projects examining challenges in, and opportunities for, delivery of cardiac rehabilitation for heart failure. The starting point was a systematic review (Chapter 3) which highlighted an ongoing gap in the scientific literature pertaining to non-patient factors linked with underutilisation of cardiac rehabilitation for heart failure – an important finding of the systematic review. Interestingly, all of the identified articles were published in the space of just over a decade between 2010 and 2020. This might be indicative of an increasing interest in understanding different causes (above and beyond patient-level factors, for which an extensive evidence-base already exists) of low uptake of cardiac rehabilitation in patients with heart failure and ways of improving this inequality. The identified studies represented mainly European and Western healthcare systems. This was not unexpected, as secondary prevention in the form of cardiac rehabilitation is available in only 40% of low- and middle-income countries [428]. Despite a confirmed cost-effectiveness of cardiac rehabilitation for heart failure in low- and middle-income countries, the uptake is low [429]. Some of the barriers to implementation uncovered in the current review were consistent with findings from a different systematic review which concentrated on barriers to cardiac rehabilitation in low- and middle-income countries [430]. The overlapping factors included a lack of cardiac rehabilitation education in the cardiology curriculum, and a lack of referrals and resources.

The current systematic review's main achievement was uncovering a vast array of factors with the potential to influence the delivery of cardiac rehabilitation in a positive or a negative

way. These were then translated into practical solutions for improving service provision for a heart failure population (Table 7 in Chapter 3). Some of the proposed solutions have the potential to be successful across low-, middle- and high-income countries, for example, introducing automated referral systems, improving insurance cover, offering home-based programmes or using novel telemedicine technologies [430]. However, due to small healthcare budgets, particularly in low-income countries, developing affordable models for the delivery of cardiac rehabilitation for patients with heart failure is a priority [429].

During the next phase of the project, implementation barriers and facilitators were identified with two cohorts of healthcare professionals (i.e., staff working at the Rehabilitation EnAblement in CHronic Heart Failure (REACH-HF) Beacon Sites and healthcare professionals who attended the remote COVID-19-response REACH-HF training). There was some overlap between factors identified in the systematic review and the qualitative study. For example, consistent barriers across the two studies were a lack of: resources (time and staff), commissioning, and referral pathways as well as poor integration between departments (e.g., due to poor communication, inefficient flow of funds, duplication of effort and gaps in the service pathways) and insufficient implementation strategies. Facilitators to implementation identified in both the systematic review and the qualitative study were developing effective communication and integration between departments and teams (e.g., by establishing commissioning structures and efficient referral systems), and generating sufficient resources for service delivery.

The qualitative study, additionally, highlighted several influences which were specific to implementing the REACH-HF programme and to the particular implementation contexts studied. For example, the REACH-HF training was not adequately pitched to the skills and experiences of many of the healthcare professionals who participated in it (specifically, that the training placed too much focus on person-centred assessment and agreeing on treatment goals and not enough on exercise prescription and the practicalities of setting up and delivering the programme by a service) or that cardiac rehabilitation teams operating over large catchment areas struggled to implement the programme in a purely home-based format.

In contrast, the systematic review uncovered barriers which were related to broader non-United Kingdom (UK) implementation contexts, for example, medical insurance eligibility criteria and insufficient medical insurance cover. Overall, the results from the systematic review and qualitative study produced insights with a different focus; one more macro (i.e., the systematic review) and one more micro (i.e., the qualitative study). Both of those studies have high clinical and service provision relevance. The systematic review suggests ways of improving the provision of a range of cardiac rehabilitation services in a wide (mainly Western) range of healthcare settings. Whereas the qualitative study can guide the specific implementation of the home-based REACH-HF programme in the context of UK healthcare. Combining the macro and micro solutions generated in the two studies could lead to improving the provision of cardiac rehabilitation for patients with heart failure nationally and internationally.

The UK-context-specific trends and the REACH-HF programme-specific trends uncovered during the qualitative study were used to inform and refine the study's main output – the REACH-HF Service Delivery Guide. This implementation manual is available from the REACH-HF website (https://blogs.exeter.ac.uk/reach-hf/reach-hf-service-delivery-guide/) and the National Institute for Health and Care Excellence Shared Learning Database website (https://www.nice.org.uk/sharedlearning/covid-19-ready-rehabilitation-for-heart-failure-reach-hf-can-deliver).

The qualitative study also highlighted some unexpected benefits of introducing REACH-HF into a service from a general service provision point of view. These included developing an awareness of service provision deficit affecting the heart failure population or increased interest in introducing more robust ways of monitoring patient's progress whilst receiving cardiac rehabilitation, for example, by conducting baseline and end of treatment exercise capacity assessments. The awareness of an unfulfilled service need is an important driver for change and can sustain ongoing delivery of the programme.

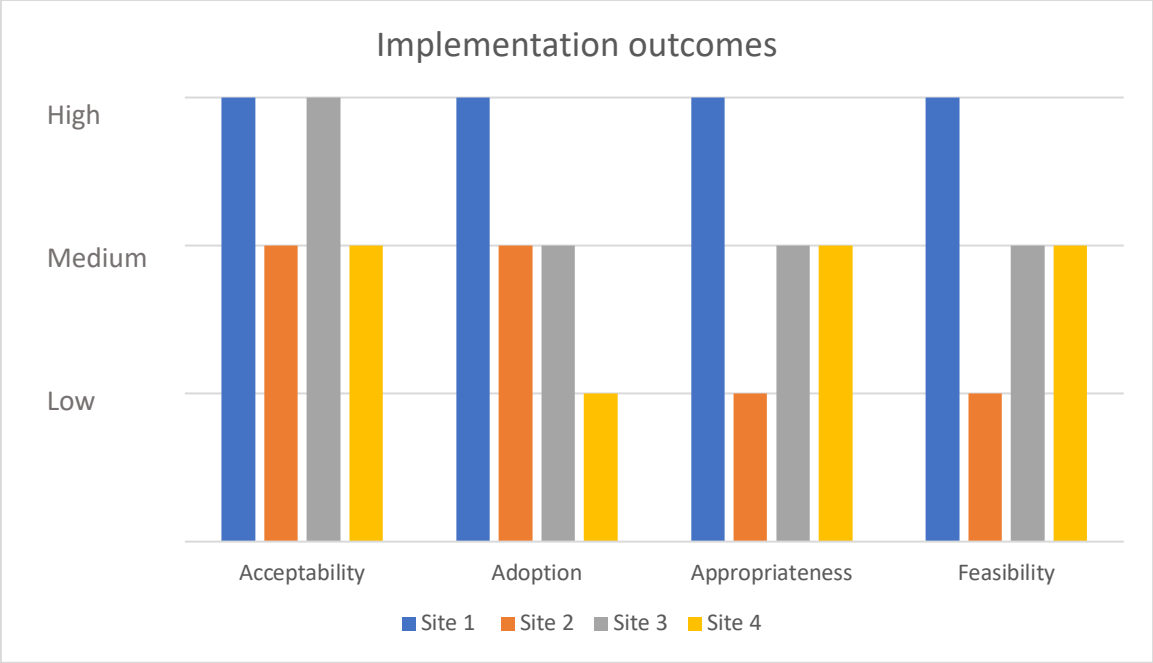
The next part of the project, the quantitative study using routinely collected audit data from the National Audit of Cardiac Rehabilitation (NACR) database, produced an insight into implementation patterns, characteristics of the patient population treated and the real-world effectiveness achieved at the Beacon Sites. There were substantial differences in the way the different Beacon Sites operationalised and delivered the REACH-HF programme (e.g., in terms of numbers of sessions offered, time in treatment or mode of delivery: purely home-based vs hybrid of home- and centre-based). There was considerable demographic and clinical

heterogeneity between the cohorts of patients considered in the study (i.e., patients recruited into the REACH-HF clinical trial, patients treated at the Beacon Sites and the general heart failure population from the NACR database). The comparison of the pre-post treatment change in the Minnesota Living with Heart Failure Questionnaire between the REACH-HF trial and the Beacon Sites favoured the trial. However, a more nuanced picture emerged when considering secondary outcome measures. For example, the pre-treatment and post-treatment effect size for the Hospital Anxiety and Depression Scale anxiety recorded at the Beacon Sites exceeded the effect size calculated from the trial data for the same measure.

Implementation outcomes

Although assessing implementation outcomes was not the aim of the study, an exploratory consideration (using Proctor et al.'s high, medium, low classification system described in Chapter 4) was applied to the outcomes of acceptability, adoption, appropriateness and feasibility [360]. This highlighted some differences in the achieved implementation outcomes between the Beacon Sites. High levels of all four implementation outcomes were only achieved at Site 1. Site 3 was the next highest achieving site followed by Site 4 and Site 2 (Figure 11).

Figure 11 Implementation outcomes at the Beacon Sites



The medium-to-high levels of implementation outcome implied here, together with the positive aspects of the qualitative findings described in Chapter 4 (e.g., awareness of the service delivery gap affecting patients with heart failure, good understanding of the intervention or generally high regard for the programme across the participating sites) are somewhat at odds with the lower-than-expected improvements in patient outcomes recorded at the Beacon Sites (described in Chapter 5). With regards to sub-optimal outcomes, Proctor et al. suggest that it is important to distinguish 'if the failure occurred because the intervention was ineffective in the new setting (intervention failure), or if a good intervention was deployed incorrectly (implementation failure)' [360]. Unfortunately, due to not being able to conduct a systematic fidelity assessment, at the moment, it is not possible to distinguish what was the case during the Beacon Site project (i.e., intervention failure vs implementation failure).

Quantitative data suggest that there were some deviations from the intervention delivery protocol, for example, in terms of the total number of sessions offered. However, the most important difference between how the programme was delivered in the REACH-HF trial and at the Beacon Sites was undoubtedly caused by the COVID-19 pandemic, which prevented regular home visits with patients enrolled onto the programme. Nevertheless, two questions remain. The first is whether the REACH-HF practitioners would have delivered the programme as fully home-based had the pandemic not got in the way. The second question is whether a fully home-based mode of delivery would have resulted in better pre-treatment to post-treatment change in patient outcome measures.

An alternative explanation (as opposed to intervention failure vs implementation failure) for the lower-than-expected improvements in patient outcomes is that the intervention did not fail at all. As the study population was very different to the trial population, it is impossible to know what would have happened to the more aged/frailer population treated if they had not received any intervention. A non-improvement (i.e., stable health-related quality of life scores) could be a good outcome for this population who are expected to otherwise decline considerably over time. This hypothesis is consistent with the evidence on population trends in quality of life for people with an average age of 75+ with multiple chronic illnesses, which suggests that this population steadily deteriorates over time [431].

Additionally, considering the implementation outcomes at Site 2, a limitation of only concentrating on the speed of dissemination when appraising the implementation process (as

introduced by Rogers in his original classification) was identified. Site 2 was the second highest recruiting site, yet the National Health Service (NHS) staff's perception of the fit between the programme and the service (i.e., appropriateness) and the ability to offer the programme on an ongoing basis (i.e., feasibility) was particularly low. The relatively high recruitment rate at this site might have been linked with healthcare staff and management feeling compelled to deliver REACH-HF to the predefined number of patients as part of the Beacon Site project, rather than to test out the implementation of the intervention which could become a viable service delivery option – this is of course speculation.

Classifying implementers

When considered together, results from the qualitative and quantitative studies could be interpreted in several ways. For example, it could be concluded that Site 1, in Rogers' terms (i.e., innovators, early adopters, early majority, late majority and laggards [157]), was an innovator (i.e., the fastest recruiting site, showing strong endorsement for the intervention and consisting of a highly innovative team) *as well as* a failing site (i.e., deterioration in all objective outcome measures and limited reach – the programme was only offered to a selected group of patients).

Building on Rogers' five broad types of implementers, modern implementation scientists proposed alternative ways of classifying implementers' behaviours and attitudes. These go beyond the speed of uptake and take into account different factors, for example, the fidelity of delivery and adaptions to the innovation. One such classification was designed by Swindle et al. [432]. It divides implementers into four categories.

- Enthusiastic adopters – healthcare professionals implementing the intervention exhibit positive attitudes towards the innovation, they achieve high fidelity of delivery and use the innovation as intended with no or little (appropriate) adaptations.
- Over-adapting adopters – positive attitudes towards the innovation, low fidelity or fidelity-inconsistent adaptations.
- Passive non-adopters/soft resisters – passive attitude towards the innovation, low fidelity, few or no adaptations.
- Active non-adopters/hard resisters – negative attitudes towards the innovation, low fidelity, no adaptations.

By considering the results from both qualitative and quantitative studies, the above classification could be applied to the Beacon Sites in the following way. Site 1 – an enthusiastic adopter – a very passionate team, keen to deliver the intervention 'as per the book'. Site 3 – an over-adapting adopter – the team at this site was positive about the intervention, but very early on during the implementation process a hybrid delivery was introduced. Site 4 – a passive non-adopter/soft resister – this team struggled to get the innovation 'off the ground', they agreed with the usefulness of REACH-HF in principle, but made only moderate attempts to implement it. Site 2 – an active non-adopter/hard resister – despite a good recruitment rate, there was a strong notion amongst this team that they could not offer a home-based cardiac rehabilitation programme on an ongoing basis.

In the case of the Beacon Sites, it is difficult to decide which site achieved the most successful implementation. Would it be the site which, for example, recruited the most patients,

achieved the highest improvement in terms of patient-reported outcomes, achieved the best completion rate, delivered the programme as close to the developers protocol as was possible, made sustainable adaptations to the programme delivery, had the most enthusiasm for the innovation or was the most committed to deliver the programme in the long term? An overall conclusion could be that none of the sites achieved successful implementation of REACH-HF, although some sites did well in some aspects. This illustrates the importance of defining successful implementation (as highlighted in Chapter 4).

Time for a paradigm shift?

The findings from the quantitative study indicated stark differences in the samples treated between the trial and the Beacon Site study. This highlighted the importance for clinical effectiveness trials of recruiting patient samples that are well-matched with the real-world patient population that the intervention is intended for. In recent years, the efficacy research community have been accused of not anticipating and considering issues that relate to dissemination and implementation processes [168]. There is a need for a greater collaboration between efficacy and implementation research communities.

Progressively, concepts from the realm of implementation science are beginning to infiltrate the traditional research projects (e.g., efficacy/feasibility studies). Implementation science researchers call for the implementation strategies and potential barriers to implementation to be considered during the intervention development and design and at various points throughout the intervention research cycle. Incorporating concepts from the implementation research as early as possible during the intervention development and evaluation process,

coupled with anticipation of dissemination and implementation setbacks, is a way of increasing the intervention chances at becoming fully adopted and part of a routine clinical practice. It is believed that the process of marrying implementation science methods and techniques with traditional healthcare research will lead to improved quality of healthcare.

Research design considerations/what went well

Mobilising different research methods (i.e., systematic review and mixed methods), led to an increased understanding of the complex phenomenon of service implementation through the prism of different perspectives (i.e., implementation theory, researchers, service providers and healthcare professionals) and in different contexts [276]. The qualitative study, within the mixed methods design, helped to (as described by Bryman) 'illustrate quantitative findings, often referred to as putting 'meat on the bones' of 'dry' quantitative findings' [433].

The use of different research methods increased the integrity and credibility of the research findings. To improve the usefulness of the study's findings, an implementation manual – the REACH-HF Service Delivery Guide (Appendix 1) was created early in the process. This resource underwent one iteration following a period of disrupted service delivery due to the COVID-19 pandemic, when many services had to adapt to remote delivery.

Effectiveness-implementation hybrid research designs combine clinical effectiveness studies and implementation research studies (each a distinctive step in the traditional research pipeline) [181]. By applying the dual focus they can lead to a narrowing of the research-to-practice gap [171, 183]. The described quantitative/quantitative parts of the project are a

worked example for conducting an effectiveness-implementation hybrid research study concerning the REACH-HF programme (the Standards for Reporting Implementation Studies checklist in Appendix 12 brings together the different elements of the two studies); the study protocol can be easily adapted to different contexts, and to various cohorts of healthcare professionals and interventions.

How the project could have been improved

The use of quantitative data from the NACR database was a convenient and inexpensive way of conducting a rapid evaluation comparing pre-treatment and post-treatment patient outcome measures. However, the downside of using routinely collected audit data was poor data quality. Due to limited sample size, I was only able to conduct minimal subgroup analyses with low power to explore variations in outcomes by characteristics of interest.

Identifying and testing implementation strategies is a primary aim of implementation scientists worldwide [181, 183, 434]. As the conducted study aimed to understand the *real-world* implementation, no predefined implementation strategies were employed during the project, apart from replicating the randomised controlled trial set up process at the Beacon Sites. More specifically, the NHS staff who delivered REACH-HF at the participating sites received the same training as the facilitators who delivered REACH-HF in the clinical trial (a three-day face-to-face training course facilitated by the Heart Manual Department, NHS Lothian in Edinburgh).

Treatment fidelity assessment is an important part of evaluating the implementation process and would have been a useful addition to the series of studies presented here. Deciding upon the quality of treatment delivery is the only way to distinguish between intervention and implementation failure. Although I had intended to conduct such an assessment [371], this was not possible due to the combination of a) reluctance from the healthcare professionals to audio record clinical sessions and b) remote delivery due to the COVID-19 pandemic made it even more difficult to audio record clinical appointments.

Future research directions

During the conduct of the thesis, several gaps in the evidence-base were identified. To address these and to build on the findings presented here, I suggest the following opportunities for future research.

- As the conducted quantitative study was not able to achieve the objective of a comparison of outcomes with the REACH-HF randomised controlled trial, further research is needed to understand the true benefits of REACH-HF in real-world settings as well how this relates to the way the programme is implemented, for example, in terms of variations in delivery format and the quality of delivery. Hence, further effectiveness-implementation hybrid studies are urgently needed to understand the real-world effectiveness of the REACH-HF programme alongside the process of its implementation.
- In order to distinguish between intervention failure and implementation failure (or other explanations for the pattern of outcomes observed), a robust assessment of

intervention fidelity needs to be conducted. Future studies can adopt the fidelity assessment procedure described in the study protocol (Chapter 2) and compare the achieved levels of fidelity with those achieved in the REACH-HF trial [263]. Fidelity scores could also be associated with changes in patient outcome measures.

- A scoping or systematic review of grey literature to further identify and understand non-patient barriers and facilitators to cardiac rehabilitation for heart failure. These can then be compared and contrasted with the influences uncovered during the systematic review and qualitative study presented here.
- High-quality survey studies investigating the prevalence of the enabling and disabling factors identified by the systematic review in different healthcare systems and in relation to different healthcare professionals.
- Innovative designs are needed to understand some of the divergent themes uncovered during the systematic review, for example, the mixed impact of large body of guidelines on improving heart failure care or whether healthcare professionals continue to exclude patients with heart failure from cardiac rehabilitation due to historical safety concerns. Mixed methods designs might be the best suited to further increase the depth of the current understanding as well as the pervasiveness of contradicting themes.
- Future research studies should also test out the effectiveness of the suggested solutions in the systematic review and qualitative study for improving the provision of cardiac rehabilitation in a heart failure population, for example, by employing interrupted time series evaluations or cluster randomised trials.

- Funded research projects which cover the cost of data collection might reduce the amount of missing data. Over time, as more services offer the REACH-HF programme, future studies will be able to benefit from a much larger NACR data set to explore the REACH-HF implementation patterns, the pre-treatment and post-treatment patient outcomes, and the sustainability of delivery of the REACH-HF programme at the Beacon Sites and beyond.

Conclusions

Through the use of different research methods and engagement with stakeholders, the doctoral project captured the challenges of, and opportunities for, delivering cardiac rehabilitation for patients with heart failure. Each part of the project revealed a more nuanced picture of the phenomenon. The systematic review highlighted non-patient factors affecting the general provision of cardiac rehabilitation in heart failure and, most notably, the negative impact of the poor 'organisation of healthcare system'. The mixed methods study exposed the complexities of the implementation of a home-based programme in different contexts (e.g., in a service which lacked sufficient commissioning structure or in a team affected by low morale) and challenging circumstances (i.e., during the COVID-19 pandemic). Each phase revealed opportunities for improving the cardiac rehabilitation service provision, for example, through better tailoring of clinical guidelines or inclusive commissioning structures.

The Beacon Site project also led to some unexpected benefits, for example, staff from one site are now involved in the REACH-HF training for new interested teams. There is also an optimism within the field for novel ways of delivering cardiac rehabilitation following the COVID-19 pandemic. The project put forward many potential solutions to overcome the low uptake of cardiac rehabilitation in heart failure and whilst no 'silver bullet' was found, the results are of high clinical and service provision relevance, and when considered together they are more than the sum of their parts.

Although I was unable to engage in some planned research activities (e.g., fidelity assessment) and the results from the quantitative study are inconclusive, the studies generated four academic publications describing different parts of the REACH-HF project and the REACH-HF Service Delivery Guide (which is now in the public domain). These are important outputs towards the overarching goal that I set myself at the beginning of my PhD, which was to contribute towards improving the provision of cardiac rehabilitation for patients with heart failure.

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Appendix 1

REACH-HF Service Delivery Guide

DELIVERY GUIDE

WHO IS THE GUIDE FOR?

NHS staff managing or providing cardiac rehabilitation services who wish to deliver the REACH-HF home-based cardiac rehabilitation programme for people with heart failure.

Contents

1. About this guide

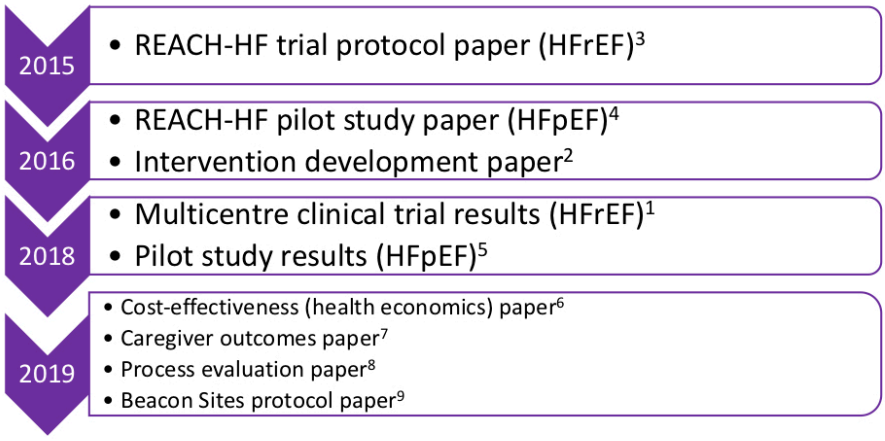
This service delivery guide is intended for teams that want to set up the Rehabilitation Enablement in Chronic Heart Failure (REACH-HF) home-based cardiac rehabilitation programme for people with heart failure within their existing service. This guide has been designed following interviews with healthcare professionals working in four National Health Service (NHS) cardiac rehabilitation centres in England and Northern Ireland in 2019. These 'Beacon Sites' were early adopters of the REACH-HF programme, piloting its roll-out in the NHS.

The guide builds on knowledge from the REACH-HF Facilitator Training Pack (part of the REACH-HF training course) but emphasises the practicalities of implementing the REACH-HF programme. Chapter one briefly describes the programme and outlines the advantages of home-based cardiac rehabilitation for people with heart failure. Chapter two outlines the necessary steps for adding REACH-HF into your service and for monitoring progress.

1.1. What is REACH-HF?

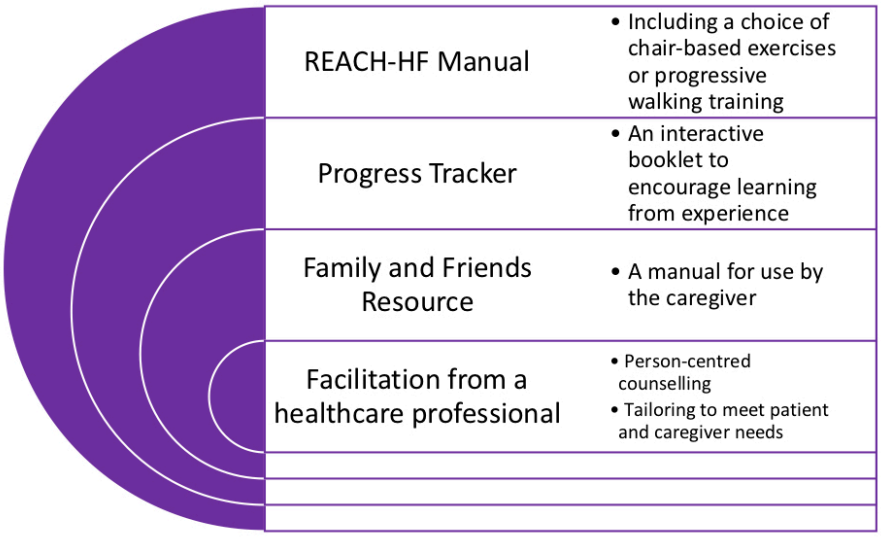
REACH-HF is a new home-based, evidence-informed cardiac rehabilitation programme for people with heart failure and their caregivers (family or friends), to help them manage their condition. The REACH-HF trial showed that the programme significantly improved the quality of life of patients with heart failure 12 months after the start of the programme[1]. The effects on quality of life (5.7 points on the Minnesota Living with Heart Failure Questionnaire) were similar to those found with centre-based programmes and over 90% of patients completed the programme.

The REACH-HF patient and caregiver materials are designed to be used with the support of a trained REACH-HF facilitator (typically, but not limited to, a specialist cardiac nurse or physiotherapist with prior experience in delivering cardiac rehabilitation). The programme, in its current format, was established in 2015[2]. Below is a brief publication history listing key scientific papers, outlining the evidence base underpinning the REACH-HF programme. You can access these papers in full on the REACH-HF website: http://sites.exeter.ac.uk/reach-hf/reach-hf-publications/



The programme has been designed to be delivered over 12 weeks, with a recommended three face-to-face contacts with a REACH-HF facilitator taking place in the REACH-HF participant's home, and follow-up telephone contacts in between. 'Real world' programme implementation, especially during the COVID-19 pandemic, has called for alternative modes of delivery. These have included: combined centre- and home-based delivery (e.g. baseline and end-of-treatment assessments conducted in clinics, with home visits and/or phone support in between) and an entirely remote delivery model, where all sessions (including assessments) were conducted by telephone.

The REACH-HF programme has four core elements:



1.2. Benefits and costs of home-based cardiac rehabilitation

Treatment of heart failure costs the NHS around £2 billion per year, with most of the cost associated with hospital admissions. Cardiac rehabilitation saves and improves lives, and reduces hospital re-admissions. Unfortunately, only 52% of cardiac patients take up the offer of cardiac rehabilitation. Uptake is even lower in patients with heart failure, with less than 20% being referred for cardiac rehabilitation, and even less (<10% overall) taking up the offer. The NHS Long Term Plan aims to increase the proportion of eligible patients with cardiovascular disease accessing cardiac rehabilitation to 85% by 2028, with a 33% target for people with heart failure.

The National Institute for Health and Care Excellence (NICE) has recommended that offering alternative modes of delivery of cardiac rehabilitation (for example home-based programmes) might reduce barriers to treatment for people that would otherwise not attend traditional centre-based provision. Offering home-based rehabilitation programmes, like REACH-HF, may therefore help to meet the ambitious aims of the NHS Long Term Plan. The ongoing need for a comprehensive, effective, and cost-effective home-based cardiac rehabilitation programmes became particularly apparent during the COVID-19 pandemic.

The health economics analysis of REACH-HF compared home and centre-based options and found the costs of home and centre-based delivery to be similar. The cost of the REACH-HF programme (estimated at £418 per patient including travel time, management and all NHS overhead costs) falls within the NHS England tariff of £477 per patient for cardiac rehabilitation. Our cost-effectiveness modelling suggested that the REACH-HF programme is a cost-effective addition to healthcare provision for people with heart failure (costing, on average, £1720 per quality-adjusted life year (QALY) gained). This is well below the typical threshold applied by NICE for approving the commissioning of clinical treatments in England (£20-30,000 per QALY).

1.3. What does REACH-HF look like in practice?

In the two out of four Beacon Sites which were already delivering a centre-based programme for people with heart failure, the REACH-HF programme was offered as an additional option, which enabled the choice of participation in either the centre-based rehabilitation programme or REACH-HF. This approach has several advantages. Some patients prefer to attend centre-based programmes. For example, they might not feel motivated enough to exercise by themselves at home, have safety concerns, or just enjoy getting out of the house every week and meeting other people with heart failure in a supportive environment. Others may struggle to attend the hospital or rehabilitation centre due to poor mobility, lack of transport or a busy lifestyle. Some feel uncomfortable in group situations and may prefer more individually-tailored advice. Since there are many reasons why patients may prefer centre-based or home-based rehabilitation programmes, offering a choice of models may improve adherence.

In some existing Beacon Sites, REACH-HF facilitators travelled to participants' homes for face-to-face contact sessions, while others delivered most face-to-face contacts (including initial assessments) at a rehabilitation centre. Services that continued delivering cardiac rehabilitation during the COVID-19 lockdown relied solely on remote delivery. Those services offered extended phone/video assessments, during which REACH-HF facilitators used the titration method (see training pack) for establishing patients' starting point for the exercise programme, followed by regular (weekly then fortnightly) review phone calls.

In some teams, home visits were delivered by a single facilitator, and in others by a pair. Our experience is that a single, trained and experienced facilitator can normally deliver the programme, although, for training purposes, it may help for more junior staff to be accompanied until competence is established.

During the early stages of delivery, REACH-HF facilitators may need to support the participant in using technology to access the chair-based and relaxation exercises (setting up the DVD player, using the DVD and/or relaxation CD, or setting up access to the online exercise videos). In the case of remote delivery, this process involves talking the participant through the set-up process over the phone.

To streamline the set-up process, and get participants exercising as soon as possible, some Beacon Sites decided to post out the REACH-HF resources to patients with their clinic invite letters. The usual clinic invite letter also asked patients to familiarise themselves with the REACH-HF manual and to try out the DVD or access the REACH-HF chair-based exercises via the web link. This initial investment (the cost of posting the manual) can save facilitator and patient time, as it helps the patient decide if the REACH-HF programme is right for them, as well as allowing them to start exercising straight after their assessment appointment. Patients that do not want to proceed with REACH-HF return the manual at their assessment appointment. In the case of remote implementation, facilitators from the existing Beacon Sites posted the REACH-HF manuals or delivered them to patients' homes in person (observing social distancing measures).

1.3.1. The REACH-HF Pathway

The REACH-HF participants enrolled in the programme typically receive five to six hours of clinical input delivered over 12 weeks. This includes a mixture of face-to-face and telephone contacts with at least one, but usually two or three home visits. Early Beacon Sites that did not have the capacity to offer regular home visits to all participants prioritised visits for participants who were frailer or had complex comorbidities (based on clinical judgement of support needs). The REACH-HF participants receiving exclusively remote delivery benefitted from the same amount of clinical input offered via an in-depth phone/video assessment, and weekly (at the beginning of the programme) or fortnightly (later in the programme) follow-up phone calls.

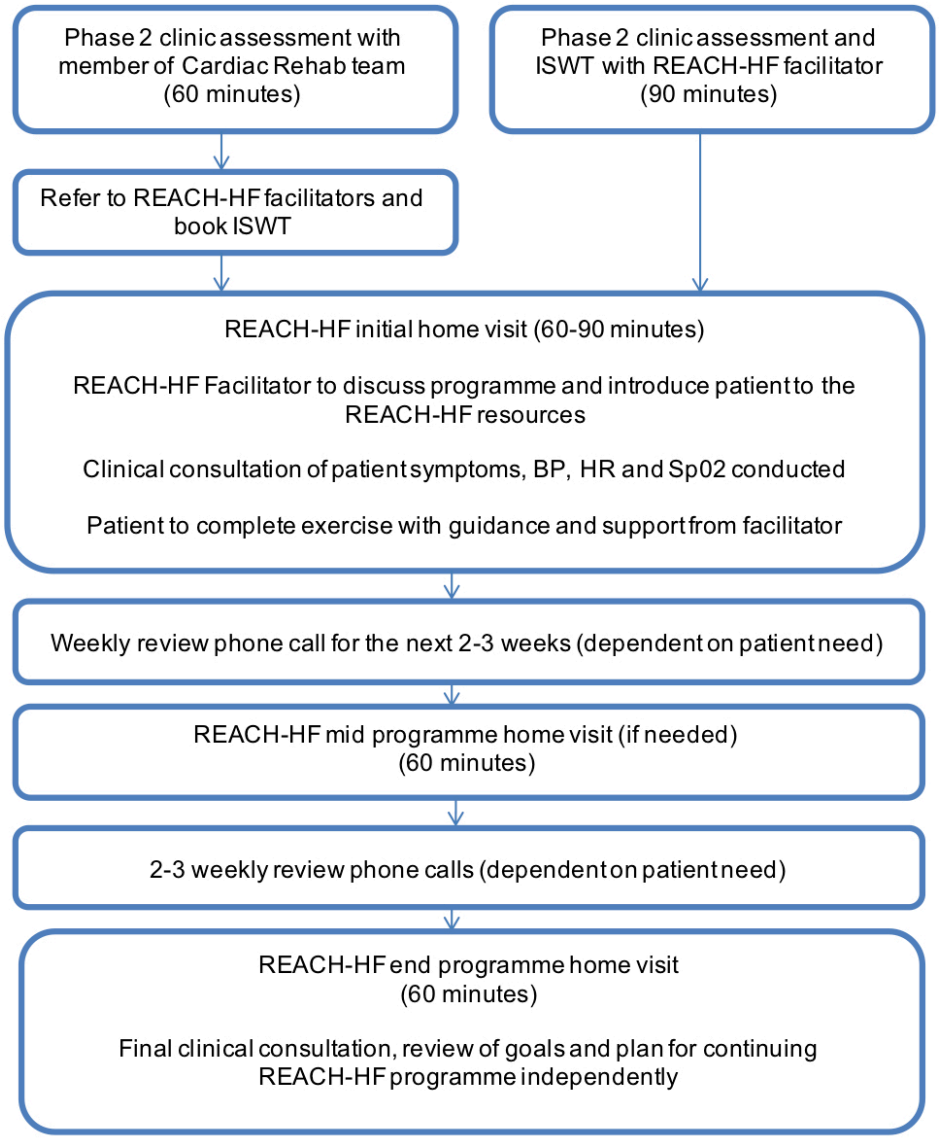
Feedback from the initial Beacon Sites highlighted that participants who were elderly, frail, or had comorbidities might require more face-to-face appointments to ensure adequate exercise monitoring and support. Some of these participants also struggled to attend centres for baseline and end-of-treatment assessments. Where an exclusively remote implementation model is used, such participants might require additional follow-up phone calls.

Below you will find a worked example of a standard REACH-HF pathway. Additional pathways adapted for remote delivery and combined delivery (social distancing and PPE) can be found in Appendix 1 and 2 respectively.

Wirral Community Health and Care NHS Foundation Trust

Wirral Cardiovascular Rehabilitation

REACH-HF programme pathway



1.3.2. Equipment required

Below you will find a list of the equipment needed to deliver REACH-HF:

- ✓ Access to phone (or video appointment technology if applicable) and quiet/private consultation space.
- ✓ Several DVD players that can be hired out to participants who do not have a DVD player available and cannot access chair-based exercises on the REACH-HF web link.
- ✓ Equipment to conduct Incremental Shuttle Walk Test (if applicable): instructions and audio recording to conduct the test, scoresheets, audio device (CD/MP3 player/mobile phone/tablet/laptop), two cones, one measuring tape, 10m string and a stopwatch.
  Instructions and audio recording for the test can be purchased and downloaded onto a portable device (e.g. mobile phone/tablet/laptop) from University Hospitals of Leicester, see link below:
  https://www.leicestershospitals.nhs.uk/aboutus/departments-services/pulmonary-rehabilitation/for-health-professionals/incremental-shuttle-walk/
  Please note that exercise capacity can also be assessed using the 6 Minute Walk Test or the titration method (during remote delivery, or in cases where exercise capacity tests are not available).
- ✓ Services that routinely collect such measures might need to source: portable heart rate, pulse oximeter, validated blood pressure and blood sugar monitors (please note that none of these are compulsory for the successful delivery of the REACH-HF programme).

1.3.3. Does REACH-HF offer the right fit for your patient?

An important finding from the early Beacon Sites was the need for a good fit between patient and programme. The flowchart in Appendix 3 gives the criteria for accepting patients onto the programme and lists questions that can be used to find the best fit between the patient's preferences and the different cardiac rehabilitation options that might be available within your service.

2. Setting up REACH-HF

Introducing a new programme into any service is an opportunity to practice a whole-team approach to communication and decision-making. Teams that include and involve all relevant healthcare professionals, managers, and support staff in the roll-out of a new intervention avoid many teething problems and cope better with any problems that arise. So keep talking – start with discussing the big picture, such as reasons why there is a need to introduce home-based cardiac rehabilitation into the service. But also consider the details, such as who will be posting out the clinic appointment letters. Why not book a regular REACH-HF implementation team meeting? Successfully introducing REACH-HF into your service is a team effort!

2.1. Preparation phase

Careful preparation for the roll-out of REACH-HF is time well spent. This allows the organisation and the team to reflect on how they want to engage with the programme, and how things will have to change as a result of introducing REACH-HF.

The infographic below breaks down the set-up process into seven tasks.

REACH-HF SERVICE DELIVERY GUIDE

Home-based cardiac rehabilitation for patients with heart failure

PROGRAMME RESOURCES

- Heart Failure Manual
- My Progress Tracker
- Family & Friends Resource
- Chair-based exercises DVD
- Relaxation CD

IMPLEMENTING THE PROGRAMME

Below you will find the necessary steps for adding REACH-HF into your service and for monitoring progress. It is, of course, possible to work on more than one step at a time!

1) MAKE THE CASE

Introducing any new innovation starts with a need. A well-defined vision for the future service that includes the opinions of the wider team is a must. This 'mission statement' will become a driving force behind the innovation and help to keep everyone on the same page.

2) GET THE TEAM ON BOARD

Innovation is a team effort. Getting people on-board from the outset will create less resistance and tension during the roll-out. Having an appointed REACH-HF champion will help drive it forward.

Contact the REACH-HF team:
reach-hf@exeter.ac.uk

3) CONSIDER THE BEST TIMING

Timing is crucial in ensuring successful roll-out. Choosing the time to start wisely will reduce the burden of an additional workload on the individuals delivering the programme and the wider team.

4) GATHER RESOURCES

Introducing any new intervention requires resources - staff, time and money. When a new programme is introduced, the team will have to adapt to incorporate new working practices.

5) ADAPT OR DEVELOP SYSTEMS

Implementing any new intervention into a healthcare team requires designing new systems of work or amending the existing ones. Good planning of such systems will avoid frustration and problems later down the line.

6) MAKE THE MOST OUT OF THE TRAINING

The decision who to train is an important one. This will influence the early success of the programme and the enthusiasm and feedback from the initial roll-out will have a knock-on effect for future implementation.

7) DELIVER, MONITOR, EVALUATE

As the programme is rolled out, you can help it to develop and evolve by monitoring and evaluating progress. Evaluations can also be used to support the case for future funding.

Contact the REACH-HF team:
reach-hf@exeter.ac.uk

2.2. Delivery phase

Hopefully, the careful planning that went into the launch of the programme will result in a few obstacles during the delivery phase. The seven tasks involved in introducing the REACH-HF programme are described in more detail (with suggested discussion points and recommendations for each) in a table below.

1. Making the case for REACH-HF
Useful questions to ask: ❖ Why does the service need to implement home-based cardiac rehabilitation for people with heart failure? ❖ What cardiac rehabilitation is currently available for people with heart failure? ❖ Will REACH-HF be provided as an additional service or an alternative to existing provision (e.g. centre-based)? ❖ What are the benefits to patients of offering REACH-HF? What are the benefits to the service? ❖ How does the service want to respond to the NHS Long Term Plan in regards to cardiac rehabilitation provision for people with heart failure (see section 1.2)?
Recommendations: ➢ Prepare a good case for introducing REACH-HF into the service. ➢ Open communication with all relevant staff and incorporate the additional feedback into the final 'mission statement' document.
2. Getting the team on-board
Useful questions to ask: ❖ Are members of the team on-board with the programme? Do they see the value of REACH-HF? ❖ How much capacity does the service have? ❖ How is the team's morale? ❖ Is the team used to dealing with changes? Are they open and receptive to them? ❖ Has there been any recent clinical or administrative changes in how the service is being run or delivered? ❖ Who wants to be involved? Who should be involved? ❖ Who else, outside of your team, needs to be involved?
Recommendations: ➢ Keep the team spirits high and ensure that no animosity is directed towards the chosen innovators and/or the programme itself. Monitor staff morale and attitudes and address any resistance through discussion and actions to address any concerns. ➢ Make an honest assessment of the capacity available for the REACH-HF roll-out. Start at a level appropriate to the available resources. It's better to start small than to overstretch the service and fail. ➢ Low morale can be overcome by increasing communication between management and front-line staff in regular staff meetings and consultations and attempting to find out the causes of the resistance and apprehension. ➢ Evaluate how you have implemented changes previously and decide what worked well. ➢ Appoint REACH-HF champions.

- Appoint a REACH-HF team - a group of people that will be involved in the initial roll-out of the programme.
- Consider referral sources: e.g. hospitals, GPs, community teams. Identify referrers who can become REACH-HF champions.
- Heart failure nurses are an important source of referrals. For services that do not ordinarily look after people with heart failure, it is a good idea to bridge the gap and increase the interdisciplinary working between cardiac rehabilitation and heart failure teams. Consider identifying a heart failure nurse that will become a REACH-HF champion in the heart failure team. If the resources allow, consider training the champion heart failure nurse to deliver the programme and offer support to the REACH-HF roll-out team.
- Open a channel of communication between service managers, lead clinicians from cardiac rehabilitation and heart failure teams and the local specialist service manager.
- If there is no rehabilitation provision for people with heart failure, the cardiac rehabilitation team will have to work closely with the local cardiology consultants (to ensure safe clinical practice and ongoing support from senior clinicians).
- Consider a pathway for advanced psychological support and nutrition input if one is needed.
- Support from senior management is a crucial part of introducing a new intervention into the service, especially if additional resources will be required to get the project off the ground. Involve the local head of department in a strategic role. It will allow for smoother implementation and increase the chances of the programme being included in any future service plans.
- Does your NHS trust have a dedicated programme and transformation team? If so, it may be helpful to involve it in the initial set-up of processes and procedures. If such team is not available, the senior management team should take on this role.
- Ongoing consultations between managers and front-line staff are essential for a successful launch.

3. Considering & choosing the best timing

Useful questions to ask:

- Are there any current staff shortages (long-term sickness, study leave or recent redundancies)?
- Is it a good time during the year to introduce REACH-HF?

Recommendations:

- Following discussions with all the relevant staff (front-line staff, managers, clinical leads, HR) - decide on the most optimal timing to introduce the REACH-HF programme in your service.

4. Gathering the resources

Useful questions to ask:

- Who will pay for the REACH-HF training?
- Where will the additional staff capacity come from? Will new staff be recruited?
- Are there additional funds to deliver the programme on a day-to-day basis (cost of the manual and travel)?
- How will any potential gaps in resources be managed?
- Who will take on any additional administrative burden?
- Is the distribution of new tasks/workload perceived as fair and acceptable?

Recommendations:

- For existing staff that will be offering REACH-HF agree on the amount of the acceptable adjustment to their usual duties, or working hours.
- Create a plan to cover the cost of delivering the programme.
- Be realistic about the resources required to integrate REACH-HF with your ongoing service delivery.
- Add REACH-HF to an existing commissioning structure or create a new business case for the additional service delivery.
- Provide the team with opportunities to voice their concerns about changing tasks/workloads.
- Create a well-defined and realistic plan that accounts for changes in workload across the service.
- Communicate with the team about how the changes can be best managed.

5. Adapting or putting new systems in place

Useful questions to ask:

- From operational, clinical, and systems points of view, what needs to happen before the first REACH-HF sessions can be delivered?
- What is the NHS trust's policy and insurance for lone working (if applicable)?
- If applicable, will home visits be conducted by individuals or pairs?

Recommendations:

- Operational: identifying suitable assessment sites, identifying patients' cohorts and referral sources, agreeing which data to capture and record, agreeing on any key performance indicators, creating sufficient project plans and risk logs, as well as identifying roles and responsibilities (ranging from who will be delivering the new treatment to who will look after the additional administrative burden).
- Clinical: patient criteria need to be agreed and, for services not ordinarily looking after people with heart failure, communication with heart failure specialist nurses and consultants may need to be established.
- Systems: the IT department may need to adapt the patient record system. You may need templates for referrals and patient communications, as well as to capture the required clinical data, document REACH-HF assessments and clinical notes from the follow-up sessions. The REACH-HF facilitators may need a 'prompt system' for booking REACH-HF intake and end-of-treatment assessments. The REACH-HF facilitators may need to develop a diary system to keep track of home visits and follow-up phone calls, as well as the participants' progress on the programme.

6. Making the most out of the training

Useful questions to ask:

- Is it possible to upskill all staff who could deliver REACH-HF?
- What is the team's experience of facilitating self-management and exercise programmes for people with heart failure?
- Who is the most suitable to attend the REACH-HF training? Who has the most enthusiasm for the programme and the experience and capacity to deliver it?

Recommendations:

- Allow equal opportunity for members of the team to participate in the REACH-HF training.
- Create fair and transparent criteria and a rationale for the selection of individuals to attend the REACH-HF training.

- Manage any possible disappointments of individuals that were not invited – discuss opportunities for any future training or other ways for these individuals to stay involved in the REACH-HF project.
- Consider training a multidisciplinary mix of healthcare professionals – for example, including a community cardiac specialist nurse, an exercise physiologist or physiotherapist and a heart failure specialist nurse (with experience in exercise prescription). Having a broad skills-mix in the delivery team will help staff to support each other and address a wider range of patient needs.
- Consider setting up regular REACH-HF peer-to-peer learning sessions to allow the REACH-HF facilitators to discuss difficult cases, hone their skills building on their REACH-HF training.
- If exercise prescription experience is lacking for some staff, consider starting with the BACPR Physical Activity and Exercise in Heart Failure training course: https://www.bacpr.com/pages/page_box_contents.asp?PageID=836
- Choose staff that are motivated, enthusiastic and see the value of the REACH-HF programme.
- Allow enough time before the training to complete the pre-training learning reading/activities and enough time following the training to digest the new information. The newly trained staff could prepare a short presentation about REACH-HF to be presented to the whole team.
- Spend some time following the training discussing as a team how you see the practicalities of delivering the REACH-HF programme and what will work best in the contexts of your service.
- Ensure training is timely (avoid having a big gap between training and delivery) – delivering REACH-HF requires skills and these will diminish without practice.
- Once the programme is in place, use the knowledge and skills of experienced staff to help newly trained staff to learn/gain experience (e.g. using shadowing of delivery for the first few patients).

7. Setting up monitoring and evaluation

Useful questions to ask:

- How can the roll-out of the REACH-HF programme be monitored and evaluated?

Recommendations:

- Make time for reflection. Evaluate the process of the roll-out itself and involve all relevant staff.
- Collect regular feedback from the REACH-HF facilitators and the REACH-HF participants.
- Use national audit (NACR) data to evaluate patient outcomes and other key metrics (e.g. throughput, uptake, completion).
- Think about collecting different level data: participants' outcomes and feedback, enrolment and the popularity of the programme, treatment attrition and completion rates and facilitators feedback.
- If you do not ordinarily report to the National Audit of Cardiac Rehabilitation (NACR) – put a system in place to monitor participants' outcomes.
- Schedule regular review/feedback meetings to identify and address any concerns or barriers about delivering the service.

2.3. Maintenance phase

It is good to develop tools for evaluating effectiveness, usefulness, or impact of the new programme, as well as finding opportunities to reflect on the roll-out process itself. The maintenance phase is an ongoing process since the landscape of healthcare delivery is always changing, staff move on, and other innovations and ideas arise over time. Ongoing monitoring and feedback will help to keep REACH-HF working well as time goes on, and/or help it to develop and adapt to changes in circumstances.

To be able to maintain programme delivery, it is important to establish an ongoing funding stream. This may be a good time to present an updated service model to your Clinical Commissioning Group (CCG) or start considering ways of sourcing additional targeted funding (e.g. under the NHS Sustainability and Transformation Plans). Such targeted funding may start to be available from 2021 as the NHS is planning to allocate £28 million over five years to improve access to cardiac rehabilitation for cardiac patients. This is part of the NHS Long Term Plan to increase uptake of rehabilitation by patients with heart failure from 8% to 33%.

Thank you for taking the time to read this implementation guide. We hope you will find REACH-HF to be a useful addition to your cardiac rehabilitation service delivery. If you have any implementation problems, please do get in touch with your REACH-HF trainers or the REACH-HF team: reach-hf@exeter.ac.uk

References:

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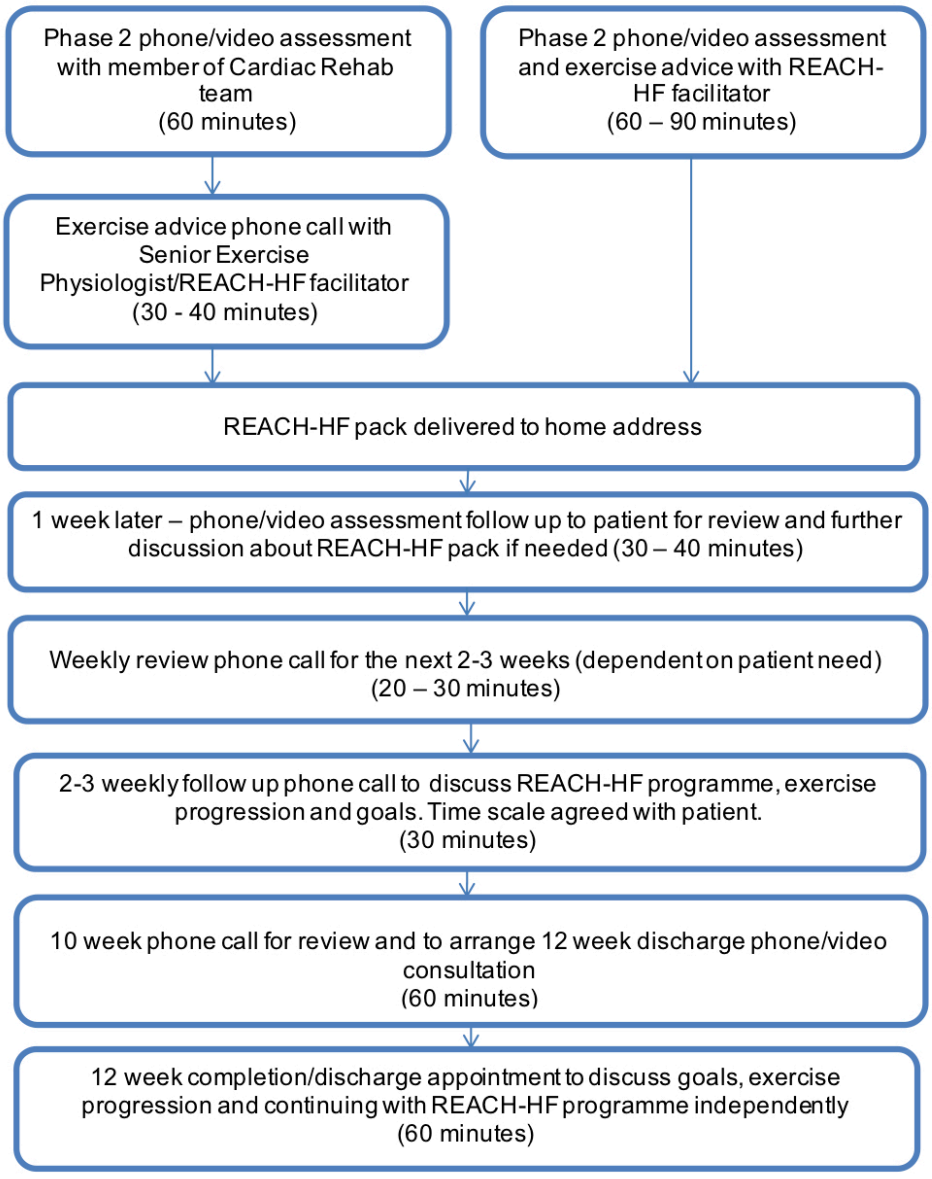
Wirral Community Health and Care NHS Foundation Trust

Wirral Cardiovascular Rehabilitation

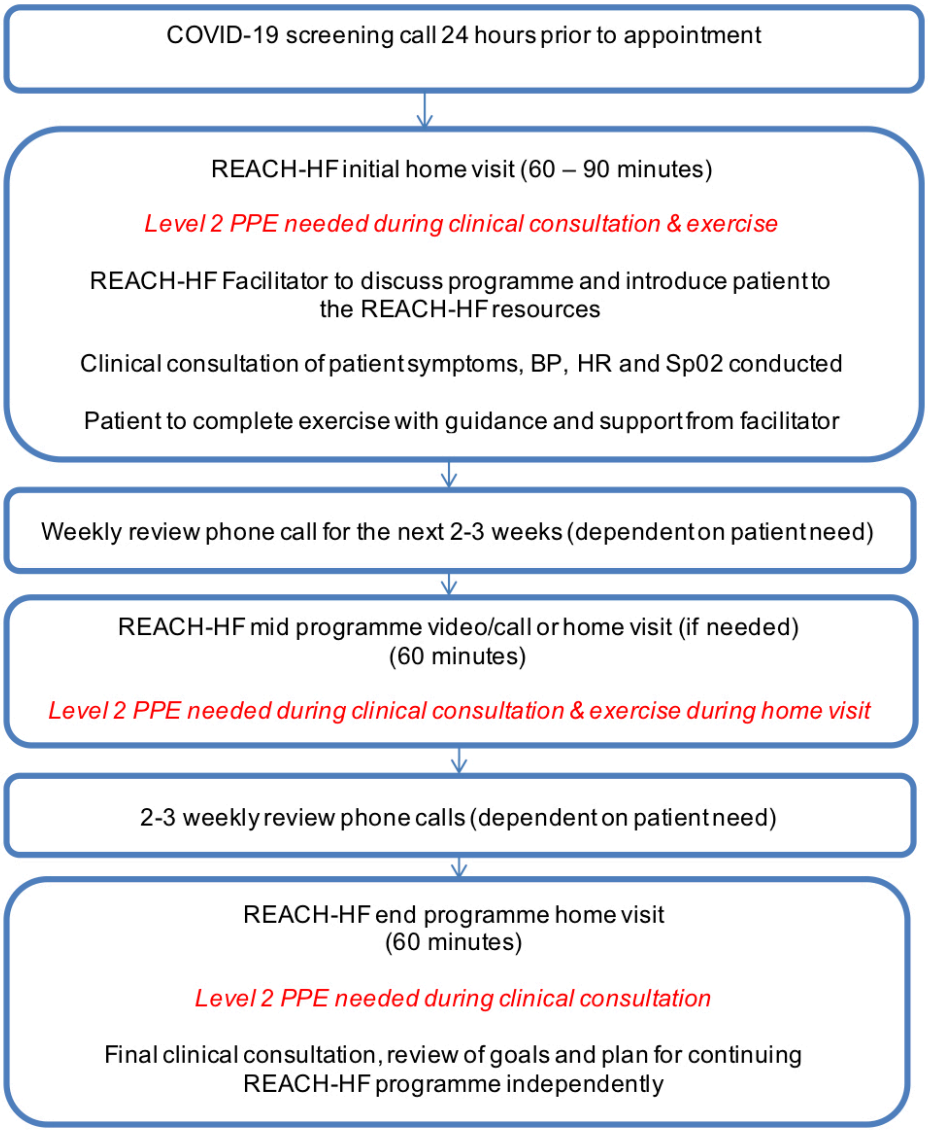
REACH-HF remote delivery pathway



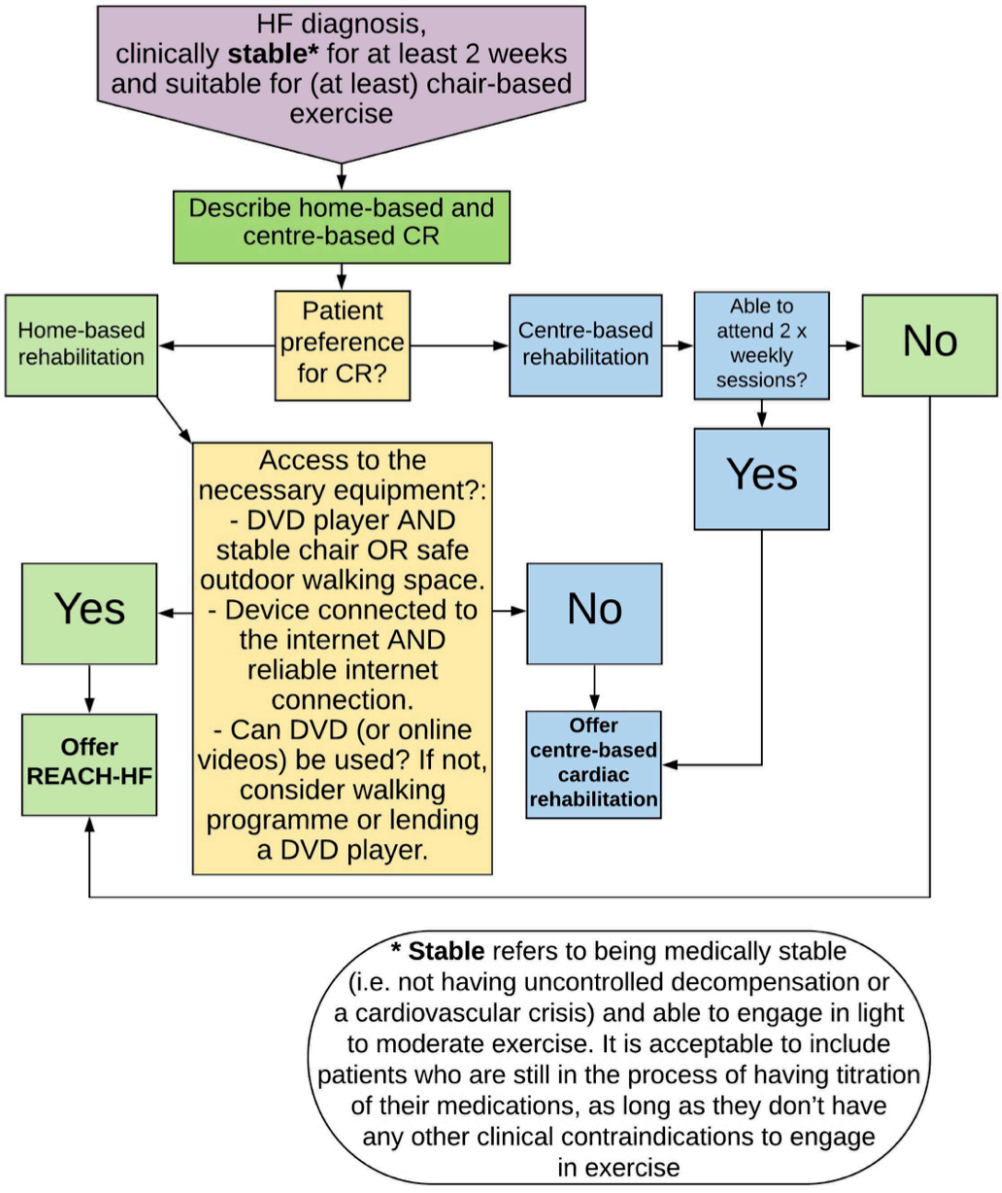
NHS
Wirral Community Health and Care
NHS Foundation Trust

Wirral Cardiovascular Rehabilitation

REACH-HF combined delivery pathway (social distancing and PPE)



Appendix 3 – patient criteria and selection tool



Appendix 2

Interview topic guide

Qualitative interview guide (initial draft*)

** The topic guide content may vary depending on feedback from stakeholders and the first few interviews*

Beacon Site: I / II / III / VI *(circle as appropriate)*

Date of interview: _____

- **Welcome and housekeeping**

  Thank you for agreeing to take part in the study. The interview will last between 30 and 40 minutes. I will ask you a series of questions and I am really interested in your honest opinion on the subject matter. If you wish to stop at any point to take a break, let me know.

- **Informed consent**

  Thank you for reading PIS and completing the consent form. Is it ok if I start recording?

- **Interview questions**

NPT	Questions	Comments
1.1	Can you describe REACH-HF intervention and how it differs from your usual way of working?	

1.3	How does the intervention affect the nature of your work?	
4.3	Do you consider it to be worthwhile?	
1.4	In your opinion what is the value of REACH-HF intervention? To you? To your patients?	
1.2	What is your colleagues understanding of the purpose of REACH-HF intervention?	
4.2	Do they consider it to be worthwhile?	
3.2	How has implementing REACH-HF affected working relationships within the team?	
2.1	Who are the individuals (you can include yourself) that drive REACH-HF forward and get others involved? What are their roles? What are they doing to support the project?	
3.1	How easy or difficult has it been to integrate REACH-HF into your existing work?	
2.2	How did the team need to change in order to introduce REACH-HF?	
2.3	How do you feel about being involved in the REACH-HF project?	
3.3	How do the skills of the staff delivering REACH-HF match the needs of the programme?	
3.4	Was REACH-HF training sufficient to allow for successful implementation? If not, what other topics or skills could have been included? Are there enough resources available to support the REACH-HF programme? Are there any other **barriers** to delivering REACH-HF on your patch?	
4.1	Are you in any way evaluating effectiveness, usefulness or impact of REACH-HF on the service?	
4.4	Can REACH-HF intervention be modified and improved to suit your way of working? If yes, in what way?	
2.4	What is the future of REACH-HF in your service? What factors can **enable** integration of REACH-HF into a cardiac rehabilitation service?	

- ***A few service-level questions:*** *What is the catchment area for your service? What population do you serve?*

- **Ending & debrief**

  Thank you for taking the time to answer my questions. Is there anything else you would like to add? Or ask me about? I am going to switch off the audio recorder now. If any of what we spoke about affected you in any way we can have a debrief session now.

Appendix 3

Coding instructions for fidelity assessment

REACH-HF FIDELITY MEASURE

The rating scale
The seven point scale extends from (0) where the facilitator did not deliver the intervention element appropriately – either they didn't do it well or didn't do it sufficiently (low fidelity) to (6) where there is the element is delivered appropriately (high fidelity). Thus the scale assesses a composite of both adherence to the intended intervention techniques and the skill of the facilitator in delivering the techniques. To aid with the rating of items, an outline of the key features of each item is provided at the top of each section. A generic description of the rating criteria is given in Figure 1.

Adjusting for the presence of patient difficulties
Adjustments may be needed when patient difficulties are evident (e.g., excessive avoidance or resistance). In such circumstances, the rater needs to assess the facilitator's therapeutic skills in the application of the methods. Even though the facilitator may not facilitate change, credit should be given for attempting to use the intended techniques and demonstrating appropriate /skilful interaction (i.e., they should do what they can, within reason, to deliver the intended intervention components).

Figure 1: The scoring system

Competence level*	Scoring	Examples
0	Absence of feature and /or highly inappropriate performance	
1	Minimal use of feature and /or inappropriate performance,	
2	Evidence of competence, but numerous problems	
3	Competent, but some problems or inconsistencies	
4	Good features, but minor problems or inconsistencies	
5	Very good features, minimal problems or inconsistencies	
6	Excellent performance	

* The scale incorporates the Dreyfus system (Dreyfus, 1989) for denoting competence. Please note that the 'top marks' (i.e., near the 'expert' end of the continuum) are reserved for those facilitators demonstrating highly effective skills,

particularly in the face of difficulties (i.e., patients with high resistance to change; high levels of emotional expression; and complex situational barriers). Please note that there are 5 competence levels but six potential scores.

When rating the item, you should first identify whether some of the 'Key Features' are present. If the facilitator includes most of the key features and uses them appropriately (i.e., misses few relevant opportunities to use them and delivers them well), the facilitator should be rated highly. It is important to remember that the scoring profile for this scale should approximate to a normal distribution, with relatively few people scoring at the extremes. **For the purposes of the REACH study, a score of 3 or more will be taken to represent "acceptable delivery or basic competence" in using the intended techniques"**

Dreyfus, H. L. (1989). The Dreyfus model of skill acquisition. In J. Burke (ed.) Competency based education and training. London: Falmer Press.

ITEM 1: ACTIVE PATIENT INVOLVEMENT

Key features: The facilitator should encourage the participant to be actively involved in the consultation. The idea is to maximise the participant's autonomy as the main agent of change, developing intrinsic rather than extrinsic motivation, and encouraging her /him to be the person coming up with ideas for improving the situation. However, the participant should not be allowed to ramble in an unstructured way and the consultation should be guided. A collaborative /shared decision-making style is appropriate and the facilitator may share his /her own expertise and ideas (as below). Overall, the participant should be increasingly empowered to take control of her /his self-care behaviour. Interactions should be encouraging, respectful and non-judgemental (the opposite of a didactic, telling or persuading style of interaction). The participant should ideally talk for at least half of the time (particularly in later sessions). The interaction should also be *individually tailored* to the patient's specific information needs, beliefs, motivations and barriers. The facilitator should engender a clear sense of warmth, genuineness and empathy (within professional boundaries).

Intervention techniques: OARS (Open questions, Affirmation, Reflective listening, Summaries). Reflective listening may include simple reflections of content but may also be more sophisticated (e.g., amplified reflection; reflection with a twist) and used to direct the conversation or highlight key strengths or barriers. Summaries to reinforce patient choices and acknowledge patient effort are particularly desirable. Individual tailoring of techniques and responses to the individual patient's existing knowledge, skills, current activity levels, needs and preferences are also desirable. The Ask-Tell-Discuss technique should be used to exchange information (e.g., to address misconceptions, or offer helpful new information). The above empathy-building techniques and individual tailoring should be used throughout the consultations – from the initial consultation through action-planning through to review /maintenance sessions.

Mark with an 'X' on the vertical line, using whole and half numbers, the level to which you think the facilitator has delivered this intervention process

1. Absence of active patient involvement techniques. An overly 'directing', practitioner-led or 'lecturing' style of interaction, which may increase or sustain client's resistance.
2. Minimal patient involvement or use of active patient involvement techniques. The practitioner dominates the discussion.
3. Some use of patient involvement techniques, but not frequent enough. The practitioner sometimes dominates the discussion.

4. Appropriate and frequent use of patient involvement techniques. Teamwork evident, but some difficulties in content or method of delivery.
5. Appropriate and frequent use of patient involvement techniques. Minor problems evident (e.g., some reflection opportunities missed).
6. Highly appropriate and regular use of patient involvement techniques, facilitating shared understanding and decision-making. Minimal problems.
7. Excellent / expert use of patient involvement techniques throughout all the consultation. A clear sense of collaborative alliance is developed.

ITEM 2: ASSESSING THE PATIENT'S CURRENT SITUATION AND NEEDS

Key features: The facilitator should work with the participant to assess the patient's current situation. They should seek to identify ALL of the following over the first 1-2 sessions: Identify and discuss the most important issue currently for the patient, how well are they managing their fluids, how appropriately are they using medications, is there any obvious immediate clinical need, how much stress or anxiety do they have, how much physical activity are they doing, and what other concerns or questions they may have.

Intervention techniques: Facilitators will use patient-centred communication techniques (as above) which may include the Ask-Tell-Discuss and 'tell me three things' technique to explore the patient's current situation.

Mark with an 'X' on the vertical line, using whole and half numbers, the level to which you think the facilitator has delivered this intervention process

0. Absence (or very poor delivery) of discussions to assess the patient's current situation.
1. Minimal (or poorly delivered) discussions to assess the patient's current situation.
2. Some discussions to assess the patient's current situation, but may not be in sufficient depth or detail, or quality of delivery may be variable.
3. Several examples of discussion to assess the patient's current situation. However some difficulties evident (e.g., missed opportunities, not covering all the key topics, or talking at odds with the patient).
4. Several examples of discussion to assess the patient's current situation. Minor problems evident.
5. Highly appropriate and sufficient discussion to assess the patient's current situation. Minimal problems.
6. Excellent / expert use of discussion to assess the patient's current situation. No real problems.

ITEM 3: FORMULATING AN APPROPRIATE (INDIVIDUALISED) TREATMENT PLAN

Key features: The facilitator should work with the participant to formulate an appropriate treatment plan based on the patient's current situation. This should aim to address (as a minimum) ALL of the following over the twelve weeks of the programme: What is the most important issue currently for the patient, are they managing their fluids well, are they using medications appropriately, any clinical needs identified, how much stress or anxiety do they have, how much physical activity are they doing, and any other concerns or questions they may have. The treatment plan will be staged over time, aiming to work on a few topics initially and introducing other elements as the programme continues. It is best practice to summarise the treatment plan at the end of the session "what we have said today is …".

Intervention techniques: Facilitators will use patient-centred communication techniques (as above) to discuss and agree what issues to address first and what order to do things in. An element of guiding to ensure the inclusion of clinical priorities (e.g., medication issues, physical activity, psychological well-being) as well as patient priorities may be appropriate. The facilitator will advise the patient (and caregiver if appropriate) to read relevant sections of the manual ahead of their next meeting.

Mark with an 'X' on the vertical line, using whole and half numbers, the level to which you think the facilitator has delivered this intervention process

0. Absence (or very poor delivery) of discussion to formulate an appropriate treatment plan based on the patient's current situation.
1. Minimal (or poorly delivered) discussion to formulate an appropriate treatment plan based on the patient's current situation.
2. Some discussion to formulate an appropriate treatment plan based on the patient's current situation, but may not be in sufficient depth or detail, or quality of delivery may be variable (e.g., not covering all the key topics, or talking at odds with the patient).
3. Several examples of discussion to formulate an appropriate treatment plan based on the patient's current situation. However some difficulties may still be evident (e.g., missed opportunities, plan not summarised at the end of the visit).
4. Several examples of discussion to formulate an appropriate treatment plan based on the patient's current situation. Minor problems evident.
5. Highly appropriate and sufficient discussion to formulate an appropriate treatment plan based on the patient's current situation. Minimal problems.

6. Excellent / expert use of discussion to formulate an appropriate treatment plan based on the patient's current situation. No real problems.

ITEM 4: BUILD THE PATIENT'S UNDERSTANDING OF HEART FAILURE/MAKING A LINK BETWEEN SELF-CARE ACTIVITIES AND THEIR HEART FAILURE SYMPTOMS

Key features: Participants' ability to make sense of how heart failure works and how self-care behaviours might influence the course of the illness will be crucial for the success of the intervention as belief in the benefit of the suggested self-care activities will increase motivation to engage in them. The facilitator should elicit the patient's current understanding of heart failure and seek to build their 'illness model' in terms of understanding the Identity, Causes, Consequences, Cure /control options and Timeline[435] associated with the condition. This process may take several weeks and should be reinforced as the programme progresses.

Intervention techniques: Facilitators will provide the REACH-HF Manual, provide a brief overview of how the manual works and, after assessing the patient's individual needs and concerns (as above), they will identify some key sections for the patient to read before the next contact, specifically including the Understanding heart failure section. Facilitators will use patient-centred communication techniques (as above) to elicit and build understanding. This should include the use of the Ask-Tell-Discuss technique and reflective listening to reinforce elements of the patient's understanding that are factually correct or which predispose towards positive self-care behaviours. They should seek to reframe negative attitudes and exchange information (Ask-Tell-Discuss) to address any misconceptions or to fill any important gaps in understanding. The facilitator will advise the patient (and caregiver if appropriate) to read relevant sections of the manual (including the Understanding heart failure chapter) to build and reinforce understanding /to address misconceptions. The way heart failure works should be explicitly discussed and referred back to /reinforced at subsequent sessions when this reinforces perceived benefits of the proposed self-care behaviours.

Mark with an 'X' on the vertical line, using whole and half numbers, the level to which you think the facilitator has delivered this intervention process.

0. Absence (or very poor delivery) of any exploration or discussion of how heart failure works. Understanding of heart failure is assumed or not mentioned or discussed.
1. Minimal (or poor delivery of) exploration or discussion of how heart failure works.
2. Some exploration or discussion of the how heart failure works, but may not be in sufficient depth or detail, or quality of delivery may be variable (e.g., telling rather than Ask-Tell-Discuss) or understanding is not checked.

3. Appropriate exploration and discussion of how heart failure works. However, some difficulties may still be evident (e.g., moving on before understanding is fully established).
4. Appropriate exploration or discussion of how heart failure works, linking changes in symptoms or mood with changes in self-care behaviour. Minor problems evident (e.g., some inconsistencies).
5. Highly appropriate and sufficient exploration or discussion of how heart failure works, facilitating a clear understanding of the process and linking changes in symptoms and mood with changes in self-care behaviour. Minimal problems.
6. Excellent / expert exploration and discussion facilitating a clear understanding of how heart failure works and the reasons for change. No real problems.

1. Leventhal H, Nerenz DR, Steele DJ: Illness representations and coping with health threats. In: *Handbook of Psychology and Health*. Volume IV. Edited by Baum AE, et al. Hillsdale NJ: Lawrence Erlbaum; 1984: 219-67.

ITEM 5a: SUPPORTING SELF-MONITORING AND PROGRESS-TRACKING

Key features: The facilitator should agree a verbal plan of action for the following week(s) with the patient. and discuss the use of the progress-tracking tools in the heart failure manual to keep track of progress and as a way of recording any problems in completing the activities and any benefits that might be associated with the planned activities.

Intervention techniques: The facilitator should encourage the participant to monitor /keep track of their activities using the progress-tracking tools in the heart failure Manual.

Mark with an 'X' on the vertical line, using whole and half numbers, the level to which you think the facilitator has delivered this intervention process

0. Absence (or very poor delivery) of encouragement of self-monitoring.
1. Minimal (or poorly delivered) encouragement of self-monitoring. Activities planned are not sustainable, or poorly specified.
2. Some encouragement of self-monitoring but lacking detail /patient involvement in the activity may be limited, or quality of delivery may be variable (e.g., telling rather than discussing).
3. Appropriate encouragement of self-monitoring. However, some difficulties evident (e.g., not explaining the rationale for using the tool as a basis for monitoring progress, sometimes providing rather than eliciting ideas).
4. Appropriate encouragement of self-monitoring. Minor problems evident (e.g., the plan is a bit less specific than it could be).
5. Highly appropriate encouragement of self-monitoring. The participant has a clear understanding of the plan for the week ahead and how to monitor progress. Minimal problems.
6. Excellent / expert encouragement of self-monitoring. The participant has a clear and realistic understanding of how to monitor progress. No real problems.

ITEM 5b: REVIEWING PROGRESS AND PROBLEM-SOLVING

Key features: The facilitator should work with the participant to review progress with all planned changes and with achieving the targets set out in the action plan. The facilitator should celebrate and reinforce and reflect on any successes. The participant and facilitator should discuss any setbacks and the patient's plans should be revised.

Intervention techniques: The facilitator should reinforce any self-monitoring activity and any successes in behaviour change (by giving praise/ using Affirmation techniques). Reframing should be used to normalise setbacks and see them as an opportunity to learn from experience (trial and error) rather than as failures. Problem-solving should use OARS (Open questions, Affirmation, Reflective listening, Summaries) and information exchange (Ask-Tell-Discuss) techniques to identify barriers and explore ways to overcome them. Problem-solving may specifically focus on issues of connectedness (social influences, involvement of others in supporting activities) and sustainability, or on breaking the problem down into more manageable chunks. Goals /action plans should be reviewed and revised if necessary.

Mark with an 'X' on the vertical line, using whole and half numbers, the level to which you think the facilitator has delivered this intervention process

0. Absence (or very poor delivery) of any progress review. No reinforcement of success and discussion of setbacks or barriers in relation to the previous weeks planned activities /problem-solving, or reviewing action plans.
1. Minimal (or poor delivery) of progress review. Minimal reinforcement of success and discussion of setbacks or barriers in relation to the previous weeks planned activities /problem-solving, or reviewing action plans.
2. Some progress review. Some reinforcement of success and discussion of setbacks or barriers in relation to the previous weeks planned activities /problem-solving and reviewing action plans, but lacking sufficient depth or detail or may be poorly delivered (e.g., providing solutions rather than using Ask-Tell-Discuss).
3. Appropriate progress review. Appropriate reinforcement of success and discussion of setbacks or barriers in relation to the previous weeks planned activities /problem-solving, and reviewing action plans. However, some difficulties evident (e.g., not reframing setbacks, not attempting to identify problems, or possible solutions).
4. Appropriate progress review. Appropriate reinforcement of success and discussion of setbacks or barriers in relation to the previous weeks planned

activities /problem-solving, and reviewing action plans. Minor problems evident.

5. Highly appropriate and sufficient progress review. Appropriate reinforcement of success and discussion of setbacks or barriers in relation to the previous weeks planned activities /problem-solving, or reviewing action plans. Minimal problems.
6. Excellent / expert progress review. Excellent reinforcement of success and discussion of setbacks or barriers in relation to the previous weeks planned activities /problem-solving, and reviewing action plans. No real problems.

ITEM 6: MAKE A SPECIFIC ACTION PLAN FOR PHYSICAL ACTIVITY, BASED ON THE ACTIVITIES SELECTED BY THE PATIENT

Key features: Using the template in the heart failure manual, the facilitator should work with the participant to agree a written or verbal plan of action for engaging in one of the physical activity /exercise options over the following week(s). This should include discussion to ensure an appropriate intensity (moderate) of any activity included in the action plan.

Intervention techniques: Making a written action plan, using the planning tool in the manual, or a verbal action plan for physical activity. The facilitator should ensure that goal-setting is realistic. The facilitator may also employ some problem-solving techniques at this stage to pre-empt and address potential problems. It is best practice to summarise the plan at the end of the session "what we have said today is …".

Mark with an 'X' on the vertical line, using whole and half numbers, the level to which you think the facilitator has delivered this intervention process

0. Absence (or very poor delivery) of activity /exercise planning for the following week(s).
1. Minimal use (or poor delivery) of activity /exercise planning for the following week(s). Activities planned are not sustainable, or representative of the routine, pleasurable and necessary activities previously identified.
2. Some use of action-planning techniques using the heart failure manual planning tool (or verbal equivalent) but lacking detail /patient involvement in the activity may be limited. Quality of delivery may be variable (e.g., providing the plan rather than discussing, not checking the patient is happy with the plan).
3. Appropriate use of action planning techniques . However, some difficulties evident (e.g., not summarising the plan at the end, sometimes providing rather than eliciting ideas).
4. Appropriate use of action planning techniques. Minor problems evident (e.g., the plan is a bit less specific than it could be).
5. Highly appropriate and sufficient use of action-planning techniques. The participant has a clear understanding of and ownership of the plan for the week(s) ahead. Minimal problems.
6. Excellent / expert use of action-planning techniques. The participant has a clear understanding of the rationale behind planning for the week(s) ahead, and has a clear and realistic action plan for the week(s) ahead. No real problems.

ITEM 7: ADDRESSING EMOTIONAL CONSEQUENCES OF HEART FAILURE

Key features: The facilitator should help the patient to recognise and address any significant stress, anxiety, anger, depression or other negative feelings that are related to having heart failure. S/he should seek to normalise such feelings and help the patient to access and work through relevant sections of the manual. If these problems are severe or prolonged the facilitator should facilitate a referral to relevant care services.

Intervention techniques: Patient centred counselling techniques (OARS) for assessment and exchanging information to build patient's understanding of the situation. Facilitation of the cognitive behavioural therapy techniques and stress management techniques contained within the manual.

Mark with an 'X' on the vertical line, using whole and half numbers, the level to which you think the facilitator has delivered this intervention process

0. Absence (or very poor delivery) of any attempts to address emotional consequences.
1. Minimal (or poorly delivered) attempts to address emotional consequences,
2. Some attempts to address emotional consequences, but lacking sufficient depth or detail. Quality of delivery may be variable (e.g., talking at odds with the patient).
3. Appropriate attempts to address emotional consequences. However, some difficulties evident (e.g., sometimes being prescriptive rather than patient-centred, not identifying all relevant sections of the manual).
4. Appropriate attempts to address emotional consequences. Minor problems evident.
5. Highly appropriate and sufficient addressing of emotional consequences. Minimal problems.
6. Excellent / expert addressing of emotional consequences. No real problems.

ITEM 8: ADDRESSING MEDICATION ISSUES

Key features: The facilitator should help the patient to recognise and address any significant problems or concerns relating to the patient's heart failure medications. S/he should help the patient to work through relevant sections of the manual. This might include problems in organising /taking the medications, knowing what to do if they get a cold or forget a dose, identifying possible side effects and seeking help to minimise them, avoiding over-the-counter medications. For some patients, it may include discussing self-titration of diuretics (water tablets) in response to symptoms /swelling (using the Traffic Light plan as a guide).

Intervention techniques: Patient centred counselling techniques (OARS) for assessment and to exchange information to build patient's understanding of the situation. Facilitation of medication planning /monitoring tools (in the progress tracker) and tips provided in the manual.

Mark with an 'X' on the vertical line, using whole and half numbers, the level to which you think the facilitator has delivered this intervention process

0. Absence (or very poor delivery) of any attempts to address medication issues.
1. Minimal (or poor delivery) attempts to address medication issues.
2. Some attempts to address medication issues, but lacking sufficient depth or detail, or quality of delivery may be variable (e.g., not picking up /addressing concerns about possible side effects).
3. Appropriate attempts to address medication issues. However, some difficulties evident (e.g., sometimes being prescriptive rather than patient-centred, not identifying all relevant sections of the manual).
4. Appropriate attempts to address medication issues. Minor problems evident.
5. Highly appropriate and sufficient addressing of medication issues. Minimal problems.
6. Excellent / expert addressing of medication issues. No real problems.

ITEM 9: CAREGIVER INVOLVEMENT (as applicable)

Key features: The facilitator should engage the caregiver as much as possible as a co-facilitator of the intervention. S/he should tailor the intervention to work with the caregiver's abilities and availability to provide support to the cared for person with self-management of their heart failure. Facilitators will provide the Caregiver Resource, a brief overview of what it contains, and identify some key sections for the caregiver to read.

Intervention techniques: Person-centred counselling techniques (OARS) for assessment and to exchange information to build the caregiver's understanding of the situation and their ability to support the person with heart failure with their self-management. The facilitator should facilitate a conversation between the patient and the caregiver to agree their roles and responsibilities and how these might change if the patient's condition declines. Attention should be given to the caregiver's needs and concerns about being a caregiver /providing care as well as those of the patient.

Mark with an 'X' on the vertical line, using whole and half numbers, the level to which you think the facilitator has delivered this intervention process

0. Absence (or very poor delivery) of any attempts to involve the caregiver or to address his /her needs.
1. Minimal (or poor delivery) attempts to involve the caregiver or to address his /her needs.
2. Some attempts to involve the caregiver or to address his /her needs, but lacking sufficient depth or detail, or quality of delivery may be variable (e.g., being mostly prescriptive rather than person-centred).
3. Appropriate attempts to involve the caregiver or to address his /her needs. However, some difficulties evident (e.g., leaving roles and responsibilities between patient and caregiver unclear in some respects).
4. Appropriate attempts to involve the caregiver or to address his /her needs. Minor problems evident.
5. Highly appropriate and sufficient involvement of the caregiver and addressing his /her needs. Minimal problems.
6. Excellent / expert involvement of the caregiver and addressing his /her needs. No real problems.

ITEM 10: ADDRESSING EMOTIONAL CONSEQUENCES OF BEING A CAREGIVER (AS APPLICABLE)

Key features: The facilitator should help the caregiver to recognise and address any significant stress, anxiety, anger, depression or other negative feelings that are related to becoming a caregiver and supporting someone with heart failure. S/he should seek to normalise such feelings and help the caregiver to access and work through relevant sections of the Caregiver Resource. This includes facilitating a referral for a carer's assessment if the caregiver wishes, plus referral to other relevant care services as appropriate.

Intervention techniques: Person-centred counselling techniques (OARS) for assessment and to exchange information to build the caregiver's understanding of the situation. Facilitation of the cognitive behavioural therapy techniques and stress management techniques contained within the manual.

Mark with an 'X' on the vertical line, using whole and half numbers, the level to which you think the facilitator has delivered this intervention process

0. Absence (or very poor delivery) of any attempts to address emotional consequences.
1. Minimal (or poorly delivered) attempts to address emotional consequences.
2. Some attempts to address emotional consequences, but lacking sufficient depth or detail, or quality of delivery may be variable (e.g., talking at odds with the patient).
3. Appropriate attempts to address emotional consequences. However, some difficulties evident (e.g., sometimes being prescriptive rather than patient-centred, not identifying all relevant sections of the manual, not facilitating onward referrals).
4. Appropriate attempts to address emotional consequences. Minor problems evident.
5. Highly appropriate and sufficient addressing of emotional consequences. Minimal problems.
6. Excellent / expert addressing of emotional consequences. No real problems.

ITEM 11: CAREGIVER HEALTH AND WELL-BEING (AS APPLICABLE)

Key features: The facilitator should help the caregiver to prioritise and look after their own health and well-being.

Intervention techniques: Person-centred counselling techniques (OARS) for assessment and to exchange information to build the caregiver's understanding of the situation – helping them recognise and manage their own health needs including mental health, physical health, and social needs. This may be a separate conversation with the caregiver alone.

Mark with an 'X' on the vertical line, using whole and half numbers, the level to which you think the facilitator has delivered this intervention process

0. Absence (or very poor delivery) of any attempts to involve the caregiver or to address his /her health needs.
1. Minimal (or poor delivery of) attempts to involve the caregiver or to address his /her health needs.
2. Some attempts to involve the caregiver or to address his /her needs, but lacking sufficient depth or detail, or quality of delivery may be variable (e.g., not picking up on /addressing some of the caregiver's concerns).
3. Appropriate attempts to involve the caregiver or to address his /her needs. However, some difficulties evident (e.g., sometimes being prescriptive rather than patient-centred, failing to identify the appropriate sections of the Caregiver's Resource).
4. Appropriate attempts to involve the caregiver or to address his /her needs. Minor problems evident.
5. Highly appropriate and sufficient involvement of the caregiver and addressing his /her needs. Minimal problems.
6. Excellent / expert involvement of the caregiver and addressing his /her needs. No real problems.

ITEM 12: BRINGING THE PROGRAMME TO A CLOSE

Key features: Progress should be consolidated and reinforced. Plans for long-term sustainability of activities and strategies learned for managing heart failure should be discussed.

Intervention techniques: The facilitator will review progress since the start of the intervention and reinforce what has been learnt. Useful strategies that were helpful should be identified. Plans to stay well /prevent relapse should be discussed as well as 'cues for action' and plans to revisit the manual in the future. The facilitator will discuss plans to sustain any new activities, identifying any potential problems and coping strategies to overcome these. The possibility of good and bad days should be discussed and normalised.

Mark with an 'X' on the vertical line, using whole and half numbers, the level to which you think the facilitator has delivered this intervention process

0. Absence (or very poor delivery) of discussion to bring the intervention to a close. Not considering progress and long term planning using the above strategies.
1. Minimal (or poorly delivered) discussion to bring the intervention to a close. Minimal consideration of progress and long term planning using the above strategies.
2. Some discussion to bring the intervention to a close. Some consideration of progress and long term planning using the above strategies, but not in sufficient depth or detail, or quality of delivery may be variable (e.g., telling /providing solutions rather than discussing or eliciting solutions from the patient (and caregiver if relevant)).
3. Appropriate discussions to bring the intervention to a close. Appropriate consideration of progress and long term planning using the above strategies. However some difficulties evident (e.g., missed opportunities to reinforce what has been learnt, facilitator sometimes dominating the conversation /telling rather than facilitating development of the patient's own ideas).
4. Several examples of appropriate discussion to bring the intervention to a close and examples of consideration of progress and long term planning the above strategies. Minor problems evident.
5. Highly appropriate and sufficient discussion to bring the intervention to a close and to consider progress and long term planning using the above strategies. Minimal problems.

6. Excellent / expert discussions to bring the intervention to a close and to consider progress and long term planning using the above strategies. No real problems.

CONTENT CHECKLIST – PATIENT

How much did the facilitator cover the following topics in this session with regard to the patient…	**Not at all**		**Partially**		**Thoroughly**
1. … Understanding heart failure	1	2	3	4	5
2. ... Management of stress or anxiety	1	2	3	4	5
3. ... Physical activity	1	2	3	4	5
4. ... Low mood /depression	1	2	3	4	5
5. … Taking medications	1	2	3	4	5
6. ... Deciding priorities/ setting goals	1	2	3	4	5
7. … Tracking and reviewing progress	1	2	3	4	5
8. ... Using the heart failure manual	1	2	3	4	5
9. ...Support from others	1	2	3	4	5
10. … Other (please state)	1	2	3	4	5

CONTENT CHECKLIST – CAREGIVER

How much did the facilitator cover the following topics in this session with regard to the caregiver …	**Not at all**		**Partially**		**Thoroughly**
1. ... Assessing the caregiver's needs e.g., understanding of heart failure, how to facilitate self-care	1	2	3	4	5
2. ... Managing the caregiver's own health and well-being	1	2	3	4	5
3. ... Facilitating discussion of /decisions about care-giving roles and responsibilities	1	2	3	4	5
4. ... Promoting physical activity for the patient	1	2	3	4	5
5. ...Encouraging self-monitoring and management for the patient	1	2	3	4	5
6. ... Helping patients who feel stressed or depressed	1	2	3	4	5
7. … Understanding and managing the patient's medications	1	2	3	4	5
8. … Other (please state) e.g., financial management, getting help from friends, uncertainty	1	2	3	4	5

Leventhal H, Nerenz DR, Steele DJ: Illness representations and coping with health threats. In: *Handbook of Psychology and Health*. Volume IV. Edited by Baum AE, et al. Hillsdale NJ: Lawrence Erlbaum; 1984: 219-67.

Appendix 4

Self-rated fidelity checklist

Dear REACH-HF facilitator,

At the end of each REACH-HF session that you have audio recorded, we would like you to take a few moments to reflect on how the session went. Each line on the checklist represents a key feature of the programme. You can rate the session from 0 to 6, where 0 means that you did not use the particular feature of the programme and 6 means that you used such feature extensively and proficiently.
There is no right or wrong way to answer these questions and your or your team's performance will not be judged in any way. We appreciate that some features will be more relevant at different points of the treatment and we do not expect you to include all features in every session. Your honesty will be greatly appreciated.

Session date: _____

Participant study number: _____

Session number: _____

REACH-HF programme feature	Absence	Minimal	Some	Sufficient	Good	Very	Excellent
1. Active patient involvement	0	1	2	3	4	5	6
2. Assessing the patient's current situation and needs	0	1	2	3	4	5	6
3. Formulating an appropriate (individualised) treatment plan	0	1	2	3	4	5	6
4. Building the patient's understanding of heart failure /making a link between self-care activities and their heart failure symptoms	0	1	2	3	4	5	6
5a. Supporting self-monitoring and progress-tracking	0	1	2	3	4	5	6
5b. Reviewing progress and problem-solving	0	1	2	3	4	5	6
6. Making a specific action plan for physical activity, based on the activities selected by the patient	0	1	2	3	4	5	6
7. Addressing emotional consequences of heart failure	0	1	2	3	4	5	6
8. Addressing medication issues	0	1	2	3	4	5	6
9. Caregiver involvement (as applicable)	0	1	2	3	4	5	6
10. Addressing emotional consequences of being a caregiver (as applicable)	0	1	2	3	4	5	6
11. Caregiver health and well-being (as applicable)	0	1	2	3	4	5	6
12. Bringing the programme to a close	0	1	2	3	4	5	6

Appendix 5

Full search strategy

1. exp heart failure/
2. heart failure.ab,ti.
3. HFrEF.ab,ti.
4. HFpEF.ab,ti.
5. HFmrEF.ab,ti.
6. 1 or 2 or 3 or 4 or 5
7. exp cardiac rehabilitation/
8. cardi* rehab*.ab,ti.
9. exp Exercise/
10. exercis*.ab,ti.
11. exp Rehabilitation/
12. rehab*.ab,ti.
13. enablement.ab,ti.
14. physical activit*.ab,ti.
15. 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14
16. offer*.ab,ti.
17. exp Health Plan Implementation/
18. exp Implementation Science/
19. implement*.ab,ti.
20. exp "Referral and Consultation"/

21. refer*.ab,ti.

22. exp "Delivery of Health Care"/

23. exp "Delivery of Health Care, Integrated"/

24. deliver*.ab,ti.

25. exp Health Services Accessibility/

26. provi*.ab,ti.

27. 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26

28. 15 and 27

29. barrier*.ab,ti.

30. exp "Attitude of Health Personnel"/

31. enabl*.ab,ti.

32. facilitat*.ab,ti.

33. factor*.ab,ti.

34. influenc*.ab,ti.

35. 29 or 30 or 31 or 32 or 33 or 34

36. 6 and 28 and 35

37. limit 36 to english language**

** The search terms were adapted as appropriate for the following databases Embase (OVID interface), PsycINFO (OVID interface), CINAHL Plus, and EThoS and ProQuest libraries

Appendix 6

Online survey

Survey questions, v2, 15.02.2021

The survey might take you between 10 and 20 minutes to complete (depending on how much detail you will go into when answering some of the questions).

You can complete the online survey regardless of whether you/your service have started offering the REACH-HF programme to your patients.

We will not ask you any identifiable information – your survey answers will not be linked to you or your service. Also, we will not share your answers with any other person or organisation (including your organisation).

By completing the survey, you agree to take part in the study.

Section A: About you

A1. What is your current job role?

A2. How would you rate your current knowledge and expertise in the following four domains?

	Novice	Intermediate	Advanced
Cardiac rehabilitation	☐	☐	☐
Heart failure	☐	☐	☐
Exercise prescription	☐	☐	☐
Person-centred communication skills	☐	☐	☐

Section B: About your service

B1. Before attending the REACH-HF training, did your service offer cardiac rehabilitation for patients with heart failure?

Yes ☐

No ☐

B2. **What are the reasons for not offering cardiac rehabilitation for patients with heart failure?**

B3. **Before attending the REACH-HF training, did your service offer home-based cardiac rehabilitation to any cardiac patients?**

Yes ☐

No ☐

B4. **What are the reasons for not offering home-based cardiac rehabilitation?**

Section C: Your thoughts about the REACH-HF programme

You can answer these questions regardless of whether you/your service have started offering the REACH-HF programme to your patients.

C1. **Since the REACH-HF training, have you used the REACH-HF programme at all?**

Yes ☐

No ☐

C2. **What are the reasons for not using the REACH-HF programme?**

C3. **How many patients have completed and are receiving the REACH-HF programme?**

Have completed ☐☐☐☐☐☐☐☐☐☐

Are currently receiving ☐☐☐☐☐☐☐☐☐☐

C4. **What has been your experience of implementing the REACH-HF programme so far?**

C5. **What helps with the implementation?**

C6. **What hinders the implementation?**

C7. **Is your service planning to continue offering REACH-HF?**

Yes ☐

No ☐

C8. **If no, why not?**

C9. **What would need to happen for you/your service to start offering the REACH-HF programme?**

C10. **If one of the reasons for you/your service not offering the REACH-HF programme is the COVID-19 pandemic, are there plans to start offering the programme once the pandemic is over?**

- Yes ☐
- No ☐
- Maybe ☐

C11. **If maybe, what factors are likely to influence that decision?**

Section D: The REACH-HF Service Delivery Guide

The next few questions are about the REACH-HF Service Delivery Guide (a pragmatic resource that might help you/your service implement the programme).

The guide was attached to the survey invitation email and is available from: http://sites.exeter.ac.uk/reach-hf/reach-hf-service-delivery-guide/

D1. **Have you read the REACH-HF Service Delivery Guide?**

- Yes ☐
- No ☐

D2. **If no, why not?**

D3. **Please indicate the extent to which you agree with each statement.**

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
It would be useful to have access to the delivery guide at the beginning of setting up the REACH-HF programme.	☐	☐	☐	☐	☐
The length of the guide is just right.	☐	☐	☐	☐	☐

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
The guide is easy to use.	☐	☐	☐	☐	☐

D4. Any other comments about the guide? What could be improved?

Section E: Your experience of the REACH-HF programme

If you have not started offering the programme please indicate what you believe will happen when you do.

E1. Please indicate the extent to which you agree with each statement.

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
I believe that the REACH-HF programme differs significantly from my usual way of working.	☐	☐	☐	☐	☐
Other members of the team have a shared understanding of the purpose of the REACH-HF programme.	☐	☐	☐	☐	☐
Using the REACH-HF programme substantially affects the nature of my work.	☐	☐	☐	☐	☐
I believe that the REACH-HF programme has a substantial value to the patients.	☐	☐	☐	☐	☐
I believe that the REACH-HF programme has a substantial value to the service.	☐	☐	☐	☐	☐
There are key people (you can include yourself) who drive the REACH-HF programme forward.	☐	☐	☐	☐	☐
I believe that delivering the REACH-HF programme is a legitimate part of my role.	☐	☐	☐	☐	☐
I'm open to working with colleagues in new ways to use the REACH-HF programme.	☐	☐	☐	☐	☐
I will continue to support the REACH-HF programme.	☐	☐	☐	☐	☐
I can easily integrate the REACH-HF programme into my existing work.	☐	☐	☐	☐	☐
I have confidence in other people's ability to deliver the REACH-HF programme.	☐	☐	☐	☐	☐
Work is assigned to those with skills appropriate to the delivery of the REACH-HF programme.	☐	☐	☐	☐	☐
Management adequately supports the REACH-HF programme.	☐	☐	☐	☐	☐
There are sufficient resources available to deliver the REACH-HF programme.	☐	☐	☐	☐	☐
I am aware of reports/articles about the effects of the REACH-HF programme.	☐	☐	☐	☐	☐

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
Other members of the team agree that the REACH-HF programme is worthwhile.	☐	☐	☐	☐	☐
I value the effects the REACH-HF programme has had on my work.	☐	☐	☐	☐	☐
I can adapt/modify the REACH-HF programme to suit my and/or the service way of working.	☐	☐	☐	☐	☐

E2. If you agree, that the REACH-HF programme differs significantly from your usual way of working, in what way?

E3. If you agree, that using the REACH-HF programme substantially affects the nature of your work, in what way?

E4. If you agree, that you can adapt/modify the REACH-HF programme to suit you and/or your service way of working, in what way?

Section F: Your thoughts about the REACH-HF training

We are interested in evaluating different ways of delivering REACH-HF training remotely.

F1. In your case, the training consisted of mostly pre-recorded lecture-style sessions with some group activities/break out rooms facilitated by a host and Q&A sessions with the experts at the end of each day.

	Definitely	Mostly Yes	Mostly Not	Not at All
Was this method of delivery sufficient for you to develop the skills required to deliver the REACH-HF intervention?	☐	☐	☐	☐

F2. How could we improve the training?

F3. Was the amount of live interaction provided enough for you?

- No, I would have preferred more live interaction tasks and discussion ☐
- Yes, the balance was about right ☐
- No, I would have preferred less live interaction tasks and discussion ☐

F4. How important are the following components for successful training?

	Not at all important	Slightly important	Neutral	Important	Very Important
Live lecture-style presentations	☐	☐	☐	☐	☐
Pre-recorded lecture-style presentations	☐	☐	☐	☐	☐
Large group activities (approximately 20 trainees) for general discussions and brain-storming	☐	☐	☐	☐	☐
Small-group activities (2-4 trainees) for practising delivery or discussing specific issues (like how the intervention might be integrated with your specific service), peppered throughout the pre-recorded presentations	☐	☐	☐	☐	☐
Engaging host	☐	☐	☐	☐	☐
Q&A sessions with experts at the end of each day	☐	☐	☐	☐	☐
Q&A sessions at the end of each pre-recorded lecture-style presentation	☐	☐	☐	☐	☐
Case studies	☐	☐	☐	☐	☐
Input from teams already implementing the intervention	☐	☐	☐	☐	☐

Section G: Thank you for taking the time to complete the survey!

G1. Would you like to receive a summary of our research report?

- Yes, please ☐
- No, thank you ☐

G2. **If yes, can you please send a blank email titled "study report" to the following email address: pxd891@student.bham.ac.uk or alternatively text "study report" to 0759 555 0720.**

Feel free to add any comments about the study or the survey itself into the comments box below.

G3. **Feel free to add any comments about the study or the survey itself into the comments box below.**

Appendix 7

Standards for Reporting Qualitative Research checklist

	Standards for Reporting Qualitative Research (SRQR)*	
	http://www.equator-network.org/reporting-guidelines/srqr/	
		Page/line no(s).
Title and abstract		
	Title - Concise description of the nature and topic of the study Identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended	146
	Abstract - Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions	147
Introduction		
	Problem formulation - Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement	150
	Purpose or research question - Purpose of the study and specific objectives or questions	153
Methods		
	Qualitative approach and research paradigm - Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., postpositivist, constructivist/ interpretivist) is also recommended; rationale**	153
	Researcher characteristics and reflexivity - Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between	68

	researchers' characteristics and the research questions, approach, methods, results, and/or transferability	
	Context - Setting/site and salient contextual factors; rationale**	151
	Sampling strategy - How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale**	153
	Ethical issues pertaining to human subjects - Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	155
	Data collection methods - Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings; rationale**	153
	Data collection instruments and technologies - Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study	154
	Units of study - Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	153
	Data processing - Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/de-identification of excerpts	153
	Data analysis - Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale**	154
	Techniques to enhance trustworthiness - Techniques to enhance trustworthiness and	185

	credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale**	
Results/findings		
	Synthesis and interpretation - Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	156
	Links to empirical data - Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings	Appendix 8, page 331 Appendix 9, page 340
Discussion		
	Integration with prior work, implications, transferability, and contribution(s) to the field - Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/generalizability; identification of unique contribution(s) to scholarship in a discipline or field	175
	Limitations - Trustworthiness and limitations of findings	179
Other		
	Conflicts of interest - Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed	None
	Funding - Sources of funding and other support; role of funders in data collection, interpretation, and reporting	Paulina Daw's time was funded by the University of Birmingham
	*The authors created the SRQR by searching the literature to identify guidelines, reporting standards, and critical appraisal criteria for qualitative research; reviewing the reference lists of retrieved sources; and contacting experts to gain feedback. The SRQR aims to improve the transparency of all aspects of qualitative research by providing clear standards for reporting qualitative research.	

	**The rationale should briefly discuss the justification for choosing that theory, approach, method, or technique rather than other options available, the assumptions and limitations implicit in those choices, and how those choices influence study conclusions and transferability. As appropriate, the rationale for several items might be discussed together.	
	Reference:	
	O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. Standards for reporting qualitative research: a synthesis of recommendations. *Academic Medicine*, Vol. 89, No. 9 / Sept 2014 DOI: 10.1097/ACM.0000000000000388	

Appendix 8

Extended Table 10 Barriers to implementation of REACH-HF with quotes

NPT construct	Barriers	*Quote*
Differentiation		
Communal specification	Confusion about patient criteria	*'Originally they, we didn't, it was because we didn't have a fair understanding of patient criteria' Site 1*
Individual specification	Initial trial-and-error with operationalising the intervention	*'I think, initially, because, obviously, you know, we didn't really know how to approach it, so there was a bit of a trial-and-error.' Site 3*
Internalisation		
Initiation	Lack of implementation plan	*'Lack of plan.' Survey participant*
	Lack of champions	*'Lack of 'drivers' in the service.' Survey participant*
Enrolment	Routine of delivering group centre-based programmes	*'We were, kind of, very stuck in, in moving with technology and now we realise we can do things differently.' Site 4*

	Practitioners being away from core cardiac rehabilitation duties/team being stretched	*'We're, we're taking, I suppose, people away from, what we would say is… their core responsibility across the two different services in order to implement something else.' Site 2* *'We were a bit stretched, incorporating [the REACH-HF] directly on top of the existing service.' Site 3*
	Low team morale and lack of enthusiasm for REACH-HF	*'The tensions that we're going on in the teams at the time and the kind of negativity that was particularly apparent in one team.' Site 2* *'Not everybody was fully on board with the concept or felt that patients that they have offered it to, didn't really want it or like it or, you know, or maybe, or maybe it was just down to the sometimes enthusiasm of different members of the team and using it.' Site 4*
	Challenging personal circumstances	*'There're also individuals... they have their own family, the work-life balance issues, so there have been some stresses associated with things outside of the project, but they can't help impacting on, on the delivery of the project.' Site 2*
	Poor communication with heart failure team	*'I think, probably, where we fell down is, probably, that link and communication and making sure, maybe our heart failure colleagues have really a better understating of what we were doing and how we were doing it.' Site 4*

Legitimation	Initial hesitation about being part of project	*'Everybody wants to do a good job and not, not fail. You know, start something and not be able to finish it, so there's always been, you know, a difficulty, not wanting to start something that, perhaps, they thought they could not finish. Which is probably, why they were reluctant to take it on... not particularly wanted to do it in the first place.' Site 2*
Activation	Perception REACH-HF in its current format as not implementable	*'I don't think, we would be able to offer it in the current format, climate if it all was home-based.' Site 2*
Interactional workability	Additional time	*'I think, it does require more time on individual nurse bases.' Site 2*
	Additional cost	*'I think, it takes a lot more resources than our set programme and, obviously, for that reason, it would be more costly.' Site 2*
	Additional admin	*'The other thing I should say – there is a lot of admin work that is behind applying this programme, because we have to do all the letters, sent out the letters and book the appointments, so there is an awful lot of admin time.' Site 2*
Relational integration	Higher opinion of centre-based provision	*'I think, because the thing is, the problem that I've had, is because I've known what we've got here. I've been leaning towards here, but I think we do offer more and we have more facilities here. Because of the service that we give here, because we push*

		them so much more. I think the level of exercise they are getting is better here than they do from the DVD.' Site 1
	Negative opinion of REACH-HF resources	***DVDs are outdated*** *'Particularly with the DVD, I think, you know, that was, perhaps, is an outdated mode of communication. I don't think, it helped the practitioners in, in getting this off the ground.' Site 2* ***Technical problems*** *'The only issue, that we are having is the DVDs, it can be very frustrating when we are going out to patients and the DVD isn't working or it's not going onto the right level.' Site 1* ***Written resources are too lengthy*** *'But others, again, haven't really read it. So for some people, if there is just too much written word, you know, they don't look at it.' Site 2*
Skill set workability (including REACH-HF practitioner's training)	Disinclination for lone working	*'Others prefer to work as part of a team and set clinics rather than that, that lone working.' Site 1*
	Disjointed working between cardiac rehabilitation and heart failure teams	*'In our case heart failure team is spread over three different sites and working separately from us.' Site 4*

	REACH-HF training not well-pitched to audience	*'I think, a lot of what the training focussed on was all… the behaviour change and motivational interviewing and that type of thing. And, I think, because of our background, we, kind of… Not that we knew it already, but we've got our skills, we've got our knowledge in those areas. And, for me, I, kind of, fell like it needed more – this is the booklet, this is what's in the booklet, this is what we want you to do at each appointment and I don't really think that was covered.' Site 1*
Contextual integration	Lack of time allocation	*'I'm not given set days to do the actual work. I've got to fit it in around. So it's a bit sporadic.' Site 1*
	Lack of staff	*'We haven't… we haven't recruited extra staff to deliver this extra service – we've done it from existing resources.' Site 2* *'Yeah, we've never got enough staff, we are always…we are a couple of vacancies down.' Site 1*
	Staff redeployment due to COVID-19	*'Many staff have been redeployed so hasn't been feasible to expand our current service.' Survey participant*
	Commissioning structure	*'As far as we are concerned here at ***Location 2*** care services, we don't deliver… we are not commissioned to deliver a rehab service for heart failure patients.' Site 2*

Systematisation	Time required for evaluation	*'I, particularly, haven't [engaged in evaluation]. But it's, probably, a lot of time on top of that.' Site 1*
	Task of evaluation lies with management	*'I think more the manages are.' Site 1*
Communal appraisal		
Individual appraisal		
Reconfiguration		
Non-NPT barriers		
Patient-level factors	Multimorbidity patients	***Frequent hospitalisations*** *'I've got three patients on my caseload at the moment, who are all, kind of, doing REACH heart failure, and they've all, kind of, had their individual medical problems, that have stopped me from starting any exercise with them. So, one of them has ended back in hospital and the other one just wasn't feeling up to it at the moment. So it's that side of it as well. The patients that we tend to be getting through for REACH heart failure, tend to be the quite poorly patients and it can be quite difficult for them, kind of, getting them to a point where you can exercise.' Site 1*

		Not stable to exercise *'A lot of these patients, you know, have other health issues or they have an exacerbation of heart failure and there are times that their health, kind of, take over and they can't exercise for a few weeks, because they have a chest infection or a urine infection.' Site 2* ***Additional time*** *'Because it is a home programme, although not all patients need a lot of face-to-face contacts, I would say most of them, because of the average age of our patient group – they are above 70 and a lot of them are in their early 80s, early 90s, so they do need face-to-face contact, so it is more time-consuming in that respect.' Site 2*
	Engaging with technology	***Lack of DVD players or internet*** *'None of the patients managed to get the DVDs to work. And, I think, a few, actually, maybe dropped out for that reason – they don't have a DVD player or they don't have internet, or they have internet, but they are not able to use it, you know, they are more elderly patients, who live on their own. And, I think, they see it as too much of a challenge and, you know, we have had a few drop out after a few weeks of starting and, I think, that, that might be one of the reasons – just the technical issues.' Site 2*

		Not being technologically savvy *'And the IT issues, you know, we have had so many patients who had so many difficulties with the IT, you know, and maybe it is due to their age, because a lot of our patients are very elderly and I suspect it is.' Site 2*
	Apparent lack of improvement following REACH-HF	*'She was clearly fitter, more mobile. She's now got back to yoga classes and she's doing amazing, but when she came in to do the walk test, she was worse when she came back. But that's only because her daughter was with her and was saying, 'Oh, you can sit down now' and she was talked out of it. If the daughter wasn't there, she would have done more. On paper it looks like she has not done as well as I should have, but, without sounding rude, I didn't really care, because I know she has. So when I said 'on paper'… I know she has done better. But to be honest, that experience has been quite good because now, unless someone's really anxious and they need their partner or their daughter or son in there. We just say 'No, go and get your cup of tea, you sit outside' and let them do it on their own. So, it's all kind of worked in a way.' Site 1*
	Expectations and preferences	***Lack of motivation*** *'I have had a few patients, who haven't continued on REACH because they are not motivated to do it at home and do the video.' Site 2* ***Preference for group-based programmes*** *'They much rather go somewhere every week.' Site 2*

		Dislike of home visits *'For one lady – she didn't want us to come to her home.' Site 3*
Geographical factors	Size and type of patch	**Large catchment area** *'I think one of the main issues, I think, for us, is the fact that we are a rural county and, you know, the distance between patients from, perhaps, where the base of the service is to where the patients are is, is significant. You know, we're not an urban sprawl, where, perhaps, clinics are easily accessible a) by the patients and b) by the staff. Where you can park up and walk to the venue. For us, there is a considerable, kind of, half a day involved in setting up a clinic and making sure people get to the clinic, so, I think, from our perspective is geography – that's an element, most definitely.' Site 2* ***Transport issues*** *'Home visits are not always easy. And for another gentleman, he was really, quite a distance. We had like two, two different buses and, I think, it took us over an hour to get there and an hour to come back. So that was not a terribly good use of time.' Site 3*

Appendix 9

Extended Table 11 Facilitators of implementation of REACH-HF with quotes

NPT construct	Facilitators	Quote
Differentiation	Good grasp of difference between REACH-HF and usual service delivery	*'I suppose the main difference really is that we are going out into their homes.' Site 1*
Communal specification	Good grasp of purpose of REACH-HF	*'Most of the nurses, that I am supporting in heart failure and cardiac rehab, undoubtedly, understand the benefits of offering a rehab service to those patients who have heart failure.' Site 2*
	Agreement that REACH-HF adds value to service	*'It's just, it's kind of, added another thing to be able to offer patients. It's always going to be, it's always going to be good and have a benefit and have positive effects, when we've got something else that we can offer a patient who's sitting in front of us.' Site 1*
	Initial dissemination of purpose and structure of REACH-HF	*'One of the things that we did when we came back from the training was we, kind of, put together a little presentation that we took to the team meeting and just went*

		through everything. All the referral criteria and everything that we do with them.' Site 1 *'So that's for us to try and, maybe go out and just see the [heart failure] service and promote REACH-HF.' Site 3*
	Awareness of service gap	*'So, you know, it's, it's been a long time coming. And the home-based is a good next step for that. Because we've got higher than average incidence of heart failure on the ***Location 1***.' Site 1*
	Clear vision for REACH-HF	*'I think, that's our main goal, really. Because, as I said, we see a lot of patients, who maybe other rehab services don't, so for us, it was about people who can't get to us, they're the ones that we wanted to get involved with REACH heart failure. We see the benefit of it for them.' Site 1*
Individual specification	Clear procedures and increased efficiency	*'We've got it more efficient now.' Site 3*
Internalisation	Good grasp of value of intervention to heart failure population	*'Obviously, there are people who can't get in, to exercise and it is beneficial for them to do that. So, I, definitely, think, it's good for the patient to be able to take part in the cardiac rehab service when they cannot get out and about and build up their strength*

		and their fitness and then they can start going out and become more independent and mobile.' Site 1
Initiation	Availability of champions	Whole team *'It's the entire team.' Site 1* Organisation *'I think, I think… it's started probably… I think, the main factor would be the organisational factor to get involved. Because, I think, the organisation wanted this as part of a transformation work that is going on across the NHS. I think there was a significant amount of organisational... not pressure, but the organisation wanted it, essentially, it was a fait accompli [a thing accomplished and presumably irreversible] that we will do it.' Site 2* REACH-HF practitioners *'So driving it forward, I think, the three of us who done the training and who, you know, made this commitment to see it through and, you know, get the patients.' Site 3* Single practitioner *'Yeah, probably just me. Yeah, I would say, probably me. And, and actually, I suppose, L***, who trained after the three of us trained, probably would have been another person.' Site 4*
	Identification of potential referrers/referral streams	*'The entire, hopefully, community heart failure team. They are where we are getting the vast majority of our referrals, because they're the ones seeing these patients in their homes. So, yeah, all of them.' Site 1*

Enrolment	Strong endorsement for REACH-HF	*'But, yeah, definitely, there are people that they will see at assessment and they will be really eager to exercise, but can't get to one of our centres. And, yeah, the team will tell them how good the programme is and really promote it.' Site 1* *'So they've pretty much bought into it as well. Which is good, because that means that they are, sort of, including it in the… in the assessment they include REACH very openly, very easily as one of the repertoire of things that we could offer.' Site 3*
	Interest in heart failure	*'Well, I was quite excited, because I recently studied… I did the heart failure module and so I wanted to, kind of, put into practice the theory I've learnt on that.' Site 2*
	Effective communication	Within cardiac rehabilitation team *'It's always an agenda item on our meeting that we go through at every, at every, kind of meeting. Juts to bring up anything that we, that we need to.' Site 1* Between cardiac rehabilitation and heart failure teams *'We keep reminding them [heart failure nurses] that this is a, a good option for some patients who they might not otherwise think of referring to us, because they know that they're relatively house-bound, or that their situation wouldn't really follow the traditional rehab expectation.' Site 3*

Legitimation	Feeling positive about involvement	*'Good. Excited. I like new things. So I… I prefer to be busy so it doesn't bother me.' Site 1* *'We know we've got something new to do and we're actually quite enjoying doing it.' Site 3*
	Feeling positive about challenge of introducing REACH-HF	*'Yeah, so, I think, it's been… it's good to, to have something that comes in as a new challenge. Because, it's very easy just to carry on delivering… if you're busy and you carry on delivering the service in much the same way. It doesn't really challenge you to think to yourself and… how would we… or could we change it?' Site 3*
	Being part of innovative team	*'I think the facilitators were… the rehab team is not afraid of change. They've done so much change. You know, they've done bigger change projects. That we've, we've, you know, totally redesigned our rehab. We are always looting to, to… For ways to better our service and do things better.' Site 1*
Activation	REACH-HF part of service going forward	*'Hopefully, it's still, it's still there, and it's a…. It's another choice, hopefully, we'll still got it.' Site 1*
	Watchful waiting	*'I think it's going to be a decision... more about when we get through… up to the, the 50 patients. As asking the big questions… have we… can, can we do this in parallel with everything else that we are trying to do?' Site 3*

	Implementing REACH-HF post COVID-19	*'I think, with COVID actually so many people now are embracing novel virtual approach.' Site 4*
Interactional workability	Gaining balanced perspective of time involved in delivery of REACH-HF	*'So, that's quite interesting as well, because we thought that was going to take us more time, but, I think, by that stage, we have settled into a process and a format, so we were more efficient ourselves in how we were doing it.' Site 3*
	COVID-19 led to changes in service provision	*'It's definitely, with COVID realised that, yeah, you know, we can do a lot more home-based stuff with people and we are probably getting better at it and seeing advantages of different types of programmes. I think, now [post COVID] that we can use cameras and, and go out to people virtually and talk to them and see them, that's, actually, it will make it less labour intensive. I think, in the future, you know, we don't actually having to leave the house, or wherever you are working to go to somebody's home and travel back.' Site 4*
	Good fit with service and with patient	*'[Implementing REACH-HF has been] dead easy, yeah, it has. It's slotted in well, because we haven't had to make any changes, because the patients would have been accepted anyway.' Site 1* *'I think, we were fortunate because we had our completely, sort of, open self-management style not a didactic, prescriptive rehab approach in our own programme*

		anyway. So there was nothing hugely new in how we were asked to deliver it. You know, when we came up to, Edinburgh and… This, this sort of self-management, facilitation approach is our style, is exactly what, you know, what we're doing anyway. So, I think, we were lucky that, that didn't come as a huge shock.' Site 3
Relational integration	More objective opinion of centre-based	*'The problem with the centre, if I'm honest, is, particularly people with heart failure, when they come to the class, or I shouldn't say just heart failure, people who are less mobile and slower, it takes a lot longer to, it takes a whole afternoon for them sometimes, like booking people in. Whereas if you hand it them the exercises and they can do it at home, they can do it in their own time. It doesn't take the whole afternoon.' Site 1*
	Positive opinion of REACH-HF resources	Written resources are just right – *'Even when I look at the pack and I, you think that's a lot to read through. But, I think, they're written really well, so.... People read them at their leisure…' Site 1* *Being able to use the friends and family resource – 'I think, having that booklet that you can give them, to the family or the cares or the friend is really good to get them involved'. Site 1*

	Trust in intervention and each other	*'But in terms of the intervention, I think, that it works.' Site 1* *'We are a really good team, we work really closely together.' Site 1*
	REACH-HF practitioner's peer support	*'So, we've been discussing clinical and rehabilitation issues relating to the individual patients that we've got. In order that we can, you know, help and support each other… maybe on decision-making and or share the patients.' Site 3*
Skill set workability (including REACH-HF practitioner's training)	Preference for home-visits	*'I love it, I would say. I've had years of home visits and I absolutely love REACH, because it opens up a bigger picture of people's lives, which we don't see here. It's a wonderful relationship, because they are very motivated and we know them for a long time, we know them for at least 12 weeks. But with home visits… it allows for a different relationship and I love it, absolutely love it! ' Site 1*
	Close working with heart failure team	*'We've got such a good community heart failure team and, I think, that helps, having the team, you know, across the way from us, because, I've noticed, you know, we don't have to go to an acute setting to get that back-up from them. If we've got any concerns about a patient while they are here, then we'll just get the girls to come and have a look at them.' Site 1*

	Choice of REACH-HF practitioners	Self-selection – *'I think the people that we've got doing it are de… definitely the best people for it. Definitely. They've put themselves forward for it. Yeah, and we knew that, that they're the best people to do it.' Site 1* *Personal attributes – 'I think, we've chosen well. I think, we've chosen three motivated practitioners, very competent. I think one individual needed something to increase her confidence and to underline her ability within her role and the other two practitioners, they are very experienced, competent, motivated practitioners. So, I think, we've chosen well, which is why we are able to push on… push through the competent conscientious practitioners. So, I think, that was... what is important is, you know, is your rationale for who you've chosen to carry out the project in the first place. It's quite important and, I think, the decisions we have made and the people we've picked seems to be correct.' Site 2* *Training more than one individual – 'I think, that's why, it was clever and good that… there were three people that had to go on the training. Which made it a multi-disciplinary team approach, because it was, you know, our lead nurse, myself and then exercise instructor. And I think it's, I think it's really important that… for it to be… to be able to deliver you need a team. And for the training itself to [be delivered]… right from*

		the outset, not to one individual. Because, it would be quite a burden on one person, I think.' Site 3 *Experiences of working with multimorbidity patients – 'I think, we're lucky because, we… J*** and I always believed that… I don't know that there are lots and lots physiotherapists involved in programme as heavily as I am. But we've always believed that for the multi-comorbidity patients and particularly those who are, the sort of, more complicated, like the heart failure patients. The… and the people that we're seeing are, you know, [are] much more still in their clinical stage, that our skillset of physiotherapists with line managing and leading exercise instructors in parallel with the nursing team, gives as a really strong ability to handle complicated patients. Site 3*
	Skills combination	*Cardiac rehabilitation, physiotherapy/exercise physiology and heart failure 'Yeah, I think, we were, kind of, selected based on our roles. So, obviously, my background is exercise physiology and we also have J***, who is a cardiac rehab nurse and R*** is a heart failure nurse. So, I think, having those three different roles work really well, because we all bring different things and can help each other. Myself, J*** and R*** meet up every four weeks, juts to have a chat about things. Kind of, we have a chat about the patients that we are seeing any issues or concerns. And, I think, the fact that we've got the three different, kind of, roles, kind of, works really well. Because, all*

		three of them [roles] are, kind of, what we need for REACH heart failure. So, I think, that all, all works really well together.' Site 1
	Improvements to REACH-HF training	*Making it more practical – 'I think, we just needed to know – this is how you do it, you either invite patients to clinics or you go to see them at home, you do the assessments. I think, it needed to be more practical, it needed to be brought back into more the practicalities of the reality of how you might implement it as a team, depending on the environment you are working, where you are, etcetera I mean, you are going to have so many patients each and you are going to see them at home and you do this and do that.' Site 2* *More emphasis on the exercise component – 'So, I think, there wasn't enough emphasis on the exercise and what they actually wanted… Because when we have seen the DVD, we've seen it after the training. And there were a few questions about exercise that we all could have asked, which would have been more… Because that's what we are going to deliver.' Site 1* *'Because we didn't do the incremental shuttle walk test – we needed training on that and, really, I would have liked that as an example on the training and more specific guidance on how to do that test.' Site 2*

		Input from previous implementers – *'I think, as well it would have been good to have nurses on that training, who actually, you know, implemented this programme and share the difficulties they have had. It would be good to know, how did they overcome [technological issues], it would be good to know all that.' Site 2* Shorter modular online training *'I probably felt the training could have been shorter or… maybe elements of it now [post-COVID] probably are going to be delivered virtually as well, so that makes it easier for people to attend training. And maybe a little bit less on heart failure management, but maybe have a module, if there are people who are not knowledgeable at heart failure management. Maybe, it could be more modular based or something that people could be… If they already have a certificate for something and they have done this before then maybe they could just have a shorter version of that and somebody doing a longer version.' Site 4* Having more in-depth pre-training reading around self-management approach *'I felt that, probably… If the teams that are choosing to do it didn't really have a, sort of, self-management approach, it might have been more useful to have a bigger, pre-course or pre-training, sort of, reading material and maybe some, sort of, exploring that with people before they, they went on the clinic. Site 3*

		Recommending pre-training course (the BACPR heart failure exercise or activity training course) – *'And, I think, there would have been some benefits since it is, it is a heart failure population to have looked at the established BACPR heart failure exercise or activity training course. Because that would have given anybody who is intending to go and expand their delivery of heart failure rehab, to've gone in already with a baseline of knowledge on activity, assessment and exercise prescription. Because, there are quite a lot of differences in… I mean, that's why, that course, that day course was set up. Because, there are a lot of concerns amongst people in rehabilitation, who are more the general rehab people, that they don't know how to manage the needs of the complex heart failure patients. And, I think, that would have been good. Because, it is quite a… I mean, I think, the 12 of us that were there, probably, would have said that it is, a quite… a big thing to go away with trying to, sort of, handle a new, sort of, functional capacity assessment, like an incremental shuttle walk test in the context of maybe not having confidence in some of the differences in the patients with heart failure versus the more regular traditional, just: bypass, graft and MI'. Site 3*
Contextual integration	Protected time	*'Now I have got a day a week, which makes things so much easier. Because you want to do... you want to, kind of, implement it as well as you can. So you know, you have to allow the time to do that. Site 2*

	Management is proactive	*Securing additional funding 'We have different income streams as well. So it's about, you know, how can we look at investing that income, you know, if we do, say, I've got an opportunity to do some practice nurse teaching, not me – the team and there might be some money that comes in from that. So say if we get two thousand pounds from that, what do I do with that? Right, oh well, okay, I could get 40, which, you know. So it's about, just thinking more fluidly about how we could deal with that.' Site 1* *Redesigning service 'We are considering how we can streamline cardiac rehabilitation and make it work better. We've just, we've looked at how we provide our service, to provide it better, leaner.' Site 1* *Offering flexible rehabilitation 'So we can really, from the beginning, we can, we can try and gauge with, you know, conversation with the patient and their family or carers what's best for them. And make sure that we're able to deliver that and by doing that, we should be able to use our resources well. So somebody who is 45, who's had an MI in a PCI, you know, they, you know, I'd like to have some, some online learning mixed in with evening gym sessions, that kind of thing, not quite as labour intensive for the staff, or they might even go off and do their own exercise, but keep in touch with us by the phone. And then, then we have more capacity to do the more labour intensive home-based rehab. And then there's everything in between. So that's why it fits in*

		nicely and it shows the breadth of the, the needs of patients, who attend any kind of long-term rehabilitation, really.' Site 1
	Commissioning structure	*Being block contractor 'Because we are community-based centre, we are not tied to the hospital. So we've always been given, we are a block contractor, we've always been given a pot of money to do with what we will.' Site 1*
	Support from management	*'My boss, they will pretty much work around you, they allow you to have your own workload and try and fit it in without affecting my heart failure job. So the leniency has been amazing. So that helps.' Site 1*
Systematisation	Planned, formal evaluation (by management)	*'We will be. Yeah, that's part of the thing, we want to put something together for… we're going to audit it all and we want to put something together for BACPR conference next year. And we've got a newsletter as well, that we're, we're looking at putting out for patients twice a year. So we're going to have to do something for that too.' Site 1* *'Yes, we are. Obviously, the first lot of data are not available yet, because we haven't completed the first 12 weeks. But, yes, we will be looking at the data so far for each cohort and see what it's telling us and what the benefits have been to the patients and will certainly use that in any business case or review of the service. Certainly, it will go*

		into, kind of, KPIs, really, and the reporting structure. For example, how heart failure has been done this year and, yes, it will be used as a reference to have the benefits of it, definitely yeah.' Site 2
	Reflective, informal evaluation (by REACH-HF practitioners)	*'I think probably as we go along. You are, kind of, reflecting on it all the time. I think, initially once we got over the "How do we do this?!", you know...' Site 2*
Communal appraisal	Developing more balanced view of intervention and implementation process	*'Obviously, that's taken our time away from the cardiac rehab programme that's here. But, again, because of the benefits for it, I think… I don't [think] that's a necessarily a massive, a massive negative.' Site 1* *'I think overall, you know, it's, it's positive… it's seen as a positive thing. Despite the, kind of, extra work that is associated with it.' Site 2*
Individual appraisal	Job satisfaction	*'And it can be really, it can really beneficial and can give you a really good job satisfaction to go out and see people and see what we are doing is really… is improving their lives.' Site 1*
	Continuous professional development	*'The exercise instructors see it as another, sort of, skill for them, more knowledge, to gain through the, sort of, structure of REACH, etcetera. So they're been quite positive, it's a personal development thing for them.' Site 3*

	Positive feedback from patients	*'Because the patients we see, the patients who are on the programme – they want to do it. They are, they are eager to take part and do something as well. So you are, kind of, working of the feedback you get from the patients. So they are eager to take part and eager to do anything to improve their quality of life.' Site 2*
Reconfiguration	Fully home-based programme	'We *wanted to try and keep it to, to similar as we were, kind of, told about it. I think our main thing was that, we didn't want to start bringing patients into the, into the centres for these things. We wanted to keep it as what we thought it was – a home-based programme, so we go to them rather than they come to us. And, you know, we shouldn't be integrating it into our traditional rehab. Because we've got the traditional rehab. You know, we should be using it for the purpose that it was designed for.' Site 1*
	Fully remote delivery during COVID-19 pandemic	*'Have adapted to COVID situation by offering more remote contact to patients and selective home visits. After being redeployed and working in Telehealth for the last 2 months, consideration has been given as to how we can possibly incorporate telehealth monitoring in the future to support monitoring of our REACH patients whilst they are on the 12-week programme. eg. Weekly pulse, BP, weight, Sats measures. Our exercise physiologist team members have adopted a TUG test to use as an exercise assessment tool within the home for REACH visits.' Survey participant*

	Smoother enrolment onto programme	*'Whereas now, we actually send the manual out to them before we see them. And we asked them to make sure they try the DVD and or get online and are able to access the website okay and are able to read. We ask them to familiarize themselves with the content and what the programme entails. So we do that now, so we are much more prepared. So, we send them out the invite letter and the manual two weeks before we see them, to give them a chance to look at it. And, actually, we have had a few, who then turn around and said "No, we don't want to do it", even before they get to the assessment which then, you know, it's better for them and us because it means we don't go through the whole assessment and the walk test and then they say, actually, it's not for them. So, yeah, and for some of the patients as well, we will ring them beforehand, because they have lots of health issues and we do as much of the assessment over the phone as well. Just so we can troubleshoot before we see them. And then they get started on the programme, I think, more smoothly.' Site 2*
	Reduced home visits	*'So it's evolved really, but we are, we are doing in, pretty much, in the style intended. We maybe don't have as many home visits.' Site 3*
	Home/centre hybrid	*'We are sort of, I think, I've said way back at the beginning, that… there are maybe ways that… we are refining it already. That we think may be useful and sometimes in life… is a little bit of a hybrid, that you end up with, something where you're, sort of,*

		between people who really just absolutely can only manage to do this on their own at home and other people with whom they really do still want a little bit of coming to the hospital in inverted commas for their... to receive their care. It's try to make sure that the patient feels that they're getting the best deal, really. So, we actually did try different styles in order to try and have a lesser impact on the one-to-one nature of things. We thought we could, maybe, be more efficient, if we had three to six people come for the introductory explanation of the resources and a more general nature of introducing programme. They all still had our highly individual assessment and one-to-one interview, but we tried to incorporate a little bit of giving the information out in a small group fashion, which actually, let those who were keen to have a look at those social contact to have that as well..*' Site 3*
	Group centre-based programme	*'In a group and do it with someone face-to-face and then they have got that social aspect of it as well and the opportunity to, kind of, get feedback or ask any questions. I think if we could also, kind of, modify version to heart failure patients in which we could invite them into a group. I think, it would be much more attractive and cheaper and easier to implement. I think you should be able to have, you know… either offer them a home-programme or a version of it in a group setting. It is something that I*

		have discussed with my manager and, I think, she would like to be able to offer a version so we could include just heart failure patients in cardiac rehab.' Site 2
	Inspiration for better service delivery in general	*'I suppose, it is looking at how we can adapt from, you know, what we've seen through REACH-HF and what we can provide to those heart failure patients. Perhaps, with a larger audience and it might be that we do that through an application on a tablet or a smartphone or something.' Site 2*
	Amendments to REACH-HF resources	*Careful wording – 'So, the resources, maybe, maybe the chair-based programme… I had some thoughts myself that, maybe, they didn't necessarily need to be called chair-based, it could, perhaps, be lightly refashioned in the name.' Site 3* *Simplified version of exercises – 'Other people… they weren't, sort of, so much concerned about that, but they didn't actually want… such a big thing to deal with, they basically just wanted a much smaller set of exercises to do. So, we have, actually, talked a bit about whether it might be useful to have a supplementary illustrated booklet, with just provided a little synopsis of some of the exercises, a little bit like we do ourselves. Which for those who don't really want to labour through all the different levels or who simply don't have the wherewithal to, sort of, cope with doing that, they're quite keen on… when we give them a little illustrated booklet of exercise. They, sort of, latch on to that. Site 3*

		Online resources – 'They just want to be able to access it, you know, on the tablet or the laptop. Because then people with visual impairments can make the print bigger.' Site 2
Non-NPT facilitators		
Patient-level factors	Simplified version of exercises	*'In some of the patients, who are much more complicated maybe with rheumatoid arthritis and other co-pathologies, they've resorted back to not wanting to have a… too challenging a programme to follow. They want a more simple format of some exercises to do and to repeat. So, we had to resort, for some of them, and just giving them basic exercise leaflets again. Because of them not wanting to do the excer… the chair-based programme. And they haven't, maybe, been able enough to really take on the walking programme as their only activity plan, you know, they need some supplementary exercise.' Site 3*
	Overcoming technological issues	*'We've just purchased some DVD players as well, so that we can, kind of, go out if they haven't got a DVD player, we can loan them one.' Site 1* *'A lot of patients we had in clinics they've got smartphones, so when we see them in clinics, we've actually download the website for them and save it onto their phone. So we are doing that as well. So we are becoming IT technicians as well.' Site 2*

	Expectations and preferences	Preference for home-based programme – '*I think, obviously, going out into, into their home and being able to speak to them in their environment, where they are comfortable, with family, friend or carer that will, obviously, help them.' Site 1* Motivation for home-based programme – *'And I think they [patients] were motivated, they were. And that helps'. Site 1*
Geographical factors	Size and type of patch	*Small catchment area 'A much smaller geographical area, so it will be easier for them to manage.' Site 2* *Availability of transport 'It might be easier with a better transport links.' Site 2*

Appendix 10

A detailed overview of barriers and facilitators relating to the NPT components

1. Differentiation

All interviewed participants had a good grasp of the difference between the usual service delivery and the REACH-HF programme (differentiation); the most frequently quoted distinction between REACH-HF and prior service delivery was seeing patients in their homes.

2. Communal specification

Mostly, interviewees confirmed a good grasp of the purpose of the intervention amongst members of the wider team (communal specification). The participants were aware of a service provision gap and healthcare inequity affecting patients with heart failure. There was agreement amongst participants that REACH-HF added important value to their services. Effective dissemination of the purpose of the intervention following the initial training was an important part of developing differentiation and communal specification. There was agreement between interviewees that the more people that know about the programme the better. Tasks associated with building the communal specification were seen as the responsibility of the REACH-HF practitioners who attended the initial training. Staff working at Site1 had a very clear vision for the intervention – offering it to patients who were not able to attend centre-based programmes. The only identified barrier linked to the communal specification was initial confusion about patient criteria.

3. Individual specification

Staff at all Beacon Sites spoke about a period of trial-and-error at the beginning of the implementation process when they were trying to make sense of the work and specific tasks required to deliver REACH-HF (individual specification). Over time the initial teething difficulties were mostly replaced with clear procedures and efficiency.

4. Internalisation

All participants had a good grasp of the value of the intervention concerning the heart failure population (internalisation).

5. Initiation

There were differences between the sites in terms of who or what was driving the implementation forward (initiation). At Site 1, champions included the whole of the team. At Site 2, it was the organisation that was propelling the implementation forward. Incidentally, the strong organisational push at Site 2 resulted in an initial lack of buy-in from the REACH-HF facilitators at this site. At Site 3, the three REACH-HF facilitators were the main driving force behind the intervention, followed by a heart failure nurse running a community-based support group. At Site 4, initially there was just a single individual who took on the role of a champion, this person was joined by a newly trained member of the team a few months following the initial training. All participants agreed that the potential referrers, most often heart failure nurses, were an important part of the initiation process.

6. Enrolment

Several different reasons were highlighted at the Beacon Sites when it comes to each team's capacity and willingness to implement REACH-HF (enrolment). The main barrier to enrolment was being in a routine of delivering group centre-based programmes, followed by the REACH-HF programme being implemented alongside the usual service delivery, leading to the team being stretched. Another barrier to enrolment was low team morale and a lack of enthusiasm for the programme, albeit the two latter barriers got better with time.

> *'Now we are in a different place, so it's not quite as negative as it was first perceived.' Site 2*

> *'Change takes time with some people, some people move a little bit faster than others in accepting change and new ways of working.' Site 4*

One interviewee emphasised that enrolment can also be negatively impacted by healthcare professionals experiencing challenging personal circumstances.

There was a very strong endorsement for the intervention amongst the wider team at Sites 1 and 3. The ability of staff to buy-in to the intervention was positively impacted by having an interest in heart failure and effective communication. The latter included communication within the cardiac rehabilitation team and between cardiac rehabilitation and heart failure teams. Poor communication, particularly with heart failure nurses, had a very detrimental effect on the implementation process at Site 4. Due to a lack of referrals, staff working at this site treated only a handful of patients and struggled to get the programme off the ground.

7. Legitimisation

Participants at Sites 1 and 3 felt very positive about their involvement in the REACH-HF project (legitimisation). An initial hesitation about being part of the project was identified at Site 2 (linked with a strong push from the organisation to implement the programme and a diminished capacity within the team), however, the initial hesitation about being involved in the project got better over time.

A stronger legitimisation was linked with healthcare professionals feeling positive about the challenge. Being part of an innovative team and prior experiences of dealing with change were factors that can strengthen legitimisation. These were identified at Site 1 only.

8. Activation

Levels of activation varied between sites, ranging from hoping that REACH-HF would be part of the service going forward at Site 1, watchful waiting at Site 3, perception of the intervention in its current format as being not implementable at Site 2 and looking forward to re-engaging with the innovation post-COVID-19 at Site 4.

9. Interactional workability

Interviewees across the Beacon Sites were unanimous that offering REACH-HF required additional time and was more costly compared to group centre-based programmes (interactional workability). Interestingly, a participant at Site 4 concluded that these factors should not be the reason for not offering REACH-HF to patients.

'For the small number of patients that we've had, it probably was more labour intensive than we had anticipated, but, I think, we shouldn't use that as our reason for not delivering that type of programme.' Site 4

Different reasons were attributed to the diminished interactional workability. They included offering REACH-HF to older/frailer patients (some of whom might need additional support with exercise prescription and the use of technology), covering a large geographical area and transport issues. An additional administrative burden involved in offering REACH-HF was identified at Site 2. This increase in administrative tasks was linked with a more elaborate way of setting patients on the programme, which included posting manuals before the assessment session and making sure that they were able to access the chair-based exercises in advance.

Over time, interviewees gained a more balanced perspective of the resources involved in delivering REACH-HF and they were able to justify offering REACH-HF despite the additional resources involved. The interviewee at Site 4 reflected on the impact of the COVID-19 pandemic and how the temporary change in service provision during this challenging time positively impacted the interactional workability of the innovation, as cardiac rehabilitation teams are now more open and able to engage with technology and use alternative models of delivery.

Additionally, interactional workability was improved when there was a good fit between the service and the innovation, and the innovation and the patient, for example, Site 1 was

already accepting patients with heart failure and staff working at Site 3 were used to using a self-management style of cardiac rehabilitation.

10. Relational integration

Trust in the programme and each other (relational integration) was linked with the interviewees' opinions of the REACH-HF resources. Some were negative, for example, perceiving DVDs as an outdated mode of communication, experiencing technical problems and perceiving the REACH-HF manual as too long. Some were positive, for example, perceiving the length of the REACH-HF manual as about right and appreciating the ability to involve a patient's family and friends in the programme with the friends and family resource. Trust in the REACH-HF intervention and the team was the most evident at Site 1.

Offering ongoing support to each other (a form of REACH-HF peer supervision) was seen as a way of improving relational integration in most sites. Interestingly, having a very high opinion of the established centre-based group programmes (a belief that they are safer and superior to home-based programmes) was a barrier to relational integration at the Beacon Sites. Developing a more balanced perspective on the centre-based provision had a positive impact on the relational integration, for example, acknowledging that complex multimorbid patients require additional support during centre-based classes and that attending such sessions creates an unnecessary burden on the individual.

11. Skills and workability

Interviewees were unanimous that the right people were trained and tasked with the implementation of REACH-HF at the Beacon Sites (skills and workability). Several important factors for selecting individuals to undertake the REACH-HF training were identified. They included allowing self-selection, choosing individuals with positive personal qualities and experience of working with multimorbid patients, and training more than one individual. We also identified a preference for home visits as a potential facilitator and a dislike of lone working as a barrier. A skill combination of cardiac rehabilitation, physiotherapy/exercise physiology and heart failure was seen as the most potent mix for successful implementation. The proximity of relationship between a cardiac rehabilitation team and a local heart failure team was perceived as a potential barrier if it was lacking or a facilitator if it was a strong well-established working connection.

Interviewees across the sites were also unanimous that the training was not correctly pitched to the skills and experiences of healthcare professionals being trained/undertaking it.
The suggested improvements to the training included making it more practical, more emphasis on the exercise prescription component, input from previous implementers, a shorter modular online version of the training, and having access to more in-depth pre-training activities.

12. Contextual integration

Interviewees reported varied levels of support and availability of resources in their services (contextual integration). The main barrier relating to contextual integration was a lack of time allocation. Being given protected time to deliver REACH-HF was a facilitator reported by most

interviewees. Another consistent barrier to implementation reported across the Beacon Sites was being understaffed. The lack of staff was exacerbated by periods of sickness.

A lack of commissioning to deliver cardiac rehabilitation to patients with heart failure was an important barrier at Site 2, whereas at Site 1 the commissioning structure (a block contract arrangement) was perceived as a facilitator – being a block contractor allows more flexibility in how the service is delivered.

Support from the management was another facilitator related to strong contextual integration. Managers working at Site 1 were particularly proactive in trying to mitigate contextual integration challenges. This included securing additional funding, redesigning the service and offering flexible cardiac rehabilitation.

13. Systematisation

Different approaches to evaluation were reported between clinicians and managers (systematisation). The interviewed REACH-HF practitioners employed more reflective, informal evaluation techniques – the lack of time prevented them from engaging in more in-depth, planned evaluation tasks. These were seen as the responsibility of the management team. The interviewed managers and service leads used more formal approaches to evaluation (e.g., looking at key performance indicators or comparing patient data and outcomes).

14. Communal appraisal

Following the initial implementation challenges, most interviewees developed a more balanced view of the intervention and the implementation process (communal appraisal).

15. Individual appraisal

An increase in job satisfaction and continuous professional development were reported as facilitators relating to individual appraisal. Positive feedback from patients further strengthened the individual appraisal at all Beacon Sites.

16. Reconfiguration

The delivery of the REACH-HF intervention can be adapted to better suit the way services are run (reconfiguration). Interviewees described different levels of reconfiguration as follows – a fully home-based programme (suggested by participants at Site 1 only), improved enrolment process, offering fewer home visits, home/centre hybrid, adapting the programme to a group centre-based programme and using the REACH-HF project as an inspiration for better service delivery in general.

The Beacon Site project took place partly during the COVID-19 pandemic. Site 1 was the only Site that continued delivering the programme during the lockdowns; this period of forced reconfiguration (due to social distancing and shielding measures) meant that the programme was delivered fully remotely. This included offering longer telephone or video assessments and using the titration method to establish the baseline exercise capacity. Most of the staff from the remaining three sites were redeployed to the COVID-19 frontline.

Reconfigurations also included amendments to the REACH-HF resources. Suggested improvements involved adapting some of the wording in the manual (i.e., replacing chair-based exercises with a more neutral term), having a simplified paper version of exercises and making the manual available online.

Appendix 11

Detailed description of primary and secondary outcome measures

Primary outcome measures – health-related quality of life

The Minnesota Living with Heart Failure Questionnaire (MLHFQ) [400] is a 21-item self-administered questionnaire that measures the patient's perception of the impact of heart failure on their quality of life. This widely used questionnaire uses a six-point rating scale (from 'no' and 'very little' to 'very much') to assess the impact of heart failure on four dimensions of a patient's life: physical symptoms of heart failure, social functioning, psychosocial and cognitive functioning, and overall adverse impact of heart failure [147]. The maximum score of 105 points indicates a poor health-related quality of life. The MLHFQ achieved good reliability and validity in studies testing its psychometric properties [436-441].

The Dartmouth Cooperative Functional Assessment (COOP) charts [401] were developed to measure patient functional status in different clinical populations [442]. This simple and easy to administer measure [443] can be used to assess health-related quality of life [444] and is made of nine pictorial charts representing the following domains: physical function, emotional function, daily activities, social activities, social support, change in health, overall health, pain and quality of life [445]. The functional status in each domain is rated on an illustrated (and numbered) five-point Likert scale, where a score of one indicates no impairment and a score of five indicates the most

impairment. The COOP charts show good reliability and validity [442, 443, 446, 447], they are used to measure functional status in different chronic diseases and settings [448], and they are used in research [449-453]. In the current study, I considered the total COOP score minus two domains (i.e., the social support and change in health) due to known issues regarding the validity – the two domains are often misinterpreted by patients [113].

Secondary outcome measures

Mental health status: The Patient Health Questionaire-9 (PHQ-9) [402] is a nine-item self-administered questionnaire widely used in primary care settings and research [454] to diagnose and rate the severity of depression [402]. Each PHQ-9 item represents a symptom of depressive disorder and is rated in terms of frequency of occurrence (not at all, several days, more than half the days and nearly every day). A total score between 20 and 27 is indicative of a severe depressive disorder, 15 to 19 – moderately severe, 10 to 14 – moderate, 5 to 9 – mild and 0 to 4 – non-clinical. The PHQ-9 is a reliable and valid measure for screening for depression [455] and for assessing depression severity [456].

The Generalised Anxiety Disorder Assessment-7 (GAD-7) [403] is a clinical measure for assessing generalised anxiety disorder and, similarly to the PHQ-9, is extensively used in primary care settings [457]. This brief (seven items) self-administered questionnaire shows good validity for screening for generalised anxiety disorder and assessing its severity [403]. The maximum score for the GAD-7 is 21; a score between 21 and 15 is

interpreted as a severe generalised anxiety disorder, 10 to 14 – moderate, 5 to 9 – mild and 0 to 4 – subclinical [458]. The PHQ-9 and the GAD-7 are used to monitor psychological therapy treatment and recovery and are the main outcome measures used in the Improving Access to Psychological Therapy services in England [459].

The Hospital Anxiety and Depression Scale (HADS) is a 14-item self-administered scale that measures anxiety and depression [404] and is widely used in clinical practice and research [460]. Each HADS questionnaire consists of two lists of seven symptoms for each disorder; each symptom statement is measured on a four-point scale (zero to three). A total depression score between 21 and 11 indicates a clinical level of depression, a score of between 10 and 8 – borderline level and 7 and 0 – non-clinical. The same cut-off points are used when interpreting a total anxiety score. The validity and psychometric properties of the measure have been confirmed in numerous studies over the years [460-462]. Authors of a recent systematic review concluded that the measure might be more suitable for detecting and measuring 'emotional distress', due to issues with its latent structure (ability to distinguish between anxiety and depression) [463].

Objective exercise capacity measures: Objective exercise capacity assessment is routinely used to assesses patients with heart failure and evaluate heart failure treatment [464] and there are different exercise testing protocols used with this clinical population [465]. Two frequently used protocols for testing exercise capacity in patients

with heart failure are the Incremental Shuttle Walk Test (ISWT) [260] and the Six Minute Walk Test (6MWT) [405].

The main difference between the ISWT and the 6MWT is that the former is externally paced and the intensity of exercise is incrementally increased during the test, additionally, assessors do not give any verbal encouragement to the patient undergoing assessment. Whereas the 6MWT allows the patient to walk at their own pace, assessors can offer standard statements of encouragement and the objective of the test is for the patient to cover as much distance as possible during the six-minute window, as opposed to keeping up with the increasing pace in the ISWT.

The validity and reliability of the 6MWT in cardiac rehabilitation patients were confirmed by Hamilton et al. [466]. A 2012 meta-analysis further highlighted that the 6MWT is responsive to clinical change following cardiac rehabilitation, but its intra-tester and inter-tester reliability and validity requires further research [467]. The ISWT shows good test-retest reliability [265] and can provide a valid estimate for physical fitness and functional capacity for patients attending cardiac rehabilitation [266].

Appendix 12

Standards for Reporting Implementation Studies checklist

Checklist item		Reported on page #	Implementation Strategy	Reported on page #	Intervention
			"Implementation strategy" refers to how the intervention was implemented		"Intervention" refers to the healthcare or public health intervention that is being implemented.
Title and abstract					
Title	**1**	i	Identification as an implementation study, and description of the methodology in the title and/or keywords		
Abstract	**2**	ii	Identification as an implementation study, including a description of the implementation strategy to be tested, the evidence-based intervention being implemented, and defining the key implementation and health outcomes.		
Introduction					

Introduction	**3**	1	Description of the problem, challenge or deficiency in healthcare or public health that the intervention being implemented aims to address.		
Rationale	**4**	152	The scientific background and rationale for the implementation strategy (including any underpinning theory/framework/model, how it is expected to achieve its effects and any pilot work).	16	The scientific background and rationale for the intervention being implemented (including evidence about its effectiveness and how it is expected to achieve its effects).
Aims and objectives	**5**	46	The aims of the study, differentiating between implementation objectives and any intervention objectives.		
Methods: description					
Design	**6**	46	The design and key features of the evaluation, (cross referencing to any appropriate methodology reporting standards) and any changes to study protocol, with reasons		
Context	**7**	47	The context in which the intervention was implemented. (Consider social, economic, policy, healthcare, organisational barriers and facilitators that might influence implementation elsewhere).		

Targeted 'sites'	**8**	47	The characteristics of the targeted 'site(s)' (e.g locations/personnel/resources etc.) for implementation and any eligibility criteria.	43	The population targeted by the intervention and any eligibility criteria.
Description	**9**	224	A description of the implementation strategy	196	A description of the intervention
Sub-groups	**10**	N/A	Any sub-groups recruited for additional research tasks, and/or nested studies are described		
Methods: evaluation					
Outcomes	**11**	53	Defined pre-specified primary and other outcome(s) of the implementation strategy, and how they were assessed. Document any pre-determined targets	201	Defined pre-specified primary and other outcome(s) of the intervention (if assessed), and how they were assessed. Document any pre-determined targets
Process evaluation	**12**	N/A	Process evaluation objectives and outcomes related to the mechanism by which the strategy is expected to work		

Economic evaluation	**13**	N/A	Methods for resource use, costs, economic outcomes and analysis for the implementation strategy	N/A	Methods for resource use, costs, economic outcomes and analysis for the intervention
Sample size	**14**	49, 50, 61,	Rationale for sample sizes (including sample size calculations, budgetary constraints, practical considerations, data saturation, as appropriate)		
Analysis	**15**	60	Methods of analysis (with reasons for that choice)		
Sub-group analyses	**16**	N/A	Any a priori sub-group analyses (e.g. between different sites in a multicentre study, different clinical or demographic populations), and sub-groups recruited to specific nested research tasks		

Results					
Characteristics	**17**	156	Proportion recruited and characteristics of the recipient population for the implementation strategy	203	Proportion recruited and characteristics (if appropriate) of the recipient population for the intervention
Outcomes	**18**	236	Primary and other outcome(s) of the implementation strategy	215	Primary and other outcome(s) of the Intervention (if assessed)

Process outcomes	**19**	N/A	Process data related to the implementation strategy mapped to the mechanism by which the strategy is expected to work		
Economic evaluation	**20**	N/A	Resource use, costs, economic outcomes and analysis for the implementation strategy	N/A	Resource use, costs, economic outcomes and analysis for the intervention
Sub-group analyses	**21**	N/A	Representativeness and outcomes of subgroups including those recruited to specific research tasks		
Fidelity/ adaptation	**22**	219	Fidelity to implementation strategy as planned and adaptation to suit context and preferences	N/A	Fidelity to delivering the core components of intervention (where measured)
Contextual changes	**23**	219	Contextual changes (if any) which may have affected outcomes		
Harms	**24**	NONE	All important harms or unintended effects in each group		
Discussion					

Structured discussion	**25**	175	Summary of findings, strengths and limitations, comparisons with other studies, conclusions and implications		
Implications	**26**	176	Discussion of policy, practice and/or research implications of the implementation strategy (specifically including scalability)	219	Discussion of policy, practice and/or research implications of the intervention (specifically including sustainability)
General					
Statements	**27**	155	Include statement(s) on regulatory approvals (including, as appropriate, ethical approval, confidential use of routine data, governance approval), trial/study registration (availability of protocol), funding and conflicts of interest		