What service and patient characteristics are associated with cardiac rehabilitation outcomes:

Evaluation of observational studies of cardiac rehabilitation as a complex intervention

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Abstract

Cardiac rehabilitation (CR) is proven to benefit patients post cardiac event, however, modern CR varies in terms of service quality, patient characteristics and outcomes. The aim was to investigate the variations and their association with patient outcomes. Five observational studies make up this thesis. The studies have some unique and shared aims and methodology leading to distinct findings summarised through a synthesis chapter showcasing the incremental nature of the analyses and progression in researcher ability. Observational methodology was justified, and variation in routine care and the association with three distinct categories of outcome: psychosocial wellbeing, physical fitness and cardiovascular risk factors.

Study one concluded that volume, as a service factor, appeared not to be associated with patient outcomes whereas multiple patient factors such as age and gender were found to be associated.

Study two, building upon the findings of the first, focused on the patient characteristics including employment status and showed that, aligning with wider literature, patient psychosocial wellbeing was poorer pre and post CR in patients who were unemployed.

This association of employment and psychosocial wellbeing was replicated in *Study three* which was the first to also assess the influence of mode of delivery. Mode was found to be not significantly associated with psychosocial wellbeing or functional capacity in *Study four*.

In *Study five*, mode was categorised as supervised or facilitated self-managed and found no association with patient outcomes, this time risk factors.

The use of routine data highlights important insights for answering research questions to inform and promote service change. Additionally, the findings may influence the methodological approach and expectations by researchers utilising the National Audit of Cardiac Rehabilitation.

The conclusions of this thesis will help to inform CR delivery, directly impacting patients and clinicians. The findings may help to shape the future services designed by policy makers.

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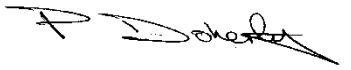
List of Accompanying Material with Signatures from Co-authors

Study one: **Doherty P, Harrison AS, Knapton M, Dale V. Observational study of the relationship between volume and outcomes using data from the National Audit of Cardiac Rehabilitation. Open Heart. 2015;2,1.**

doi: 10.1136/openhrt-2015-000304

The candidate jointly developed the idea for the study, the study methodology and contributed substantially to the preparation of the manuscript and critical revisions to the study following reviewer comments.



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***Study two*: Harrison AS, Sumner J, McMillan D, Doherty P. Relationship between employment and mental health outcomes following cardiac rehabilitation: An observational analysis from the National Audit of Cardiac Rehabilitation. International Journal of Cardiology, 2016;220:851-854**

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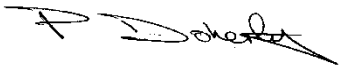

Patrick Doherty

***Study three*: Harrison AS, Doherty P. Does the mode of delivery in Cardiac Rehabilitation determine the extent of psychosocial health outcomes? International Journal of Cardiology. 2018;255:136-139.**

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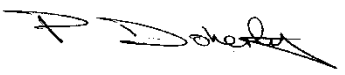

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***Study four*: Harrison AS, Tang L, Doherty P. Are physical fitness outcomes in patients attending cardiac rehabilitation determined by the mode of delivery? Open Heart. 2018;0.**

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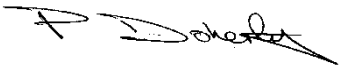
Lars Tang



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Study five: **Harrison AS, Doherty P. Does the mode of delivery in routine cardiac rehabilitation have an association with cardiovascular risk factor outcomes? European Journal of Preventative Cardiology. 2018;25,18-1925-1933.**

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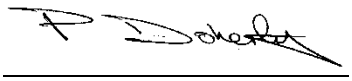

Patrick Doherty

Author’s declaration

I declare that this thesis is the product of my own work other than that duly acknowledged to others. The material contained in this thesis has not been submitted for a degree in this or any other awarding institution. Any use of journal articles, books or other resources have been appropriately referenced and the authors declares no plagiarism has been performed.

Chapter 1: Introduction and Aims of Thesis

History Cardiac Rehabilitation

Through the 20th and 21st Centuries, there has been an increase in life expectancy worldwide; correspondingly there has been an increase in the burden of chronic diseases such as cardiovascular disease (CVD), cancer and diabetes.(WHO 2017) Globally, CVDs were the largest cause of death in 2016; an estimated 42,000 people died of CVD in England and Wales.(BHF 2018) In Europe, the estimated number of people living with CVD is in the region of 85 million.(WHO 2017) In 2018, seven in every ten people experiencing a heart attack survived, further increasing the number of people living with CVD.(BHF 2018)

The impact of CVD events affects not only the individual, in terms of loss of biological functioning, psychosocial distress and overall quality of life (QoL), but also their family and support network too.(BACPR 2017, BHF 2018) For many years, people with post-heart events such as myocardial infarction (MI) were treated solely with bed rest. Over the last three decades, the recommended treatment has changed to include physical activity, and into the multi-component lifestyle, risk factor and fitness-based cardiac rehabilitation (CR) that exists today.(Al Quait, Doherty 2017) The adoption of CR in its modern form is global and particularly prominent across the UK, Europe, Canada, Australia and America.(Stone, Arthur 2005, Woodruffe, *et al*. 2015, Santiago de Araujo Pio, *et al.* 2017) CR guidelines are often very similar across countries, however, its delivery and the populations being served can vary widely, indicating a complex intervention, which requires continual evaluation.(Ibanez, *et al.* 2017, BHF 2018, Knuuti, *et al.* 2019)

For the purpose of this thesis and related papers, the term patients was used as an operational definition covering participants as the population is based on routine practice National Health Service (NHS) data.

Cardiac Rehabilitation Guidelines

The core components of CR have been defined across many guidelines and governing bodies worldwide such as; the American Heart Association (AHA), guidelines from the European Association of

Cardiovascular Prevention and Rehabilitation and in the UK the British Association of Cardiac Prevention and Rehabilitation (BACPR).(Leon, *et al.* 2005, Thomas, *et al.* 2010, Piepoli, *et al.* 2014, CACR 2015, BACPR 2017) A unifying factor of modern CR is that it is a personalised approach identifying risk factors, promoting psychosocial wellbeing and underpinned by thorough long term self-management.(BACPR 2017) All recent sets of CR clinical guidelines are informed by research evidence of different types, underpinning the delivery of effective CR.

The core components of CR are generally nutritional counselling, risk factor modification, psychosocial management, patient education and exercise training, with some variation. A review in 2018 investigated the effects of each of the components on outcomes.(Kabboul, *et al.* 2018) It highlighted the centrality of the exercise component of CR, as per other reviews, whilst also evidencing the unique health benefits of each component individually, particularly psychosocial management. (Anderson, *et al.* 2016)

Existing within these guidelines are a variety of recommendations. This variation includes programme duration, mode of delivery and programme volume.(BHF 2016, Santiago de Araujo Pio, *et al.* 2017, Taylor, *et al.* 2017, Abreu, *et al.* 2019) Definitions of programme volume vary depending on the setting and intervention. Within this thesis, volume was defined as the total number of patients who had undergone baseline assessment and entered the standard core delivery of CR, which in the UK is delivered as an outpatient service. Globally, volume of CR can vary, shown recently in the survey of programmes, and this large level of variation may, based on other literature evidence, have association or influence on patient outcomes.(Abreu, *et al.* 2019) The mode of delivery is split in the literature into centre vs. home-based or supervised vs self-delivered. A possible reason for CR variability is that these factors essential to 'real world' delivery of CR are often excluded or not represented in randomised control trials (RCTs).(Freemantle, Calvert 2009, Anglemyer, *et al.* 2014) The largest UK based CR trial, called Rehabilitation After Myocardial Infarction Trial (RAMIT), highlighted variation in the service delivered currently. Differences in terms of duration (above or below 21h/ 8 weeks) and class sizes (above or below 13 patients) were examples of this service variation.(West, *et al.* 2012) This led to questions about the presumed quality of CR and therefore its potential effectiveness.

Recent publications, such as the National Audit of Cardiac Rehabilitation (NACR) Quality and Outcomes report, have shown that only 30% of programmes are meeting minimum standards including waiting times and duration.(Doherty, *et al.* 2017, BHF 2019) This study alongside RAMIT raises questions of the quality of CR and whether this variation in CR delivery impacts on patient outcomes. One recent example of the variation is included in the 2019 Quality and Outcomes report (NACR), which showed that routine UK CR duration is delivered heterogeneously.(BHF 2019) The level of variation above and below the minimum recommended guideline (BACPR 2017) of 8 weeks (56 days) demonstrates the kind of heterogeneity that occurs in routine practice (**Figure 1**).

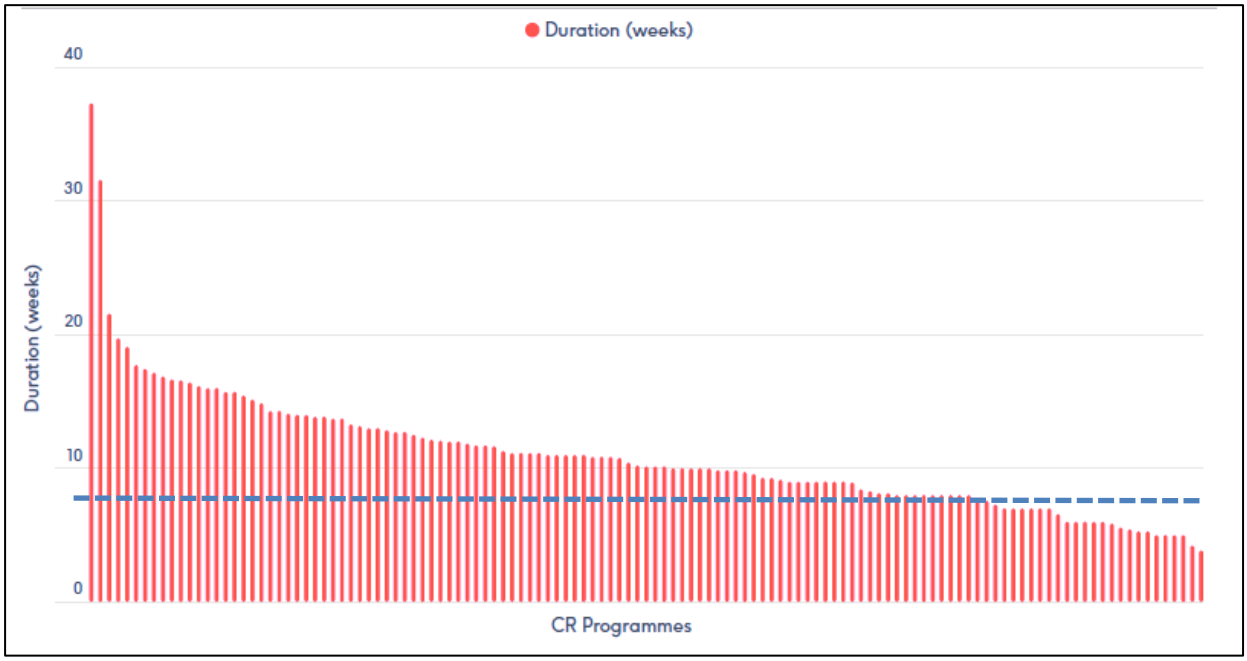

Figure 1. Duration in England at a programme level, the dotted line indicates the 8-week threshold for the key performance indicator and national certification programme.(NACR 2019)

The UK CR and the NACR are in the privileged position of being able to evaluate CR provision as it is presently being delivered. NACR is a non-mandated charity funded organisation operating since 2005, with its first annual report in 2007. (Al Quait, Doherty 2017) The purpose of collecting routine data on CR provision is to monitor service quality, report on the population and to perform research informing service quality and improvement. The NACR is a routinely collected clinical registry that covers three

of the four nations in the UK (Scotland is not presently included). Total programme coverage is around 80% of all phase 3/core rehabilitation programmes as well as many tertiary in-patient or phase 4 exercise programmes. Each year, over 100,000 events are captured in the NACR. The data recorded are presented in **Table 1**,.This includes baseline characteristics, risk factors, type of care and outcomes post CR of patients undertaking CR.(BHF 2019)

Table 1 Showing the record types within the NACR dataset and the included data fields

NACR Record Type	NACR Data Field Collected
Initiating Event Record	Initiating Event (diagnosis), Comorbidities, Previous Events, Age, Treatments, Dates (Initiating Event, treatment and discharge)
Patient Record	Gender, Marital Status, Ethnicity, LSOA and CCG
Rehabilitation Record	Mode of Delivery, reasons for not taking part/completing CR, dates (Referral, Start and Completion) *
Assessment Record	Height, Weight, BMI, Cholesterol, blood pressure, HADS scores, Smoking status, Physical Activity, Dartmouth Questionnaire Fitness measures (ISWT 6MWT), Diet measure
**Dates are used to calculate the waiting time, duration* *LSOA – Lower Super Output Area, CCG – Clinical Commissioning Group, BMI – Body Mass Index, HADS – Hospital Anxiety Depression Score, ISWT - Incremental Shuttle Walk Test, 6MWT – Six Minute Walk Test*	

The assessments include the Hospital Anxiety Depression Score (HADS) (Zigmond, Snaith 1983), Dartmouth Cooperative (COOP) questionnaire (Jenkinson, Mayou *et al.* 2002) and finally walking ability through the Six Minute Walk Test (6MWT) (ATS 2002) and the Incremental Shuttle Walk Test (ISWT).(Singh, *et al.* 1992)

Research Evidence for Cardiac Rehabilitation

The research evidence for CR is summarised in three recent systematic reviews (SR); a Cochrane review summarising the trial evidence, the Cardiac Rehabilitation Observational Study (CROS) review investigating the modern era of studies and finally work by Powell *et al.*(Anderson, *et al.* 2016, Rauch, *et al.* 2016, Powell, *et al.* 2018)

The Cochrane review included 63 trials conducted between the 1980s and the modern period of CR (2000 onwards), that overall indicate both a reduction in cardiovascular mortality (Risk Ratio (RR) 0.74 95% confidence interval (CI) 0.64 0.86) and reduced readmissions (RR 0.82 95% CI 0.70 0.96).(Anderson, *et al.* 2016)

The modern period of CR is defined as post 2000, when the National Service Framework for coronary heart disease was published, setting a new landscape for what CR should be.(NSF 2000) The inclusion of RAMIT and older studies within contemporary SR of CR has led to all-cause mortality no longer being significant as an outcome of CR, when in previous SR of CR it was.(Anderson, *et al.* 2016) This highlights a possible limitation within some SRs in that they tend to include earlier trials, which may not represent modern CR interventions/populations and often include 'usual care' arms that are out of date compared to modern era trials, thus potentially impacting on the outcomes and recommendations arising from such reviews.

The CROS review was the first to tackle this issue and included only one RCT of the original Anderson review due to its inclusion criteria of: time (post 1995 studies only); or low-level comprehensiveness of CR interventions.(Rauch, *et al.* 2016) The systematic review found that attending CR was associated with reduced mortality, however, heterogeneity of study designs and CR programmes prompt the need for defining international standards for CR.

The final SR also tried to account for older trials by only including studies published post 2000.(Powell, *et al.* 2018) However, this review had major shortcomings by including a wide range of interventions and diverse populations (non-evidenced stable angina). Again possibly diluting the findings. This review was criticised for the inclusion of these populations and interventions along with populations outside of their date range of 2000.(Cowie 2018)

Against this landscape of reviews, the context in which CR is delivered has also changed.(Anderson, *et al.* 2016) CR is now being delivered against a backdrop of new treatments and wider referral criteria. Therefore, the evidence that underpinned the initial cohort of patients and CR services, is now less relevant to the populations receiving CR.

The varied results, inclusion of different studies and overall lack of real-world representation raises an interesting critique of these reviews and makes a strong case for real world data to assess CR in its modern form. Utilising routine data from the NACR, or other CR registries, could aid in this new need for research.(Zwisler, *et al.* 2016, Poffley, *et al.* 2017)

In recent years, the large levels of variation worldwide, and specifically in European CR, has been captured by wide reaching surveys. These pieces of work are useful for highlighting service and country variation, such as that of volume, dose and care provider differences.(Abreu, *et al.* 2019, Supervia, et al 2019, Turk-Adawi, et al 2019, Chaves, et al 2020). These papers, however, due to their methodology, i.e. self-reporting of CR variation and outcomes, and level of data recorded, mean that they would be inappropriate for analysing outcomes based on multiple patient and service factors. It is instead more suitable to seek the use of large registers at the patient level such as the NACR.

The NACR is a rich registry-based data source that collects data on patient and service provision and is comparable with other leading CR registries across the globe, such as the Danish cardiac rehabilitation database.(Neil, *et al.* 2017, Poffley, *et al.* 2017) The training and support provided by NACR facilitates high-quality recording of data.(Egholm, *et al.* 2019) Working in collaboration with the NACR, the BACPR are helping to promote a CR service that is world-leading in uptake and delivery. The working relationship between the BACPR and NACR is mutually beneficial with combined working definitions, the national certification programme (NCP_CR) and promotion of service change.(BHF 2019).

Research Methods and Design

Multiple methodologies for evaluating healthcare interventions exist. They range from RCTs to observational studies (OS), qualitative interviews and surveys.(Petrisor, Bhandari 2007) The selection of research methodology depends largely on the research question. As the intervention and population being tested, in this body of work, are thought to be complex and are being investigated in situ, within routine care, the selection of OS was appropriate.

RCTs, such as those in the Cochrane review, included participants 10-years younger than the NACR and are under representative of the older patients seen in routine practice (range 18-108).(Anderson, *et*

al. 2016, BHF 2019) In addition to age, trials often exclude or fail to recruit patient sub-groups such as those who are frail, or have multi-morbidity and females; the latter two make up 50% and 30% of the receiving population respectively.(BHF 2019)

Observational research including methodologies such as cohort studies, are by their nature more representative of routine populations. These studies involve utilising routine care data collected prospectively or retrospectively and, if performed well, they enable researchers to monitor and evaluate interventions in situ with potential for including more representative populations.

A recent review showed that well conducted OS can not only address the effectiveness of treatments, but, moreover, the findings are equivalent in terms of point estimate differences to that of RCTs.(Anglemyer, *et al.* 2014) The additional benefit of OS being representative, low-cost and less hampered by recruitment challenges, position this methodology as highly suitable to evaluate already established interventions such as CR. However, as with all research methodologies, appropriate reporting (such as STOBE (Vandenbrouke et al 2014)), implementation and acknowledgement of limitations are essential for the correct conclusions to be applied, thus researchers need robust training, measurable criteria and observational competence.(Carthey 2003)

The NCP_CR aims to report and assess on quality of delivery and highlight opportunities for programmes to improve. In the 2019 NACR Quality and Outcomes Report, the NCP_CR reported all programmes and assessed for service quality.(BHF 2019) **Figure 2** outlines criteria or key performance indicators (KPIs) that the NCP_CR uses to assess programme quality. The 2019 report confirmed that huge variability exists within the programmes in the UK: 66 were certified (met all 7 standards), 79 were classified Amber (4-6 standards), 61 Red (1-3 standards) and 22 failed. **Figure 2** shows the breakdown of the standards and criteria based on the 2018 Quality and Outcomes report.

NCP_CR KPIs	
Minimum standard 1: MDT	At least three health professions in the CR team who formally and regularly support the CR programme
Minimum standard 2: Patient group	Cardiovascular rehabilitation is offered to all these priority groups: MI, MI+PCI, PCI, CABG, HF
Minimum standard 3: Duration	Duration of core CR programme: ≥ national median of 56 days
Standard 4: National average for assessment 1	Percentage of patients with recorded assessment 1: ≥ England 80%; Northern Ireland 88%; Wales 68%
Standard 5: National average for CABG wait time	Time from post-discharge referral to start of core CR programme for CABG: ≤ national median of England 46 days, Northern Ireland 52 days, Wales 42 days
Standard 6: National average for MI/PCI wait time	Time from post-discharge referral to start of core CR programme for MI/PCI: ≤ national median of England 33 days, Northern Ireland 40 days, Wales 26 days
Standard 7: National average for assessment 2	Percentage of patients with recorded assessment 2 (end of CR): ≥ England 57%, Northern Ireland 61%, Wales 43%

* Information on staffing profile and MDT, which forms one of the NCP_CR KPIs, is taken from the NACR annual paper survey. This information is not available from the electronic NACR database. In order for certification to be validated each CR team must return the NACR annual paper survey form with staffing detail section completed.

***Figure** 2 The NCP_CR standards, from the 2019 Quality and Outcomes report, for the three countries in the NACR, as according to the 2019 Quality and Outcomes report. Standard 1-3 are the same for all three, whereas standard 4-7 are based on 2016 NACR report and national averages.*

Investigating the Complexity of Cardiac Rehabilitation

Complex interventions are defined as containing several interacting components. The components could be and are not limited to: *a number of experimental and control interventions, a range of behaviours required by those delivering or receiving the intervention, a plethora of groups either delivering or receiving the intervention, a large range of variability and flexibility in the delivery or receiving population.*(Skivington, *et al.* 2018) Modern CR fits the definition of complex due to the variable nature of delivery, as highlighted in the different guidelines and associated evidence.

CR is a complex intervention and as such can differ largely in the service quality, but also in the delivery and characteristics of the population being treated. These variations are yet to be assessed for their effect on patient outcomes.(Doherty, Lewin 2012, BHF 2019) It is imperative in modern CR to determine

whether variation in delivery is associated with patient outcome to inform practice and maximise patient benefit.

Additionally, programmes are often underfunded and often competing for limited resources which may influence the lack of uptake and variability in delivery.(Beswick, *et al.* 2004, Gore, Doherty 2017, BHF 2019, Moghei, *et al.* 2019) Taking account of all of the available variation is important in assessing the association with outcomes post CR, which is what the five studies set out to do.

Based on the type of intervention that CR is, and the high-quality data available through the NACR, it was timely in 2015 to investigate patient and service level factors thought to be associated with patient outcomes. This thesis will form a bridge between five independent studies; highlighting their similarities, detailing advancements made in methods and overall conclusions, presented as one comprehensive body of work.

Literature Search

To contextualise the studies included in this thesis since their production and publication, a literature search was performed on key factors represented in each of the studies. The literature search was undertaken systematically with the aim of incorporating contemporary and relevant literature. The search was performed initially in June 2018, re-run in March 2019 and again in January 2020. The search strategy and preferred reporting items for systematic reviews and meta-analyses (PRISMA) flow diagram are summarised in **Appendix 1-4**.(Methley, *et al.* 2014) The literature does not form its own chapter but is included in chapters relating to the studies. Studies were assessed for methodological quality using appropriate tools (**Table 2**). Standardised scores used the grading of recommendations, assessment, development and evaluations (GRADE) system, High (100-75), Moderate (50-74), Low (25-49) and Very Low (0-24).(Schunemann, *et al.* 2019) The scores, GRADE standardised scores and information on all included studies are presented in **Appendix 5**

Table 2 The study designs and the assessment tools used to assign quality standardised scores for reporting.

Type of Study Design	Assessment tool
RCT	PEDro, *used pre published scores where available or manually graded trials using PEDRO tool* (De Morton 2009)
Systematic Review	CASP* (Ibbotson, *et al.* 1998)
Cohort Study	CASP* (Ibbotson, *et al.* 1998)
Cross Sectional Study	AXIS Tool (Downes, *et al.* 2016)
PEDro – Physiotherapy Evidence Database CASP- Critical Appraisal Skills Programme AXIS – Appraisal toll for cross-sectional studies *CASP is not designed as a scoring tool, however, standardised scores were applied to group the range of quality studies. The full information was used when assessing their methods, results and conclusions.*	

There were 33 studies identified and included through the systematic search; these were spread across the topics covered in each of the five studies. At the end of each chapter, a small review of the studies, their quality and how they compare with the findings will be presented.

From here on, to identify the studies of which this thesis is comprised, italics and capitals will be used to discern from other literature e.g. *Study one*.

Thesis Aims

The overarching aim was to investigate whether variations in CR delivery, such as mode, volume and patient populations are associated with patient outcome.

Thesis Objectives

The aim relates to understanding, identifying and evaluating factors associated with patient outcome, within an established evidenced based intervention. The preferred approach was OS based on routine care. The thesis' aim will be achieved through the following objectives:

1. Implement the following studies using a robust observational approach:
    a. *Study one*, investigation into the influence of CR programme volume on patient's CR outcomes

b. *Study two*, explore patient level factors that may be associated with psychosocial wellbeing Post-CR
c. *Study three-five*, assess the degree that modalities delivered in routine CR define health outcomes and risk factor change

2. Review the methodological techniques used and assess the findings of each study individually and together as a body of work
3. Utilising a systematic search of the literature, compare the findings in the context of publications during the period

Outline rationale for approach

The association between programme volume and patient outcomes are well established in healthcare interventions.(Jenkins, *et al.* 1995, Gammie, *et al.* 2007, Sepehripour, Athanasiou 2013) In 2015, an OS investigated the association of volume with nine patient outcomes. Chapter 2 reviews the methods and findings of *Study one* and the impact on the surrounding CR volume and outcome literature.

It is established that the CR populations are heterogenous, for example their baseline risk factors and socioeconomic background.(Ardiana, Radi 2017, Christensen, *et al.* 2017, Dean, *et al.* 2018) To understand how patient characteristics can influence their outcomes, *Study two* investigated employment status and psychosocial wellbeing post CR. Chapter 3 will review the findings, methodology and influence.

Modern CR is delivered in a variety of ways, however, it is still dominated by supervised CR.(Thomas, *et al.* 2010, Piepoli, *et al.* 2014, BACPR 2017) A review concluded that home-based CR is equally effective as group-based CR for patient outcomes.(Anderson, Sharp *et al.* 2017) Chapter 4 will review three studies that investigated mode of delivery and psychosocial, physical and risk factor outcomes in routine care. The chapter will look at methods and analysis techniques and impact on evidence.

Chapter 2: Investigation into the influence of CR programme volume on patient outcomes

Background

The evidence that volume, as a service characteristic, influences outcomes was widely accepted in 2015 across numerous populations and interventions.(Jenkins, *et al.* 1995, Gammie, *et al.* 2007, Sepehripour, Athanasiou 2013) An illustration of this in CVD populations are interventions such as surgery, which showed evidenced influence on the patient mortality.

UK guidelines guided the delivery of CR in 2015 when this research was conducted.(SIGN 2002, Buckley, *et al.* 2013) The BACPR had no mention of class sizes whereas the Scottish Intercollege Guidelines Network (SIGN) had a value of 500 patients for the programme. At the time, the only research that included class size and patient outcomes was the RAMIT study stating that increased mortality was associated with smaller class size (<13 patients per group). This dearth of evidence of the volume-outcome relationship (VOR) in CR, was the justification to investigate whether this existed in routine care.

Study one: Observational study of the relationship between volume and outcomes using data from the National Audit of Cardiac Rehabilitation

The aim of *Study one* was twofold; firstly, to address whether NACR had the quantity and quality of data to address research questions, as this had not previously been explored and, secondly, to assess the association between programme volume and patient outcomes.

Study population

The research used NACR data from the financial year 2012-2013. All categories of patients who receive CR including MI, percutaneous coronary interventions (PCI) and coronary artery bypass graft (CABG) were included. The inclusion criteria applied were; patients who started and completed CR, and those having pre and post measures for at least one outcome measure. The initial study population, used to calculate volume was 48,476 patients. Ultimately, only 21,966 patients were included when post CR

measurement was applied as selection criteria. Although the population included was compared to those excluded, the drop in sample size does highlight a limitation in routine care data which is missing data. The overall impact of this was that less than 50% of the total group were included.

The study was unique as, firstly, there had previously been no studies published using the routine audit data from the NACR and, secondly, this was the first publication investigating VOR in CR.

Volume was defined as the 'number of patients receiving CR'; operationally different from programme size which was the total number of patients registered. This allowed the analysis to estimate volume relative to the programme size, which is important because the two variables are different. Size is relative to funding, staffing and infrastructure, whereas volume is patients seen relative to maximum throughput. In addition, the programme's staffing profile was also included which enabled more detailed analysis of funding and resources. This was total staff hours and delivery by a multi-disciplinary team (MDT) (≥3 different staff disciplines).

Analysis

Linear and logistic regression were used, utilising data structured hierarchically, to assess volume in association with patient outcomes. This allowed the effect of the continuous variable 'volume' to be calculated, while factoring in known patient level covariates, e.g. age, gender, marital status and the comorbidity status. Additionally, baseline scores for each outcome variable were included. Staffing information came from the NACR annual survey which collects information on the staff types, grade and hours (**Appendix 6**). This information allowed more detailed programme information to be included alongside volume.

In accordance with statistical literature, p-value of <0.05 was deemed as statistically significant.(Concato, Hartigan 2016, Stone 2018) Data model checking was performed using evidenced assumptions for linear and logistic regressions.(Hosmer, *et al.* 2013, Casson, Farmer 2014)

Outcome variables were continuous except smoking status and physical activity status (achieving 150 mins moderate activity per week) that were treated as binary variables. This allowed more predictive power of associations between factors such as age and volume against body mass index (BMI).

However, this meant that associations were based on coefficients rather than odds ratios of being in a target category. This was performed to maximise the statistical power, although this may have been at the cost of clinical relevance. This was explored in the development of the study, but it did not make it into the final manuscript. Future studies utilised categorical outcomes for most variables, increasing the clinical relevance for CR users and commissioners.

All variables included in this and subsequent *Studies* analysis are shown in **Appendix 7**.

Results

The results showed patients improved upon completion of CR, however, the regression models showed no significant association between the programme volume and outcome. Patient improvement included a 38.6% increase in physical activity status and a mean increase of 94 metres in the ISWT.

An additional finding was that 32% of CR programmes failed to carry out assessment 2 (outcome measures post CR) which is a minimum standard as recommended by BACPR.(BACPR 2017).

An aim of the study was to address whether it was possible to develop and perform research within this clinical audit. At the point of publication, no other published research had come from the NACR database. This research demonstrated large-scale OS is possible. Additionally, the source data was of sufficient quality and size to perform in-depth statistical analysis factoring in known covariates; a novel aspect in CR research at that time.

Discussion

This study utilised routinely collected post CR outcomes, including measures of lifestyle change, risk-factor reduction and exercise capacity. These have been shown to be useful for estimating subsequent prognosis including all-cause mortality.(Lavie, *et al.* 2019) However, future work should look to link to data sources such as General Practice (GP) registry and Hospital Episode Statistics that will allow assessment of a true measurement of the association with mortality.

This study has been cited in publications detailing benchmarking CR registries across the globe (Pesah, *et al.* 2017, Poffley, *et al.* 2017) and CR delivery,(Davos 2017).

The literature search found no studies further investigating volume or class size and thus to date this study appears to be the only published study on VOR in CR. This study concluded that volume has no significant association with outcome which will be validated in studies in chapter 4.

The conclusions of this study continue to play a vital role in contemporary CR. The finding that volume was not associated with outcomes may be the cause for such volume variation across the globe. In a survey of CR programmes, large variation existed between and within countries such as in Romania, with 1,400 and Finland with 55.(Abreu, *et al.* 2019) The range in volume internationally is interesting as this may allow for wider validation of these UK findings.

There are some limitations associated with this study which were addressed in later work. For example, within this study, there is no presentation of the descriptive data for the population. This means that for researchers they would not be able to assess representativeness. Future work included tables that directly discuss descriptive statistics including demographic variables such as age, gender and marital status.

Lessons Learnt

The key finding from this paper were that programme volume was not associated with the multiple patient outcomes. In addition, the use of the NACR data was appropriate and should continue to be used for observational studies

Chapter 3: Employment Status and Psychosocial Wellbeing Change Post-CR

The association between psychosocial wellbeing and CVD is well documented.(Strens, Colle *et al.* 2013) With almost 30% being borderline or clinically anxious and 20% being depressed, the burden is clear for patients entering into CR.(BHF 2019) The prevalence of psychosocial problems is associated with reduced participation in healthcare inventions including CR.(Anne, 2012, Ruiz, *et al.* 2017, Dean, *et al*. 2018) A factor that is closely associated with psychosocial wellbeing is socioeconomic status, specifically employment status. The association is evidenced in many condition-specific populations, including CR.(Leslie, *et al.* 2007)

Both psychosocial wellbeing and employment status have shown to be associated with the utilisation of CR. At the time *Study two* was conducted (2016), there was no evidence to suggest that employment status in CR routine care was associated with baseline scores and post CR outcomes of psychosocial wellbeing.

Study two: Relationship between employment and mental health outcomes following cardiac rehabilitation: An observational analysis from the National Audit of Cardiac Rehabilitation

The aim of this study was to assess whether patient employment status was associated with their psychosocial wellbeing post CR, factoring in patient demographics and an estimation of deprivation.

Study population

The study population was drawn from audit data collected between 2013 to 2015. All patients receiving routine CR were included. The total number of eligible patients were 49,512, however, only 24,242 patients were included when post CR measurement was applied as selection criteria. The study sought to take account of covariates/confounders by including more relevant variables, such as employment status, duration of CR and index of multiple deprivation (IMD). All of which, through the need for valid cases, required a relatively larger data set to identify sufficient valid cases due to the extent of missing cases within the selected variables.

The IMD score was assigned to patients based on clinical commissioning group (CCG) of responsibility, e.g. where patients were registered with a GP. This allowed the allocation of the indices to be assigned at a patient-level and included in the analysis. There are limitations with the present allocation process. The CCGs are somewhat large areas and patients may not live within their CCG of responsibility. However, at the time this was the only location field available.

The inclusion criteria included patients starting and completing CR, having pre and post measures for HADS or Dartmouth COOP and valid employment status.

In CR literature, there is large variation in how employment status was coded. This varied from binary employed/unemployed, through to the 12 categories in the NACR annual report.(BHF 2019) Three groups were created; employed (used as base group for regression), unemployed and retired. This was justified due to the evidenced differences in employed/unemployed patients, however, retired made up >55% and was thought to be significantly different in age and other confounders.(Strens, *et al.* 2013)

Analysis

Outcomes in this study were categorised into clinical sub-scales which were '0' was Normal (0-7) range and '1' was Anxious/depressed (8+). This enabled the study to report odds ratios which is more clinically relevant for the CR team. The employment status and other variables were inputted into the model based on the evidence around their associations with psychosocial wellbeing or other CR outcomes.(Leslie, *et al.* 2007, Strens, *et al.* 2013)

IMD was used as categorical based on quintiles. Odds ratios were calculated based on differences from the highest deprived to the four quintiles. The analysis included descriptive information for the population, allowing readers and other researchers to assess its representativeness. Included variables in the analysis are shown in **Appendix 7.**

Results

The results show that patients from all employment groups show a positive reduction in terms of their psychosocial wellbeing. It was found that there was an average reduction of 6.1% and 5.7% for anxiety and depression and a 5.3% and 2.6% reduction in the two Dartmouth COOP measures.

However, though all groups improve, the level of improvement is less in the unemployed group after accounting for lower starting point. Unemployed patients were 10% and 13% higher by proportion in the anxious and depressed categories respectively. Overall, this finding is aligned with the wider literature that found that unemployment was correlated with poorer psychosocial health. (Leslie, *et al.* 2007)

The study was unique in its design and pivotal in informing clinicians of unemployed patients' shortfall in change post CR. However, it clearly shows that, despite its reduced benefit in this population of patients, CR should be provided because, for all outcomes, there was reduced burden of psychosocial problems post CR.

Finally, the results also found a novel finding whereby employed and retired patients were not significantly different in their outcomes. This shows that if age, gender and other covariates are accounted for, retired and employed patients can be grouped together for future analysis.

Discussion

This study's findings are novel as it was the first to assess employment status and its association with psychosocial wellbeing. It further enforces the findings of the first study in demonstrating that CR results in positive change for patients, and that NACR is an appropriate data source from which robust OS can be performed.

A common limitation is the extent of missing data within routine data which potentially could compromise generalisation through a lack of representativeness. To counter this issue, this study assessed the demographics at baseline and found they were representative of the wider CR population,

but by including fields such as IMD, which reduces the numbers, may introduce unknown selection bias.

A further limitation of this analysis was that programme level variables were not employed. This was done to maximise the sample as when IMD was included as a covariate the cases available for the analysis were reduced. However, as employment status and this outcome were included in *Study 3*, we are confident that these findings were accurate.

The literature review identified eight OS and one survey related to this study. The studies were of mixed quality, three high quality and the remaining six were moderate to low quality. This was assessed using the checklists set out in Chapter 1.

The high-quality studies were one longitudinal study from Canada and two were cross-sectional studies. All three included employment status in the analysis with outcome. Both Sverre and Summer *et al* studies also found that unemployment was negatively associated with outcomes post CR.(Sverre, *et al.* 2017, Sumner, *et al.* 2018) However, the study by Alharbi et al, showed no significant association between employment status and outcomes (p-value >0.05); this may be due to the small size and differing outcomes used.(Alharbi, *et al.* 2016)

The moderate and low-quality studies were retrospective and prospective OS, cohort and a multi-centre survey. Only three of the studies included employment status in the final analysis which included depression, anxiety and exercise capacity as outcomes.

Pourafkari *et al* showed that unemployed/retired patients had worse depression and anxiety before and after CR in comparison to employed patients.(Pourafkari, *et al.* 2016) The average age of the population was 60 years (±8) indicating a younger population than NACR and probably more unemployed than retired. There was greater improvement in the unemployed group for depression and anxiety post CR than the employed group (Depression 24% and Anxiety 22% greater improvement), however, unreported factors not presented may have distorted this finding.

Three studies showed poorer psychological and physical outcomes in unemployed patients or in lower levels of socio-economic work in comparison to higher level or employed patients.(Szalewska, *et al.* 2015, Mikkelsen, *et al.* 2018, Sutherland, *et al.* 2018)

The remaining studies showed no significant association between employment and outcomes.(Caccamo, *et al.* 2018, Thomas, *et al.* 2019) However, there was relatively poor reporting in the study by Caccamo et al, and the results table did not provide sufficient details. The study by Thomas showed no association although this was investigating the association with admissions, different to the outcome identified here.

Across the literature, it is apparent that there is a diverse methodology for categorising employment status. The NACR collects a wide range of status for the purpose of audit, however, future research should adopt the two categories of employed\retired and unemployed especially when using psychological outcomes.

Overall, although no direct repetition or analysis was performed post publication, the wider literature both pre and post conform with the conclusion that unemployed patients are worse at baseline in terms of risks factors

Lessons Learnt

The key finding from this paper demonstrated that employment status was associated with pre and post psychosocial wellbeing; a finding validated in the wider literature. In addition, as the employed and retired group were not similar in pre post scores, future studies may seek to group them together for analysis.

Chapter 4: Mode of Delivery and Outcomes Post-CR

For over 10 years, the method of delivery for CR has been dominated by group-based versions. Even though a menu-based approach has been encouraged in guidelines, such as the BACPR, this method still appears to be, for many patients, the only offer.(BACPR 2017, BHF 2019) In 2018, the NACR showed that 80% of patients are receiving group-based with home and web versions often being underutilised. The most recent guidelines, published this year by the AHA, specified the core elements to which home-based CR must adhere.(Thomas, Beatty *et al.* 2019) The guidelines also summarised the potential benefits and disadvantages that home-based version may have which are shown in **Table 3**.

Table 3 *Showing the potential advantages and disadvantages of Home-based CR models with Centre-based CR as shown in the Scientific Statement published by the AHA 2019 (Thomas, et al. 2019)*

Potential Advantages	**Potential Disadvantages**
Reduced enrolment delays	Lack of reimbursement
Expanded capacity/access	Less intensive exercise training
Individually tailored programs	Less social support
Flexible, convenient scheduling	Less patient accountability
Minimal travel/transportation barriers	Lack of published standards for HBCR
Greater privacy while receiving CR services	Less face-to-face monitoring and communication
Integration with regular home routine	Safety concerns for patients at higher risk

Considering that the uptake has remained relatively stagnant, around 50% over recent years, this highlights a potential threshold whereby group-based CR is at capacity. There has been a push for more modes as part of the CR menu to increase uptake with home-based emerging, based on RCT evidence, as a viable alternative. There is limited research on how home-based is working as part of a clinical practice offer.

A recent Cochrane review published in 2017, assessed the trial evidence for home versus group-based CR.(Anderson, *et al.* 2017) The conclusion was that outcomes in home-based CR in terms of mortality, readmission and quality of life were not significantly different to group-based. Moreover, the evidence suggests a better adherence to CR in the home-based group.(Anderson, *et al.* 2017)

Due to poor representativeness of trial patients to wider routine care populations, rationale existed to assess whether using routine care outcomes, the same effect could be found in OS. Three unique studies were performed, each using different outcomes, accounting for different confounders and a progressive analytical approach to address that gap in the literature.

Study three: Does the mode of delivery in Cardiac Rehabilitation determine the extent of psychosocial health outcomes?

Study three aimed to investigate whether the two different modes of delivery were associated with psychosocial wellbeing as measured by HADS and the Dartmouth COOP questionnaire.

Study population

The data used for this study was from 2012-2016 financial years. The inclusion criteria were that all patients needed to have started and completed CR in the time period and have a recorded mode of delivery. A total of 120,927 cases were used for demographic and population descriptive work, however, for the main analysis patients needed to have completed pre and post assessment measures of the four psychosocial wellbeing scores and this resulted in 34,305 cases included. The measures were HADS and the Dartmouth COOP measures, coded in the same manner as S*tudy two*. The final sample for the regression analysis was 34,305.

Analysis

The analysis used in this study is similar to that of the first two studies. Firstly, the outcomes were similar in terms of HADS and Dartmouth COOP. In addition, the employment status was coded as per the result of the second study with patients being coded as Employed/Retired or Unemployed.

Secondly, the regression analysis was structured hierarchically, accounting for the different levels of data. Mode of delivery was a patient level variable, however, it was likely to be significantly associated with the programme. Thus, the data were structured into three levels, patient level, mode and the service level variables such as MDT, staffing hours and volume.

Mode of delivery is a patient level variable that is completed by the clinician during or after the patient receives core rehabilitation. The selection of mode is non-exclusive, so patients can have a combination of the options, thus the study recoded the modes into supervised and self-delivered. The supervised modes included group-based whereas the self-delivered included home-based, web-based and telephone. The completion of GP practice was poor and thus, to maximise sample size and reduce selection bias, IMD was not included in this study. All variables included in this analysis and subsequent *Studies* are shown in **Appendix 7**.

Results

The analysis initially compared the study population to the wider UK CR population. This was found not to be significantly different in terms of age and gender. The study also identified that the patients taking up self-delivered were more likely to be female, older and employed/retired. This is an important finding as it informs clinicians that specific subgroups, often underrepresented in routine CR, are either more willing to take up this alternative offer. In addition to the specific demographic subgroups, it was also apparent that baseline psychosocial wellbeing status were worse in the self-delivered group with 1-3% less likely to be in the target category.

The regression showed no significant association between the two methods of delivery and the scores of patients, for all measures, post CR. The co-variates input into the model such as staffing and employment were significant which represents a new finding and adds to the existing literature.

Additionally, this study included programme volume as a co-variate. This is the first study that has included volume as a co-variate since *Study one* was published in 2015. This study found that programme volume, included as a continuous independent variable, was not significantly associated

with the outcomes. Whilst this was not included in the study, as it was outside of its main aim the results are presented in **Table 4**, showing a >0.05 p value for all four outcome measures.

Table 4 Results from the logistic regression analysis; association between volume and psychosocial health outcomes post CR

Outcome measure post CR	**Odds ratio**	**Sig.**	**95% CI**		**Observations**
HADS Anxiety	0.999	0.681	0.999	1.000	33,748
HADS Depression	1.001	0.987	0.999	1.000	33,719
Dartmouth COOP Feelings	0.999	0.881	0.999	1.000	28,982
Dartmouth COOP Quality of Life	1.000	0.662	0.999	1.001	28,982

Limitations

The study had some limitations with some common to the data source and one identified through the peer review process.

Firstly, the analysis was affected by missing data which was a common theme in OS using routine data. Only 56% of the population in the data had post CR assessment which reduces the sample size for analysis and introduces the risk of bias in the sample. This bias is reporting bias, whereby a specific group or subgroup are more likely to engage and be recorded, other groups which are significantly different populations are missing. The study commented on this bias and tried to account for this by comparing analysis population with wider CR groups and tested for differences.

Another limitation was suggested by a reviewer and was subsequently inserted on resubmission. The reviewer highlighted limitations associated with the use of self-administered questionnaires. As a result, the study was edited around the use of self-administered questionnaires in assessing psychosocial wellbeing. Self-assessment questionnaires, although easily administered, have potential limitations specifically in an older population such as that in CR.(Balsamo, *et al.* 2018)

Discussion

This study was the first to investigate in routine populations the association between mode and outcomes. It enabled the framework for *Study four* and *five* and prompted an editorial to be published at the same time. This editorial, by Risom, reviewed the study in the light of literature in the area and its methodological choices. Key sections of this editorial backed up the rationale, such as stating that this study supports the belief that we can transfer the knowledge we had from clinical trials into the real world and that finding solutions to issues. such as largely varied and multi-morbid populations, can be integrated into the 'real life' data sets.(Risom 2018) The editorial also highlighted the findings and limitations of the study, such as the poor offer of self-delivered CR (~40% of programmes offer this method) and the lack of completed questionnaires. However, this was known by the authors at the time and causation was not inferred.

The subsequent review of literature identified 19 studies which investigated mode of delivery and its association on outcomes. Of these studies, nine utilised psychosocial wellbeing or quality of life as the outcome. Six of these studies showed no association between mode and the outcomes,(Mosleh, *et al.* 2015, Piotrowicz, *et al.* 2015, Anderson, *et al.* 2017, Bravo-Escobar, *et al.* 2017, Gabelhouse, *et al.* 2018, Aronov, *et al.* 2019) two showed group/centre-based had greater outcomes (Najafi, Nalini 2015, Bravo-Escobar, *et al.* 2017) and one showed individualised combined exercise was positively associated in comparison to CR.(Christle, *et al.* 2017)

The six studies were a mixture of study designs (2 RCT, 1 SR and 2 non-RCT and 1 cohort study), with varied quality (2 high quality, 2 moderate and 2 low quality). Although these studies do differ in the outcome tools used, e.g. short form 36 (SF-36) (Piotrowicz, *et al.* 2015), the lack of an association between the mode of delivery and patient outcome is consistent. This further supports the conclusion that patients benefit from both modes of delivery, and any offer should be based on patient preference. A SR published in 2019 investigating the predictors of enrolment, adherence and completion, identified a positive association between distance sessions and completion. This further supports the utilisation of a 'menu' approach especially when considering no difference in psychosocial wellbeing outcomes was identified.(Pio, *et al.* 2019)

The two studies showing a positive association between group/centre were a mixture of designs, a RCT and an OS, had moderate quality and the outcome was SF-36 as well as anxiety.(Najafi, Nalini 2015, Bernocchi, *et al.* 2018) The differences in outcomes in relation to mode are significant and does highlight further clarification with the exact type of intervention and details of patient type and the staffing profile. Additionally, both populations were significantly younger, over 10 years younger than the present study, and one was exclusively male. This highlights that they are largely different samples and thus may explain the different outcomes.

The last study showed greater improvement in an individualised combined exercise intervention.(Christle, *et al.* 2017) This highlights a potential greater improvement in patients with an individualised combined exercise intervention. This is supported in the benefits listed in the AHA guidelines which suggest potential tailored patient centred programmes.(Thomas, *et al.* 2019)

Overall, when comparing the results of this study to others published since, there is a large level of conformity in the lack of an association between mode and outcome which reinforces the findings. Where there are differences, the moderate reporting, differences in modes being assessed and specifically sub-group populations may explain the variation.

Lessons Learnt

The key findings from this paper were that, even when accounting for programme level variation, the findings of unemployment and its association, like *Study two*, still hold. Additionally, the analysis showed that self-delivered CR was equivalent in relation to psychosocial wellbeing outcomes for patients.

Study four: Are physical fitness outcomes in patients attending cardiac rehabilitation determined by the mode of delivery?

Following the successful study and analysis in *Study three,* the natural next step was to focus on physical fitness measures as a CR outcome. The aim was to adapt the mode of delivery methodology to ascertain if there were associations between mode, supervised vs. self-delivered, and the two fitness measures, the ISWT and the 6MWT.

Study population

The study population included patients from 2012-2017 within the NACR. All patients except those with heart failure were included. The total number of eligible patients was 165,435, however, only 10,142 patients were included when post CR measurement was applied as selection criteria. The lengthening of the time period allowed more up-to-date data into the analysis which contained a higher rate of completion of post CR assessments. The inclusion criteria were similar to *Study three*; patients needed to have completed CR and have recorded mode of delivery**. Appendix 7** shows which patient and service variables were included.

Analysis

The model was using data structured hierarchically which allowed for the inclusion of both patient and service level variables like age, gender and staffing information. As in previous studies, this analysis included programme information such as volume, staff type and MDT. The patient level information included age, gender, employment status and duration of CR.

The duration of CR was calculated from the start or pre-assessment until completion date or post assessment date. The length of CR was thought to be significant in its association with outcomes. This is partly because a longer duration would indicate a more intense and influential intervention, but also as longer time between pre and post could result in a higher change in fitness. Previous work highlights

the length of CR as an influential factor, justifying the inclusion in the analysis.(Morrin, *et al.* 2000, West, *et al.* 2012, Sandercock, *et al.* 2013)

The analysis utilised the outcomes of patients post CR from two well established walking assessments. The first was the ISWT, an externally paced walking test, where patients follow audio cues around a 10 metre circuit that becomes increasingly more challenging (faster) each minute.(Singh, *et al.* 1992, Singh, *et al.* 2008) The total distance covered indicates the level and sub level covered by the patient. In addition to the ISWT, 6MWT was used which is a test whereby patients walk at their natural cadence or preferred pace for a period of 6-mintues.

The outcomes were used as continuous variables thus allowing for the comparison between modes and the change in scores of patients and the Minimal Clinically Important Difference (MCID) to be used as an indicator of clinically meaningful change across the groups.(Singh, *et al.* 2008, Gremeaux, *et al.* 2011, Houchen-Wolloff, *et al.* 2015) MCIDs, specific for acute coronary syndrome (ACS) patients, are cross validated distances and are deemed meaningful to the patient and clinician. MCIDs have been generated for the two measures of fitness: for ISWT a distance increase of 70 metres, and for 6MWT a distance of 25 metres. Studies showed patients having an increase at or above the threshold resulted in a significant improvement physically but also the psychologically benefits too.(Singh, *et al.* 2008, Gremeaux, *et al.* 2011, Houchen-Wolloff, *et al.* 2015)

Results

The demographics of the full included study population were presented (*Study four, page 4, table 1*). The study population had 80% receiving supervised CR. The supervised population was predominantly male, employed, had a partner, and had PCI or CABG. The average age in the supervised group was younger and had shorter CR duration than the self-delivered group.

At baseline, the self-delivered group scored lower on both tests. The change evident in the study shows that for the 6MWT the supervised group experienced a larger improvement whereas ISWT showed a

larger change in the self-delivered mode *(Study four, page 4, table 3*). Both groups had average changes larger than the MCID.

The regression model showed, in addition to positive changes experienced in both modes, no significant association between mode and the post CR score for either walking test. The inclusion of potential confounders, such as age, gender and duration were justified.

Limitations

Of all the studies within this thesis, this study experienced the largest drop in patient cases in the analysis due to the missing data. In the NACR dataset, the completion of functional capacity measures (FCM) are one of the lowest completed of all assessment fields. The reasons for this included lack of training and space within CR programmes, but also a potential barrier, whereby more complex and high-risk patients are not assessed for FCM. These reasons were verified by clinicians in a survey of UK routine care.(Alotaibi 2018)

Another limitation was the unknown variability in how the FCM tests were run within each centre. For example, the length of corridors, differing levels of encouragement from clinicians or number of practice runs may have altered outcomes for patients with the same functional capacity. However, as their baseline scores were accounted for, and much of the variability would not differ within programmes, the methodology accounted for this.

Discussion

The conclusion of this study was that in two walking tests, patients attending either mode of delivery had meaningful positive improvement post CR. Moreover, there was no significant association found with mode and fitness results matching the previous study and wider literature.

In the literature search studies assessing mode with outcome, 18 included a FCM. Twelve of these studies found no significant association with traditional or distance CR in terms of FCM outcomes. These studies included four high-quality, six moderate-quality and two low-quality studies from a mixture of research methods including a Cochrane review.(Huang, *et al.* 2015, Mandic, *et al.* 2015, Najafi, Nalini 2015, Aamot, *et al.* 2016, Chen, *et al.* 2016, Tang, *et al.* 2016, Anderson, *et al.* 2017,

Christle, *et al.* 2017, Bernocchi, *et al.* 2018, Gabelhouse, *et al.* 2018, Imran, *et al.* 2019, Mujeeb, Kazi 2019) The review showed no difference in mortality and hospital admissions aligning with the results for routine practice and exercise capacity.

The remaining studies showed that mode of delivery was associated with functional capacity. Five studies (3 RCT, 2 OS) showed a positive association with traditional group-based CR, and one study showed the opposite.(Ramadi, *et al.* 2015, Bertelsen, *et al.* 2017, Avila, *et al.* 2018, Chen, *et al.* 2018, Laddu, *et al.* 2018, Parreira, *et al.* 2018)

Across all studies, a variety of different FCM measures were used, such as volume of oxygen (VO2) max,(Chen, *et al.* 2016) and metabolic equivalent of tasks (METs) scores (Ramadi, *et al.* 2015, Chen, *et al.* 2018) and 6MWT. (Parreira, *et al.* 2018) The different outcome measurements used may explain some of the varied results. In addition, the variation in definitions of different modes may also be the cause. The study by Parreira et al, showed an association between the supervised CR as opposed to self-delivered, however, this differs to the comparison in the review.(Anderson, *et al.* 2017, Parreira, *et al.* 2018) With a growing emphasis on innovation and utilisation of different modes of delivery, clear definitions should be sought.

The overall consensus from the review of literature and this study is that functional capacity, for the most part, is improved through attending CR regardless of its mode of delivery and the evidence suggests that self-managed patients benefit to the same extent as supervised patients.

Lessons Learnt

The key findings from this paper build upon those found in *Study three* in that mode of delivery, defined as supervised or self-delivered, was equivalent in terms of FCM outcomes. In addition, the amount of data available for analysis of the FCM was such that future studies should seek to include the ISWT and 6MWT as outcomes.

Study five: Does the mode of delivery in routine cardiac rehabilitation have an association with cardiovascular risk factor outcomes?

The method deployed in this study was informed by the first study, and subsequently improved because of Studies two-four. It investigated the association between mode and outcomes as per studies three and four, factoring in key variables such as programme volume (*Study one*), employment status and IMD (*Study two*).

The aim of this study was to, using refined terminology, assess the association between supervised and Facilitated Self-Managed (FSM) CR with four key risk factors.

Study population

This study used data covering the period 1st Jan 2012 to 30th April 2018 with patients being included if they had completed CR and had a recorded mode of delivery. The total sample included were 81,626 patients. This remained at this level as multiple imputation was run for any missing fields of which 51,915 had at least one imputed value.

Based on feedback from clinicians about our published studies, conference presentations and NACR reporting, the mode of delivery was redefined in this study to better represent the work done by CR staff and the clinical infrastructure used to support CR. The terminology used was FSM replacing 'self-delivered' as used in studies three and four. This was compared with Supervised CR.

A common thread throughout the previous studies was missing data. It was decided to implement a statistical method to estimate or generate missing cases. Two options were considered for this; expectation maximisation and multiple imputations.

Expectation maximisation is a method whereby missing values are imputed into a single dataset with estimated maximum likelihoods generated.(Rubin 1977) This method allows the analysis to be performed with one singular dataset, which is the same upon repetition, thus differing from multiple imputation. The limitation with this is that if data is considered missing 'not at random' then the expected and maximum meeting point can be skewed.

Multiple imputation is an alternative method whereby new data is generated based on pre-existing limits within the original dataset.(Hosmer, *et al.* 2013) The imputation is run multiple times resulting in as many new versions of the data as required. The benefit of this method is that the original and new imputed versions can be used in the same regression and this allows for comparisons to be made. Caution is needed when imputing the data as key examples in the literature have shown poor imputation procedure has resulted in erroneous or lack of known associations such as cholesterol and CVD risk.(Hippisley-Cox, *et al.* 2010)

Ultimately, the method chosen for this analysis was that of multiple imputations. This is because of the wide adoption and pre-existing utilisation in the literature of this method ultimately led this to method being chosen to increase interpretability. The analysis used 20 imputations giving sufficient different iterations to account for the random imputation.

Analysis

The outcomes for this study were four key CVD risk factors including smoking, BMI >30, physical inactivity and blood pressure >140/90. Each variable was recoded into dichotomous variables (i.e. meeting or not meeting health targets), which resulted in interpretable, usable odds ratios that could inform clinical practice.

The analysis was a logistic regression with multiple confounders and predictors inserted at different blocks. These included patient factors such as age, gender, employment status and duration of CR and the programme factors staff hours and volume. The IMD in this study was assigned to the patient based on residential Lower Super Output Area (LSOA). This improved the accuracy of deprivation as the LSOA level is smaller than the CCG.

Imputed values were generated for employment status, duration of CR, staffing profile, comorbidities, waiting times and baseline psychosocial wellbeing scores. In total, 81,626 patients were eligible and 51,915 had at least one measure imputed. This meant that across the four regression models, a total of 81,626 cases were used. Mode of delivery was not imputed as it was an inclusion variable.

All variables included in this and subsequent *Studies* analysis are shown in **Appendix 7**.

Results

Mode of delivery was compared against patient demographics, and again, the FSM had a greater proportion of females, older, white, single and less multi-morbid patients. A novel finding was that patients taking up FSM were in greater proportion from lower IMD groups, were symptomatic of depression (<8 HADS), had a previous diagnosis of depression and a shorter waiting time.

At baseline, FSM patients had greater lifestyle risk factors e.g. smoking. Post CR, the change was varied with greater change in smoking and BMI but less change in blood pressure and physical activity. (*Study five, table 1*)

The regression showed no significant association between mode, smoking and blood pressure, whereas, for the FSM patients, the odds of patients being physically active was 13.7% and were 11.4% more likely to have BMI <30 (p value <0.001 and 0.0016 respectively).

The results showed that patients undergoing both FSM and supervised modes benefit from CR, however, for physical activity and BMI risk factors, accounting for confounders and baseline scores, patients from the FSM mode were more likely to be in the active and normal BMI. This differs to the findings of the recent Cochrane review.(Anderson, *et al.* 2017) The differing results should be interpreted with caution as the review compared centre group-based CR with mortality and readmission of patients and not risk factors such as BMI and physical activity. In addition, this population is more diverse than many of the trials included in that review such as a mean age of 56 years compared to 66 years, and females made up ~10% compared to 24-28% of the populations (depending on mode).

Limitations

The overarching limitation of this study was the missing data. Although this study utilised multiple imputation that accounted for missing cases, it was still a limitation in that over half of the total sample needed at least one imputed value. Assumptions were that all imputed variables were missing at random,

with those thought to be not missing at random excluded. In future work, inclusion of all variables and adjustments for non-random missing would further validate the findings.

Discussion

The results of this study confirm the previous work, further consolidating the findings of each individual study. Of the 19 studies that have investigated mode since 2015, there were ten studies that had at least one risk factor in their outcomes.

Seven of the studies showed no association between mode and outcomes. These included SR (two), RCTs (one) and OS (four) and they were of mixed quality (4 high, 1 moderate, 2 low). There were three studies that showed centre-based CR was positively associated with improving risk factors. These included greater cholesterol improvement in centre-based CR, greater physical activity and body composition.(Ramadi, *et al.* 2015, Chen, *et al.* 2016, Christle, *et al.* 2017) Across all the studies, the risk factors included physical activity, smoking, weight and cholesterol.

As per the findings of this study, patients do benefit from CR regardless of the mode of delivery. As the composition of different modes of delivery can vary widely between studies, this may account for the heterogeneous results in the literature. Future work should seek to standardise what is meant by FSM and home-based versions.

Lessons Learnt

One of the key findings from this work was that a redefinition of mode of delivery clarified a potential misleading categorisation that may have validated an inferior mode. Additionally, the findings that FSM was equivalent in terms of smoking and blood pressure aligns with the previous studies in the NACR and the wider literature. The more unique findings that physical activity and BMI were positively associated may be down to better tailoring and that baseline prevalence was different between groups. Future work should seek to explore these findings in more detail.

Chapter 5: Discussion and Conclusion of Thesis

The aim of this thesis was to investigate whether variations in CR delivery, such as mode, volume and patient populations, are associated with differences in patient outcome. The aim was met in that key patient characteristics were identified to be associated with outcomes, e.g. employment status and IMD. Additionally, the analysis found that service characterises, e.g. mode of delivery and volume were not associated with the three outcome groups. Moreover, the findings align with the literature, utilising different methodologies, either supporting the association between employment and psychosocial wellbeing or little to no association with mode and outcomes

In addition to the initial aim, this thesis has shown that well performed OS can guide and support decision making in healthcare. This collection of *Studies* may be an example of that. The conclusions of this body of work allow clinicians to adjust care or, equally, continue with methods that are working well in practice. Adopting a broad range of methods in clinical practice allows for comprehensive evidenced based medicine and evaluation to take place.

When the methodological capabilities offered by OS align with the study aims and research questions, utilisation of this method is clearly justified and appropriate.(Black 1999, Carthey 2003, Silverman 2009, Anglemyer, *et al.* 2014) The OS design allows for assessment of multiple factors at once utilising routine care data and, as a result, conclusions can be made in a timely manner.

The studies that make up this thesis represent a progressive and sequential methodological approach, whereby analyses were built upon, resulting in clear conclusions used to inform and improve clinical practice.

Two themes have emerged from this body of work that can be taken forward into both research and clinical practice. Firstly, the findings of key patient and service variables that are, or are not, associated

with outcomes helps to inform service and tailor the intervention. Secondly, the methodological development by which future OS can be conceived, designed and conducted.

Thesis findings influencing CR practice

Validation of improvement in routine patient outcomes

CR has been well established as an effective intervention through RCTs and SR over the past 40 years.(Anderson, *et al.* 2016) The thesis found that, in addition to this efficacy evidence, there were substantial changes in routine outcomes, such as BMI, ISWT and smoking cessation. In all studies, there was positive reduction in risk factors and, based on this evidence, there is now a real understanding that patients benefit from attending CR further justifying its wide adoption in the NHS. This is extremely timely as it gives a strong basis for commissioners to develop CR and help to influence uptake to meet the new 85% uptake target set by the NHS long term plan.(NHS 2019) This result aligns closely with other work on routine populations in CR.(Mandic, *et al.* 2015, Najafi, Nalini 2015, Gabelhouse, *et al.* 2018)

Association between programme volume and outcome

Study one indicated that, contrary to other healthcare settings, VOR were not present in CR. At the time, this finding was novel, however, the subsequent inclusion of volume in *Studies three, four and five*, found that volume did not have a strong statistical association further consolidating this result. This finding across multiple years of CR, in varying populations, provides further evidence for CR providers and clinicians that volume of patient throughput is not directly related to outcomes.

In addition, since the inception and publication of *Study one*, VOR appeared to be widely accepted. A range of other healthcare interventions have shown less support for VOR. This includes a published

study showing no VOR in PCI surgery.(Hulme, *et al.* 2018) The VOR model was based on the principle 'practice makes perfect' and was well accepted in 2015. However, more recently, it may be that in centre interventions or populations, the patient choice and individualised care counters this. In addition, with the varied nature of CR delivered across the world, future research should investigate whether CR in large or small programmes have higher utilisation by patients and whether they are cost effective.

Patient benefit exists through all modes of CR

An important aim of the thesis was to ascertain if a variety of outcomes were associated with the patient level mode of delivery. The findings from the final three studies (*three, four and five*) was that mode of delivery, such as supervised or FSM, was not, for the most part, associated with outcomes and is similar to that of the trial evidence summarised in the recent Cochrane review.(Anderson, *et al.* 2017) Each paper separately accounts for service and patient characteristics, such as age and volume, support the utilisation of a menu based approach, tailoring for the patient need. This set of results was timely in 2018-19 as recent AHA guidelines support the wider utilisation of modalities.(AHA 2019) In addition, the growing need for increases in uptake as stated by the NHS long term plan can only be achieved through wider modes of delivery.(NHS 2019)

The wider benefits associated with home-based CR presented in **Table 3** (page 36) should be the basis of future research paralleling the emphasis on supervised CR.

In addition to the studies discussed in this thesis, other studies have showed comparable benefits with FSM CR, such as risk factors and FCM. The varied nature of the CR delivery, as shown in the literature, is a possible reason for the heterogeneous levels of association with outcomes.(Najafi, Nalini 2015, Ramadi, *et al.* 2015)

It is apparent that uptake in the UK may be at a capacity threshold with 50% being the average over recent years (BHF 2019). The only way that services will meet the needs of patients is to incorporate wider modes. Evaluation of these modes such as app, web and self-managed versions should be of upmost importance. In the past year, many studies and innovations have made inroads into this area of care.(Vieira, *et al.* 2017, Torri , *et al.* 2018, Piirainen, *et al.* 2016) One such innovation is the Rehabilitation Enablement in Chronic Heart Failure (REACH-HF) mode of care. This has a strong trial-base and is now being evaluated in routine care to see if it meets the needs and has comparable outcomes for patients in routine practice. Alongside producing OS, this is another avenue by which clinical audits such as NACR can help to evaluate and shape the future of CR. This is especially timely for services to reach the 85% NHS uptake targets.(NHS 2019)

Populations represented in routine clinical audit

A justification for the use of routine clinical registry data is that the populations contained in such registries are arguably more representative of patients accessing routine care than those who are recruited into trials. In addition, patients on average had at least one additional co-morbidity to their CVD event with many having more than one additional comorbidity. The varied nature of staffing hours, type and volume presented in the *Studies* is rarely seen in trials.(Anderson, *et al.* 2016, Anderson, *et al.* 2017) The high level of representativeness in terms of routine care patients is valid and vital for informing clinicians, health commissioners and providers about the actual/potential level of service change and improvements expected in respect of the CR intervention (mode) delivered.

Synthesis of findings and studies

A consistent and progressive body of OS findings alongside robust methodology are presented through this body of work. It is timely to utilise observational methodologies to identify and evaluate how best to deliver CR as part of a complex intervention.

This collection of studies demonstrates some major innovations and developments in producing and reporting on studies. It also promotes the use of routine data for the assessment of new modes of delivery such as the routine care evaluation site for REACH-HF assessment. As a result, routine data (NACR data) is now established as a way of evaluating modes of delivery of CR across the range of CVD populations.

Methodological development and recommendations

A strength of the thesis is the sequential development of the methodological approach through the five studies. The culmination of this development is summarised in the final study and the key developments are shown below.

Reporting of data

As the development of the studies progressed, the quality and transparency of the reporting increased; this resulted in more replicable and clear studies. In terms of presenting the data, *Study one* had significant drawbacks. The strengthening of reporting of observational studies in epidemiology (STROBE) guidelines in the early work were used as a checklist to include important sections. (Vandenbrouke, et al 2014) However, in subsequent studies from the point of conception STROBE was considered and this allowed for inclusion of data, categorisations to be justified and bias in sampling to be assessed. For example, in *Study One* lack of presentation of a demographic table of the study population hindered assessment of bias. This thesis can be used as an example of how aligning with

STOBE more throughout the process increases quality of the completed research papers. In addition, closer alignment with STROBE guidelines would provide a more robust reporting technique.(Vandenbrouke et al 2014)

Regression patient and centre levels

The structuring of the different levels in the NACR data in the regression design was implemented in all studies except *Study two*. The inclusion of a centre variable would have allowed the analysis to account for other service factors not measured. However, the findings of study of *Study two* were validated in follow-up work which included centre level data and the psychosocial wellbeing outcomes. Structuring the data hierarchically remained justified as each study had a mixture of service and patient level variables.(Gelman, Hill 2007) The different layers of data allowed for the patient and service variables to be included. It is important to implement this methodological approach in studies which are similar in design or specific complexity of intervention or populations. This is because structuring by levels allows the factoring of multiple service and patient factors at once and has been shown to be more accurate than analysis done at the single level.(D'Errigo *et al* 2007) The advantages of this approach include correct inference estimation and the ability to ascertain group effects more accurately. Although there are a variety of different methods for building regression models, especially due to the high variable nature and many complex components this approach is suitable. The thesis supports the further adoption of hierarchical modelling when the data is structured in the appropriate manner and the sample allows for power in the model.

The ability to take account of covariates/confounders by including relevant variables, such as employment status, duration of CR and IMD across multiple levels is a strength of *Study two* onwards.

Assessment of Sample Representation

This collection of studies, specifically *Study two* onwards, increasingly compared the included populations with the wider NACR data. The comparison allowed conclusions that were made to be more externally validated to the UK CR population. Generalisability and transparency of potential sampling bias is vital in robust OS.(Anglemyer, *et al.* 2014) In *Study two* onwards, there was assessment of reporting bias such as comparisons in observable demographics e.g. age, gender and ethnicity. This allowed for the conclusions to be extrapolated to the wider CR population which is more informative for clinicians and allows increased confidence that the sample is representative.

Accounting for Missing Data

Specific variables such as the IMD, employment status and FCM were all highly exclusive and introduced significant drops to the population size. In *Study five*, the methodological approach of multiple imputation was utilised. This was deemed suitable both for the data source, due to its large need for data imputation, and also the potentially non-random missing of data.(Hosmer, *et al.* 2013)

Within the analysis, variables with assumed non-random missing were only included if they had valid cases, these included core variables such as age, gender and mode of delivery. Imputation was run on all other included variables, and therefore, deemed missing at random. The exclusion of missing cases in variables with missing data was a limitation of this *Study five*. In future work, utilisation of sensitivity analysis exploring departures from the missing at random assumption would be informative.

There have been other studies in the CR literature that have been published with multiple imputation showing it as a viable and understood solution for missing data.(Al Quait, *et al*. 2017, Al Quait 2018) These studies were performed prior to *Study five* which informed the analysis and our results and

successful imputation further validate this methodological approach, thereby adding to the body of work justifying multiple imputation.

Going forward, the NACR and other clinical audits and registries being used for research should continue to pursue more strict inclusion of data which would result in less missing cases. However, researchers should also seek to employ multiple imputation or other statistical approaches where appropriate.

Utilisation of Routine Patient Outcome Measures

All the studies undertaken for the thesis used routinely collected pre- and post-scores that were available in the NACR. Measures such as risk factors, psychological wellbeing and FCM are useful indicators of patient improvement and, moreover, are relevant to clinical practice.(BACPR 2017) Although these measures are good indicators for reductions in mortality and readmissions, it would be beneficial for the routine data and OS in future work to look at associations with outcomes in the trial evidence such as long term mortality.(Lavie, *et al.* 2019) Inclusion of outcomes such as readmissions and mortality in registry-based OS will help to increase the influence on literature, help with other aspects in influence such as costing models and, overall, allow comparisons between routine patients and trial patients. The inclusion of mortality in routine care based research was the aim of RAMIT trial in 2011, however, its justification is more evident now.(West, *et al.* 2012) With access to over 300 programmes, over 1,000,000 cases from 10 years and using methods and techniques developed in this thesis' *Studies*, linking with hospital episode statistics may be the next stage in analysis for CR.

Potential findings and conclusions for relevant stakeholders and beneficiaries of care

Patient – The findings of the thesis that may impact on patients are the acknowledgment and evidence that the FSM modes evaluated through the thesis are equivalent,. This provides reassurance to patients that they are receiving CR of at least as good standard as to any CR previously delivered e.g. traditional centre/supervised CR. In addition, the altered rehabilitation tailoring of routine CR may directly impact on their future care.

Health Care providers – The information around alternative modes of delivery will allow the clinicians to have confidence in offering FSM methods. In addition, acknowledgment of patient characteristics associated with poorer outcomes will help tailoring at the start of CR.

Policy makers – The findings that mode of delivery and volume are not associated with outcomes will help to inform funders when developing programmes or reviewing investment. In relation to volume, higher volume is not associated with outcome variability, and either economies of scale or patient accessibility may be more relevant.

Researchers – The summary of methodological advantages listed above will help to drive quality research that is performed and written in clear and transparent ways. This will continue to showcase OS as an integral method for health service research.

Conclusions

In 2015, there was a need for evaluation of routine CR. The evidence for CR being effective was well established, however, large levels of variation in service delivery and populations led the researcher to question the association with service quality. Five primary OS were conducted in a sequential manner. These were investigating whether programme variation, such as volume and mode, and patient difference such as employment status was associated with outcomes. These included risk factors such as BMI and smoking, psychosocial wellbeing and functional capacity measures (e.g. ISWT and 6MWT).

The findings from the sum of studies were twofold i.e. methodological development has led to a template from which future work is now reported, tightly following STROBE guidelines, and performed e.g. multiple imputation may be used to account for missing data. Furthermore, that service variations investigated such as mode and volume was not, for the most part, associated with routine outcomes and that patients do benefit from CR. It did find, however, that variations in patient profiles such as employment status and their IMD profile were shown to be associated with outcome. Additional findings beyond the initial aims were that methodological developments have led to the development of a template from which future work is both now reported, following STROBE guidelines, and performed e.g. multiple imputation may be used to account for missing data.

Based on the synthesised findings of this thesis, there are clear recommendations for future research and how it should be undertaken. Moreover, the variations in care identified, such as different modalities, should be acknowledged and given further credence as they represent viable additional

options to a traditional care menu with potential to increase CR uptake which is now a stated target (85% by 2028) for the NHS England Long Term plan.

Appendix 1

MEDLINE Search Strategy

Database: Ovid MEDLINE(R) Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) <1946 to Present>

search date 11th July 2018 using OVID SP

Search Strategy:

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1 exp heart diseases/ (1040273)

2 myocardial infarction/ (157650)

3 percutaneous coronary intervention/ (12087)

4 coronary artery bypass/ (46429)

5 coronary disease/ (129293)

6 ((cardiac or cardiovascular or coronary or heart) adj2 disease$).ti,ab. (373083)

7 ((cardiac or cardiovascular or coronary or heart) adj2 condition$).ti,ab. (8468)

8 heart failure.ti,ab. (143523)

9 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 (1277972)

10 Telerehabilitation/ (163)

11 (telerehab$ adj2 (model$ or deliver$ or program$ or intervention$ or mode$)).ti,ab. (125)

12 10 or 11 (252)

13 9 and 12 (26)

14 limit 13 to (english language and yr="2000 -Current") (25)

15 *cardiac rehabilitation/ (1232)

16 ((cardiac or cardiovascular) adj2 rehabilitation).ti. (3654)

17 ((cardiac or cardiovascular) adj2 telerehabilitation).ti. (14)

18 15 or 16 or 17 (4161)

19 limit 18 to (english language and yr="2000 -Current") (2735)

20 cardiac rehabilitation/ (1617)

21 ((cardiac or cardiovascular) adj3 rehabilitation).ti,ab. (5964)

22 ((cardiac or cardiovascular) adj3 telerehabilitation).ti,ab. (20)

23 20 or 21 or 22 (6612)

24 9 and 23 (5174)

25 limit 24 to (english language and yr="2000 -Current") (3336)

26 Socioeconomic Factors/ (140900)

27 Employment/ (42867)

28 employment status.ti,ab. (5955)

29 working status.ti,ab. (615)

30 ((sociodemographic or socioeconomic) adj2 factor$).ti,ab. (13126)

31 intrapersonal factor$.ti,ab. (167)

32 26 or 27 or 28 or 29 or 30 or 31 (189838)

33 25 and 32 (142)

34 Telemedicine/ (17664)

35 (telehealth or telemonitor$).ti,ab. (4034)

36 (e-based or e-coach$ or e-deliver$).ti,ab. (304)

37 (internet based or internet-based or internet-deliver$ or internet deliver$).ti,ab. (7594)

38 (m-based or m-deliver$ or mhealth or m-health or mobile health or mobile-health).ti,ab. (3323)

39 (web based or web-based or web deliver$ or web-deliver$).ti,ab. (24544)

40 (home based or home-based or centre based or centre-based or center based or centre-based or group based or group-based).ti,ab. (15992)

41 Self-help Groups/ (8639)

42 Group Processes/ (13362)

43 Self Care/ (30470)

44 (self care or self-care or self deliver$ or self-deliver$).ti,ab. (14881)

45 care model$.ti,ab. (5877)

46 (deliver$ adj2 care).ti,ab. (26508)

47 (deliver$ adj2 (mode or method$)).ti,ab. (16131)

48 ((deliver$ or provid$) adj2 home).ti,ab. (4583)

49 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 (173258)

50 25 and 49 (387)

51 (volume adj2 outcome$).ti,ab. (1587)

52 (volume adj2 relation$).ti,ab. (4657)

53 (volume adj2 predict$).ti,ab. (2202)

54 (volume and outcome).ti,ab. (30080)

55 high volume$.ti,ab. (13231)

56 (class$ size$ or programme$ size$ or program$ size$).ti,ab. (768)

57 51 or 52 or 53 or 54 or 55 or 56 (47942)

58 25 and 57 (13)

59 14 or 19 or 33 or 50 or 58 (2938)

Appendix 2

EMBASE Search Strategy

Database: Embase <1974 to 2018 July 10>

searched 11th July 2018 via OVID

Search Strategy:

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1 exp heart disease/ (1688911)

2 heart infarction/ (257767)

3 percutaneous coronary intervention/ (63847)

4 coronary artery bypass graft/ (67544)

5 coronary artery disease/ (185319)

6 ((cardiac or cardiovascular or coronary or heart) adj2 disease$).ti,ab. (536209)

7 ((cardiac or cardiovascular or coronary or heart) adj2 condition$).ti,ab. (12278)

8 heart failure.ti,ab. (234903)

9 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 (2006989)

10 Telerehabilitation/ (416)

11 (telerehab$ adj2 (model$ or deliver$ or program$ or intervention$ or mode$)).ti,ab. (159)

12 10 or 11 (502)

13 9 and 12 (54)

14 limit 13 to (english language and yr="2000 -Current") (54)

15 *heart rehabilitation/ (5359)

16 ((cardiac or cardiovascular) adj2 rehabilitation).ti. (5809)

17 ((cardiac or cardiovascular) adj2 telerehabilitation).ti. (15)

18 15 or 16 or 17 (7000)

19 limit 18 to (english language and yr="2000 -Current") (4723)

20 heart rehabilitation/ (9229)

21 ((cardiac or cardiovascular) adj3 rehabilitation).ti,ab. (9738)

22 ((cardiac or cardiovascular) adj3 telerehabilitation).ti,ab. (21)

23 20 or 21 or 22 (12236)

24 9 and 23 (9868)

25 limit 24 to (english language and yr="2000 -Current") (7236)

26 Socioeconomics/ (134614)

27 Employment/ (55938)

28 employment status.ti,ab. (8160)

29 working status.ti,ab. (911)

30 ((sociodemographic or socioeconomic) adj2 factor$).ti,ab. (15943)

31 intrapersonal factor$.ti,ab. (184)

32 26 or 27 or 28 or 29 or 30 or 31 (200149)

33 25 and 32 (161)

34 Telemedicine/ (18880)

35 (telehealth or telemonitor$).ti,ab. (5238)

36 (e-based or e-coach$ or e-deliver$).ti,ab. (397)

37 (internet based or internet-based or internet-deliver$ or internet deliver$).ti,ab. (10262)

38 (m-based or m-deliver$ or mhealth or m-health or mobile health or mobile-health).ti,ab. (3511)

39 (web based or web-based or web deliver$ or web-deliver$).ti,ab. (34457)

40 (home based or home-based or centre based or centre-based or center based or centre-based or group based or group-based).ti,ab. (21976)

41 Self-help Groups/ (12180)

42 Group Processes/ (9140)

43 Self Care/ (48453)

44 (self care or self-care or self deliver$ or self-deliver$).ti,ab. (20703)

45 care model$.ti,ab. (8020)

46 (deliver$ adj2 care).ti,ab. (33618)

47 (deliver$ adj2 (mode or method$)).ti,ab. (27885)

48 ((deliver$ or provid$) adj2 home).ti,ab. (5820)

49 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 (228434)

50 25 and 49 (660)

51 (volume adj2 outcome$).ti,ab. (2280)

52 (volume adj2 relation$).ti,ab. (5905)

53 (volume adj2 predict$).ti,ab. (3479)

54 (volume and outcome).ti,ab. (50115)

55 high volume$.ti,ab. (21545)

56 (class$ size$ or programme$ size$ or program$ size$).ti,ab. (967)

57 51 or 52 or 53 or 54 or 55 or 56 (77074)

58 25 and 57 (28)

59 14 or 19 or 33 or 50 or 58 (5101)

60 limit 59 to (english language and yr="2000 -Current") (5101)

Appendix 3

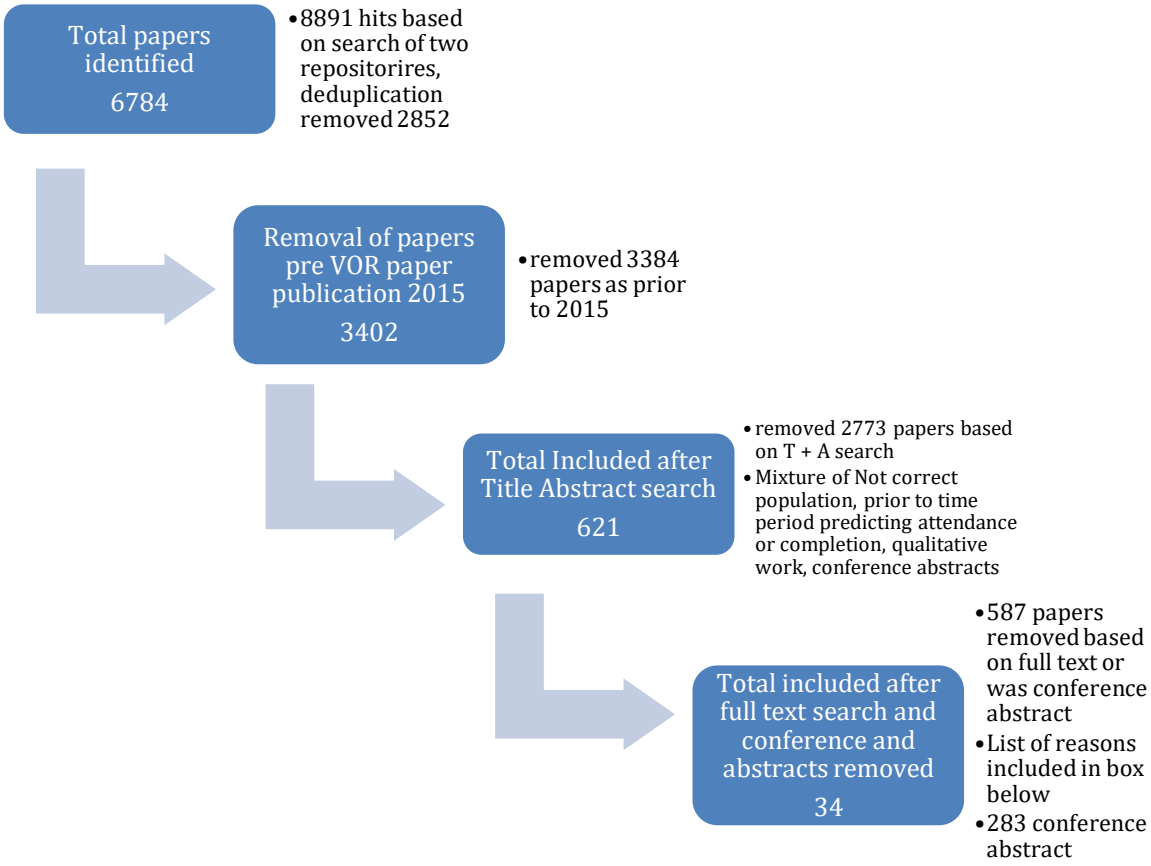
PICO

P	Male or Female adult populations with Acute Coronary Syndrome, Revascularisation and or Heart Failure. The population can include both ST-elevated Myocardial Infarction (STEMI) and non ST-elevated Myocardial infarction (NSTEMI) patients. Revascularisation included Percutaneous Coronary Intervention patients and Coronary Artery bypass patients. Heart Failure patients were included with either LVEF restriction or HREF and HPEF. Date restriction were put on patients recruited before 2000, and studies had to be published >=2000
I	Cardiac Rehabilitation was included as the type of intervention, but to meet with specific questions within the review, studies needed to address either; Volume of the programme (also described as class size or patient throughput), specific employment status as a demographic factor and method of delivery. Method/mode of delivery included Home- or Group-based, tele-rehabilitation, supervised or self-managed rehabilitation, distance rehab, e-rehab.
C	The comparison group was investigating the difference in outcomes based on the three sub variables of Cardiac Rehabilitation which were, Volume, Employment and Mode of Delivery
O	Based on patient and intervention previously, the outcomes were immediately post Cardiac Rehabilitation, Core/Phase3 (phase II for Europe), including weight change, Smoking, BP, Physical Activity, HADS, Quality of Life and exercise capacity/walking fitness.

The search was designed around the Population and Intervention. Manual screening to assess whether the study was addressing the three different intervention differences; Volume, Employment status and Mode, in associated of outcomes.

Appendix 4

Flow diagram of studies



First run

MEDLINE = 2938 retrieved, after duplicates were removed (from within MEDLINE) there were 2933 records

EMBASE = 5101 retrieved, after duplicates were removed (from within EMBASE) there were 4991 records

Total 7924 records - When combined 5485 studies

Re run in March

MEDLINE = 3210

EMBASE = 5681

After deduplication these against each other and the original search results there were 688 extra records.

Total for review after both searches 6037

The 32 studies have been pulled and are currently being analysed for their findings, how they sit against the 5 studies and also their quality.

Re run in Jan

After deduplication these against each other and the original search results there were 747 extra records.

Total for review after both searches 6784

The 38 studies have been pulled and are currently being analysed for their findings, how they sit against the 5 studies and also their quality.

Appendix 5

Studies included in Literature search and quality scores

Title	Authors	Study Design	CASP Score	Score Max	Study score	Relative Score %	Quality
Home-based cardiac rehabilitation improves quality of life, aerobic capacity, and readmission rates in patients with chronic heart failure	Chen, Y. W.: Wang, C. Y.: Lai, Y. H.: Liao, Y. C.: Wen, Y. K.: Chang, S. T.: Huang, J. L.: Wu, T. J.	Randomised prospective trial	3/10	10	3	30	Low
Home-based telerehabilitation in older patients with chronic obstructive pulmonary disease and heart failure: A randomised controlled trial	Bernocchi, P.: Vitacca, M.: La Rovere, M. T.: Volterrani, M.: Galli, T.: Baratti, D.: Paneroni, M.: Campolongo, G.: Sposato, B.: Scalvini, S.	RCT	4/10	10	4	40	Low
Traditional Versus Hybrid Outpatient Cardiac Rehabilitation: A COMPARISON OF PATIENT OUTCOMES	Gabelhouse, J.: Eves, N.: Grace, S. L.: Reid, R. C.: Caperchione, C. M.	Prospective nonrandomised trial	4/10	10	4	40	Low
Predictors of Clinical Anxiety Aggravation at the End of a Cardiac Rehabilitation Program	Saeidi, M.: Komasi, S.: Heydarpour, B.: Karim, H.: Nalini, M.: Ezzati, P.	Retrospective cohort	4/10	10	4	40	Low
Long-term Exercise Adherence After High-intensity Interval Training in Cardiac Rehabilitation: A Randomized Study	Aamot, I. L.: Karlsen, T.: Dalen, H.: Stoylen, A.	RCT	5/10	10	5	50	Moderate
Effectiveness and safety of a home-based cardiac rehabilitation programme of mixed surveillance in patients with ischemic heart disease at moderate cardiovascular risk: A randomised, controlled clinical trial	Bravo-Escobar, R.: Gonzalez-Represas, A.: Gomez-Gonzalez, A. M.: Montiel-Trujillo, A.: Aguilar-Jimenez, R.: Carrasco-Ruiz, R.: Salinas-Sanchez, P.	RCT	5/10	10	5	50	Moderate

The positive impact of a four-week Cardiac Rehabilitation program on depression levels of cardiological patients	Caccamo, F.: Saltini, S.: Marogna, C.: Sava, V.: Carlon, R.: Vignaga, F.	Prospective cohort study	5/10	10	5	50	Moderate
Beneficial effects of home-based cardiac rehabilitation on metabolic profiles in coronary heart-disease patients	Chen, J. T.: Lin, T. H.: Voon, W. C.: Lai, W. T.: Huang, M. H.: Sheu, S. H.: Chen, C. K.	RCT	5/10	10	5	50	Moderate
Web-based cardiac REhabilitatioN alternative for those declining or dropping out of conventional rehabilitation: results of the WREN feasibility randomised controlled trial	Houchen-Wolloff, L.: Gardiner, N.: Devi, R.: Robertson, N.: Jolly, K.: Marshall, T.: Furze, G.: Doherty, P.: Szczepura, A.: Powell, J.: Singh, S.	RCT Feasibility study	5/10	10	5	50	Moderate
Quality of life in heart failure patients undergoing home-based telerehabilitation versus outpatient rehabilitation--a randomized controlled study	Piotrowicz, E.: Stepnowska, M.: Leszczynska-Iwanicka, K.: Piotrowska, D.: Kowalska, M.: Tylka, J.: Piotrowski, W.: Piotrowicz, R.	RCT	5/10	10	5	50	Moderate
Home-Based Cardiac Rehabilitation Alone and Hybrid With Center-Based Cardiac Rehabilitation in Heart Failure: A Systematic Review and Meta-Analysis	Imran, H. M., Baig, M., Erqou, S., Taveira, T. H., Shah, N. R., Morrison, A., Choudhary, G. and Wu, W. C.	2019	meta-analysis	6/11	11	6	55%
Home-Based Rehabilitation With Telemonitoring Guidance for Patients With Coronary Artery Disease (Short-Term Results of the TRiCH Study): Randomized Controlled Trial	Avila, A.: Claes, J.: Goetschalckx, K.: Buys, R.: Azzawi, M.: Vanhees, L.: Cornelissen, V.	RCT	6/10	10	6	60	Moderate

Cardiac rehabilitation after acute coronary syndrome comparing adherence and risk factor modification in a community-based shared care model versus hospital-based care in a randomised controlled trial with 12 months of follow-up	Bertelsen, J. B.: Refsgaard, J.: Kanstrup, H.: Johnsen, S. P.: Qvist, I.: Christensen, B.: Christensen, K. L.	RCT	6/10	10	6	60	Moderate
Individualized vs. group exercise in improving quality of life and physical activity in patients with cardiac disease and low exercise capacity: results from the DOPPELHERZ trial	Christle, J. W.: Schlumberger, A.: Haller, B.: Gloeckl, R.: Halle, M.: Pressler, A.	RCT	6/10	10	6	60	Moderate
Efficacy of Home versus Centre-Based Cardiac Rehabilitation in Improving Functional Capacity and Left Ventricular Ejection Fraction in Coronary Artery Bypass Graft (CABG) Patients	Mujeeb, K. F. M. and Kazi, A.	Prospective nonrandomised trial	6/10	10	6	60	Moderate
Factors influencing change in walking ability in patients with heart failure undergoing exercise-based cardiac rehabilitation	Sutherland, N.: Harrison, A.: Doherty, P.	Retrospective cohort study	6/10	10	6	60	Moderate
The impact of professional status on the effects of and adherence to the outpatient followed by home-based telemonitored cardiac rehabilitation in patients referred by a social insurance institution	Szalewska, D.: Niedoszytko, P.: Gierat-Haponiuk, K.	Multi-centre survey different professional status	13/20	20	13	65	Moderate
Depression, Socioeconomic Factors, and Ethnicity as Predictors of Cardiorespiratory Fitness Before and After Cardiac Rehabilitation	Mikkelsen, N.: Dall, C. H.: Frederiksen, M.: Holdgaard, A.: Rasmusen, H.: Prescott, E.	Retrospective cohort	7/10	10	7	70	Moderate

Hospital-based versus hybrid cardiac rehabilitation program in coronary bypass surgery patients in western Iran: effects on exercise capacity, risk factors, psychological factors, and quality of life	Najafi, F.: Nalini, M.	Retrospective cohort study	7/10	10	7	70	Moderate
Comparison between supervised and partly supervised cardiac rehabilitation protocols in hypertensive patients: a randomized controlled trial	Parreira, L. B.: de Oliveira Vitorino, P. V.: Jardim, Pcbv: Sousa, A. L. L.: Jardim, T. V.: de Moura Sousa, W.: Justo, A. F. O.: Barroso, W. K. S.	RCT	7/10	10	7	70	Moderate
The psychological effects of cardiac rehabilitation after coronary revascularization	Pourafkari, L.: Ghaffari, S.: Shahamfar, J.: Tokhmechian, L.: Nader, N. D.	Retrospective cohort	7/10	10	7	70	Moderate
Long-term outcomes from Healthy Eating and Exercise Lifestyle Program for overweight people with heart disease and diabetes	Alharbi, M.: Gallagher, R.: Kirkness, A.: Sibbritt, D.: Tofler, G.	Longitudinal design	15/20	20	15	75	High
Clinical Efficacy of a Medical Centre- and Home-based Cardiac Rehabilitation Program for Patients with Coronary Heart Disease After Coronary Bypass Graft Surgery	Aronov, D., Bubnova, M., Iosseliani, D. and Orekhov, A.	prospective interventional cohort study	8/10	10	8	80%	High
Home-based telerehabilitation is not inferior to a centre-based program in patients with chronic heart failure: a randomised trial	Hwang, R.: Bruning, J.: Morris, N. R.: Mandrusiak, A.: Russell, T.	RCT	8/10	10	8	80	High
The sustainability of exercise capacity changes in home versus center-based cardiac rehabilitation	Ramadi, A.: Haennel, R. G.: Stone, J. A.: Arena, R.: Threlfall, T. G.: Hitt, E.: Aggarwal, S. G.: Haykowsky, M.: Martin, B. J.	Prospective cohort study	8/10	10	8	80	High

Does service timing matter for psychological outcomes in cardiac rehabilitation? Insights from the National Audit of Cardiac Rehabilitation	Sumner, J.: Bohnke, J. R.: Doherty, P.	Retrospective cohort study	8/10	10	8	80	High
Medical and sociodemographic factors predict persistent smoking after coronary events	Sverre, E.: Otterstad, J. E.: Gjertsen, E.: Gullestad, L.: Husebye, E.: Dammen, T.: Moum, T.: Munkhaugen, J.	Cross sectional	16/20	20	16	80	High
Community-Based Cardiac Rehabilitation Maintenance Programs: Use and Effects	Mandic, S.: Body, D.: Barclay, L.: Walker, R.: Nye, E. R.: Grace, S. L.: Williams, M. J.	Cross sectional	17/20	20	17	85	High
Effects of community based cardiac rehabilitation: Comparison with a hospital-based programme	Mosleh, S. M.: Bond, C. M.: Lee, A. J.: Kiger, A.: Campbell, N. C.	Prospective cohort study	9/10	10	9	90	High
Is the Cardiovascular Response Euqilivent Between a Supervised Center-based setting and a Self-care Home-Based Setting When Rating of Percieved Exerction is Used to Guide Aerobic Exercise Intensity During a Cardiac Rehabilitation Program?	Tang LH, : Zwisler AD, : Berg SK,	Retrospective cohort study	9/10	10	9	90	High
Effect of cardiac rehabilitation on 24-month all-cause hospital readmissions: A prospective cohort study	Thomas, E.: Lotfaliany, M.: Grace, S. L.: Oldenburg, B.: Taylor, C. B.: Hare, D. L.: Rangani, W. T.: Dheerasinghe, D. A. F.: Cadilhac, D. A.: O'Neil, A.	Prospective cohort study	9/10	10	9	90	High
Home-based versus centre-based cardiac rehabilitation	Anderson, L.: Sharp, G. A.: Norton, R. J.: Dalal, H.: Dean, S. G.: Jolly, K.: Cowie, A.: Zawada, A.: Taylor, R. S.	Sys review	8/8	8	8	100	High

Telehealth interventions versus center-based cardiac rehabilitation of coronary artery disease: A systematic review and meta-analysis	Huang, K.: Liu, W.: He, D.: Huang, B.: Xiao, D.: Peng, Y.: He, Y.: Hu, H.: Chen, M.: Huang, D.	Sys review	8/8	8	8	100	High

Appendix 6

NACR Annual survey

Dear

PLEASE CHECK AND IF NECESSARY AMEND YOUR CONTACT DETAILS

Name

Telephone

Email

Fax

Programme details

Unique ID

NACR ID

Unless you tell us otherwise, we will assume that this survey return includes the above named programme and all of the following programmes

---

If this is <u>not</u> correct or there are programmes we have missed, please amend the form

CONFIRMATION OF FIGURES

As previous years, the data we use in the Annual Report needs to accurately reflect your programme, and needs to be available directly from the NACR database so it is verifiable in order to meet the purpose of audit. Therefore, this survey details the figures which **will** be reported on. Unfortunately, there are no facilities to change your figures manually as has been available in previous years but if you are behind with data entry for this period please contact me to discuss.

Please check questions 1 – 5 (completing the number of sessions and duration) and then complete question 6 & 7.

1. I confirm that NACR is up to date for this period **Yes ☐**

If NACR is not up to date please contact us to discuss timescales for updating NACR

2. The total number of patients who started core delivery rehabilitation CR programme between 01/04/2016 and 31/03/2017 was ☐

3. Breakdown of Question 2, by gender

Number of men ☐

Number of women ☐

Number of unknown gender ☐

4. Numbers received core delivery rehabilitation by diagnosis/treatment.

Reason referred	**Number seen**
Myocardial infarction alone	
Myocardial infarction with PCI to relieve an acute MI (Primary PCI) or a PCI a time after acute event (previously these figures were provided separately)	
Myocardial infarction and CABG	
CABG	
PCI (not counted above) (previously elective angioplasty)	
Cardiac arrest	
Angina (not counted above)	
Valve surgery	
Other surgery	
MI with Heart Failure	
Heart failure	
Pacemaker	
ICD	
Others - please describe ……	
Others - please describe ……	
Unknown diagnoses	
Total *(the same total entered under Q2)*	

Questions 5-7 concern rehab provided by your CR programme

5. Number of people seen between 01/04/2016 and 31/03/2017?

Seen in Phase I/Early ☐

Seen in Phase II ☐

Seen in Phase III/Core ☐

Referred out / seen in Phase IV ☐

6. Did your programme start after 01/04/16? Yes ☐ No ☐

If **YES**, which month and year did your programme start?

……
.....

If your programme was suspended or interrupted between 01/04/2016 and 31/03/2017 please explain for how long, to what extent, and why:

……
.....

……
.....

Continued

7. Staffing

See the guidance notes pages 2-4 for further details on how to complete this section

Please indicate what staff provided CR (**for all rehab you provide**) in a typical week during 01/04/2016 to 31/03/2017. For each type of staff member listed, please indicate their NHS salary band (if known) and the number of hours they worked on CR in a typical week.

Staff job title	**NHS Salary band***	**Hours a week**
Nurse		
Physiotherapist		
Occupational Therapist		
Pharmacist		
Dietitian		
Psychologist		
Social worker		
Counsellor		
Doctor		
Health Visitor		
Health Care Assistant		
Secretarial/Clerical/Audit/Admin		
Administrator (Manager)		
Physiotherapy Assistant		
Exercise specialist: Describe ……..		
Other: Describe ……..		
Other: Describe ……..		
Other: Describe		

…… ……..		

* Please indicate if staff are on a manager (M) or specialist (S) grade

Thank you very much for completing this questionnaire. Please take a copy for your records before sending it back to us.

Appendix 7

List of all variables included in the *Study* analysis

Level of Data	Variable	Study 1	Study 2	Study 3	Study 4	Study 5
Outcomes	Psychosocial Wellbeing (HADS, Dartmouth)	✔	✔	✔		
	Functional Capacity (ISWT, 6MWT)	✔			✔	
	Risk Factors (BMI, smoking, blood pressure, physical activity)	✔				✔
Patient	Baseline outcome score	✔	✔	✔	✔	✔
	Age	✔	✔	✔	✔	✔
	Gender	✔	✔	✔	✔	✔
	Comorbidities	✔	✔	✔	✔	✔
	Duration (days)		✔	✔	✔	✔
	Index of Multiple Deprivation		✔			✔
	Type of event/treatment		✔	✔	✔	✔
	Employment status		✔	✔	✔	✔
	Waiting time (days)					✔
	Baseline psychosocial wellbeing					✔
Patient/Service	Mode of Delivery			✔	✔	✔
Service	Volume	✔		✔		
	Staffing Hours	✔		✔		
	Multidisciplinary team (3 or more)	✔		✔		

Abbreviations

6MWT – Six Minute Walk Test

ACS – Acute Coronary Syndrome

AHA – American Heart Association

BACPR – British Association of Cardiac Prevention and Rehabilitation

BMI – Body Mass Index

CABG - Coronary Artery Bypass Graft

CCG- Clinical Commissioning Group

CI – Confidence Interval

CR – Cardiac Rehabilitation

CROS – Cardiac Rehabilitation Outcome Study

CVD – Cardiovascular Disease

Dartmouth COOP- Dartmouth Cooperative

FCM Functional Capacity Measures

FSM – Facilitated Self-Managed

GP – General Practice

GRADE – Grading of Recommendation Assessment, Development and Evaluation

HADS- Hospital Anxiety Depression Score

IMD- Index of Multiple Deprivation

ISWT – Incremental Shuttle Walk Test

LSOA- Lower Super Output Area

MCID – Minimal Clinically important Difference

MDT – Multi-disciplinary Team

METS – Metabolic Equivalent of Tasks

MI - Myocardial Infarction

NACR – National Association of Cardiac Rehabilitation

NCP_CR – National Certification Programme

NHS – National Health Service

OR – Odds Ratio

OS - Observational Study

PCI – Percutaneous Coronary Intervention

PRISMA – Preferred Reporting Items for Systematic Reviews and Meta-Analyses

QoL – Quality of Life

RAMIT – Rehabilitation After Myocardial Infarction Trial

RCT- Randomised Control Trial

REACH-HF –Rehabilitation Enablement in Chronic Heart Failure

RR – Risk Ratio

SF-36 – Short Form 36

SIGN – Scottish Intercollegiate Guidelines Network

SR- Systematic Review

STROBE -– The Strengthening The Reporting of Observational Studies in Epidemiology

VO2 max –Volume of Oxygen

VOR – Volume-outcome Relationship

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Observational study of the relationship between volume and outcomes using data from the National Audit of Cardiac Rehabilitation

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ABSTRACT

Objective: Cardiac rehabilitation (CR) is an evidence-based intervention delivered by a wide range of high-volume and low-volume centres; however, the extent of volume–outcome relationship is yet to be studied. There is a lack of consensus about the effect of volume on outcomes, with evidence of mixed effects in acute and chronic care. The aim of this study is, to investigate the extent of association of outcomes in CR with patient volume.

Methods: Data was validated and extracted from the national audit from 2012 to 2013 for each CR centre. Volume was calculated as the total number of patients entering outpatient CR. Hierarchical multiple regression models were used to test for relationships between volume and outcomes. The outcomes included body mass index, blood pressure, psychosocial well-being, cholesterol, smoking cessation and physical activity. The analyses were adjusted for centre and patient characteristics and confounders.

Results: The number of patients included in the volume analysis was 48 476, derived from 178 CR centres. The average age per centre was 66 years with a 70% male distribution of patients enrolled. Regression analysis revealed no volume–outcome relationship, additionally no statistical significance existed.

Conclusions: Unlike cardiac surgery this study, after accounting for staffing, age, gender and comorbidity, shows no effect of volume on outcome following CR delivered by high-volume and low-volume programmes. Based on our data there is no support for centralisation of services. Our findings and methodology can be used as a benchmark for future volume–outcome relationship studies in CR.

KEY QUESTIONS

What is already known about this subject?

- Current literature supports a positive volume effect, with increasing patient throughput leading to improved outcomes in cardiac surgery but not in cardiac rehabilitation (CR).

What does this study add?

- This is the first volume–outcome relationship (VOR) study in the UK of CR. The methodology takes account of potential confounders such as age, gender, comorbidities and staff details.

How might this impact on clinical practice?

- Unlike the positive cardiac surgery VOR findings in favour of high volume, our study suggests that clinical strategies to optimise uptake to CR could be achieved through either approach.

INTRODUCTION

Research from more than 45 clinical trials has shown that cardiac rehabilitation (CR) is a clinically effective secondary prevention programme leading to a significant reduction in premature cardiac mortality (26%; 95% CI 13% to 37%), total mortality (13%; 95% CI 1% to 25%) and improved quality of life.[1 2] CR is also a cost-effective therapy with an estimated cost per life year gained of less than £2000.[3] National recommendations for CR and National Institute for Health and Care Excellence (NICE) guidelines state that programmes should be comprehensive including education, support with health behaviour change and exercise training and should be delivered by a multidisciplinary team (MDT).[2 4]

The National Audit of Cardiac Rehabilitation (NACR), which is funded by the British Heart Foundation, collects clinical data from programmes allowing it to monitor and report on the quality of CR services in the UK. As with other health services; the size, resources and the extent of patient throughput varies across CR programmes. The extent of this variability, demonstrated in the literature and through the UK national audit, could give rise to a potential volume–outcome relationship (VOR) in CR.[5 6] With respect to volume expectations only the Scottish Intercollegiate Guidelines Network (SIGN 57) states a value for the

delivery of MDT CR of 500 patients per year which is based on expert opinion rather than clinical outcome assessment.[7]

VOR have been investigated in other areas of cardiology and cardiac surgery identifying that large volume centres are associated with better outcomes.[8 9] This has led to significant centralisation of cardiac surgery services with specific staffing requirements and resources being made available for large volume centres only.[10] The source of the relationship is believed to relate to higher volume of patients resulting in institutional experience, selective referral and improved process of care at higher volume institutions.[8]

It is expected that this volume effect may be mirrored in CR; this is because the quality of care may improve with increased patient throughput. There is an underlying assumption that 'practice makes perfect' which should mean that high-volume CR leads to a positive improvement in outcomes.[8] There is a caveat to this in that national guidance and recent trial data from the UK express concern about the quality of CR delivery in routine practice.[4 5 10 11] There are national recommendations that CR is based on assessment and is delivered to a minimum standard by a MDT.[4 10] This team should implement risk factor management and facilitate health-related lifestyle changes in an increasingly multimorbid patient population. If a VOR were to be identified, then perhaps this finding would prompt policy for increased CR centralisation.

There is little VOR-specific research in CR. The one UK study relates to exercise class size rather than total volume and concludes that smaller class sizes was associated with increased mortality.[5] In the context of risk factor outcomes one study from a similar care approach to CR (eg, psychiatric care) found a detrimental effect of volume on outcome, with increased hospital readmission in larger centres (OR of 30 day readmission, 3.0; 95% CI 2.8 to 3.2).[12]

Current CR although effective, has been shown to have low uptake with over half of eligible patients not receiving the programme.[10] A possible method of improvement is to increase accessibility; this could be done through increasing number of centres.[13] Although this study is not looking directly at accessibility, an offshoot is that changes to the way CR is run, large volume centres or many small volume centres, will impact accessibility.

Our study aims to investigate the relationship between volume of patients seen per year, with an experimental hypothesis that a positive VOR exists in CR.

METHODS

Data collection

The analyses were conducted using individual patient data collected from the UK NACR 1 April 2012 to 31 March 2013. The NACR is a routinely administered audit within the National Health Service, which has approval to collect anonymised patient data for a range of clinical variables.[10] The data is hosted by the Health and Social Care information Centre (HSCIC), to which approval is granted annually to use this data to monitor and report on the quality of CR. The audit collects data for patients who undergo CR in the UK including details of the patients initiating event, treatment, risk factors, medication, patient demographics and outcomes. UK CR is administered based on the British Association for Cardiovascular Prevention and Rehabilitation (BACPR) national guidelines which aim to reduce cardiovascular risk and promote quality of life through coordinated core components of cardiovascular disease prevention and rehabilitation using exercise training (moderate intensity twice weekly), diet and education support.[4]

Patients were included in the analyses, if they started CR and been assessed at baseline and had follow-up data at an assessment 2 (post-CR). This observational study was reported following the guidelines of the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE).[14]

In addition to electronic data collection reported above, staffing details, per centre, were collected from the annual NACR paper survey, which collects data on types of staff, hours worked and numbers of staff per programme. The multidisciplinary nature of a CR programme was defined by having a minimum of three different professionals working in the team.

Nine key clinical outcome measures, deemed as important for risk factor management and routinely reported by the NACR were selected. These patient outcomes form part of national CR minimum standards.[4] The outcomes were body mass index (BMI), blood pressure (BP), psychosocial health (Hospital Anxiety and Depression Scale (HADS) scores: anxiety and depression),[15] total cholesterol, a measure of exercise capacity through the incremental shuttle walk test (ISWT), smoking status (yes/no) and self-reported moderate physical activity (PA) (150 min/week; yes/no) conforming to the Department of Health guidelines for 19–64 and 65+ age groups.[16]

Volume was defined as the total number of patients who had undergone baseline assessment and entered the standard core delivery of CR which in the UK is delivered as an outpatient service. This measure was used as it reflects the number of patients assessed (eg, starting CR) and the associated staffing requirements delivering the service.

Statistical analysis

The analyses were conducted in STATA 13. The data was hierarchical with patients nested within centres, multilevel models were used for the analyses, with CR centre treated as a random effect. Volume, the number of patients with a baseline assessment per centre, was included as a continuous variable. A selection of known confounding factors reported in the literature was used

as covariates in the analyses. These were age, gender, number of comorbidities and staffing details. The staffing details included total staff hours and whether the centre met the multidisciplinary criteria of three or more professional groups.[9 12 17] Comorbidities are any of 19 commonly associated conditions that patients who undergo CR have, such as angina, diabetes and cancer. These comorbidities are routinely collected by the NACR and reported in the national statistical report.[6] Owing to the high level of heterogeneity in the length of CR, duration could not be used as a possible confounder in this analysis, additionally the number of sessions is a new variable in the NACR since 2014. The models were also adjusted for the baseline value of the dependent variable in the model.

A linear mixed model, accounting for centre variation by hierarchical modelling, was used to assess the extent by which volume determined outcome for BMI, HADS Anxiety and Depression and a mixed model for categorical data was used for smoking and PA. Patients were included in the outcomes analysis, if they had complete data, that is, baseline characteristics recorded and had follow-up data at an assessment 2 (post-CR). Data model checking was performed to ensure that the models were a good fit, through assumptions associated with the regressions.

RESULTS

Study population

The study population is summarised in figure 1 based on a total of 48 476 patients included in the volume measure from 178 centres. The population was 70% male (34 067), with an average age of 66 years (SD=12.37) from postmyocardial infarction, coronary artery bypass grafting and percutaneous coronary intervention. Median comorbidity of the population was 1. Of the total included patients in the volume denominator, 21 966 also completed the full rehabilitation programme and attended post-CR assessment.

Baseline characteristics were collected for patients at the start of the programme (table 1) showing that the population was representative of patients with cardiovascular disease with above average baseline measures for BMI and correspondingly low levels of PA.

Only patients with pre-CR and post-CR assessments were included in the analysis. Table 2 shows a comparison between pre and post assessment across all measures. The exercise capacity measure (ISWT metres) is the only measure that has a reported minimum clinically important difference measure, which is above 70 m in CR populations.[18] As shown in table 2 on average the population is achieving above this figure by 24 m.

To account for the variation and staffing between centres in the analysis, total staffing hours and whether the centre met the three MDT professional minimum criteria were included as covariates. Overall 77.7% of centres met the minimum criteria, and the average

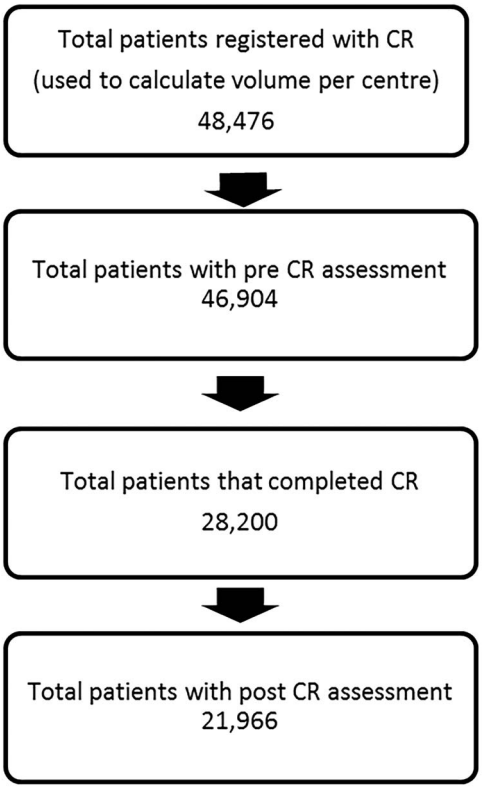

Figure 1 A flow diagram showing the total population in the data set with subsequent numbers for precardiac rehabilitation (CR) assessment, completed CR and patients with a follow-up assessment.

number of total staff hours per week was 197.4 (SD=116.03), which equates to approximately 5.5 full time staff members. The average number of patients in a centre was 368 patients with a large SD (196.92) leading to a range from a minimum of 42 in the smallest centre to 1417 in the largest centre. The median number of

Table 1 Baseline characteristics for each of the nine clinical measures for the total CR population

Pre-CR assessment	Mean	SD	N
BMI (kg/m^2) mean	28.12	(5.89)	25 385
Systolic BP (mm Hg) mean	128.92	(20.99)	32 273
Diastolic BP (mm Hg) mean	73.37	(12.17)	31 324
Total cholesterol (mmol/L) mean	4.65	(1.31)	19 491
HADS Anxiety score mean	6.8	(3.82)	22 135
HADS Depression score mean	5.8	(3.43)	20 329
ISWT (m) mean	338.36	(168.28)	5011
Percentage of patients smoking at baseline	14.65%		21 576
Percentage of patients achieving physical activity	12.1%		5878

BMI, body mass index; BP, blood pressure; CR, cardiac rehabilitation; HADS, Hospital Anxiety and Depression Scale; ISWT, incremental shuttle walk test.

Table 2 Baseline and outcome values for patients with valid follow-up included in the analysis

	Pre Mean	Post Mean	N
BMI (kg/m^2) mean	28.01	28.02	11 332
Systolic BP (mm Hg) mean	128.92	128.99	11 864
Diastolic BP (mm Hg) mean	74.15	73.70	11 843
Total cholesterol (mmol/L) mean	4.69	4.01	5003
HADS Anxiety score mean	7.08	6.33	8872
HADS Depression score mean	6.09	5.37	7207
ISWT (m) mean	350.52	444.26	2560
Percentage of patients smoking at baseline	5.4%	4.3%	1874
Percentage of patients achieving physical activity	36.9%	75.5%	2164

BMI, body mass index; BP, blood pressure; HADS, Hospital Anxiety and Depression Scale; ISWT, incremental shuttle walk test.

patients was 341. Figure 2 shows the volume per centre plotted against of nine outcomes, such as HADS Anxiety and Depression, BMI and cholesterol. The measure of outcome is the percentage of patients who reached the target reading for each outcome per centre. The error bars represent the 95% CI based on the collection of different centres inside each group of volumes, 1–100 and 101–200. The target reading was a measure of the scale for the continuous outcomes (HADS<8, BMI<30 kg/m^2, cholesterol <4 mmol/L, BP<140/<90 mm Hg), whereas the dichotomous variables, smoking and PA, were 'not smoking' and reaching 150 min exercise per week, respectively. The target readings were created using the CR outcomes used in the NACR annual report.[6] This could not be performed for the ISWT as yet there is no suggested minimum target for patients at baseline. In all the clinical outcomes shown in figure 1, there was no clear association between volume and the extent of patient outcomes.

The results from the regression analysis are in table 3. For the predictor variable, total volume per centre, there were no significant relationships observed in any of the outcomes.

Model checking was performed to ensure that the models were a good fit for the data. The covariates included such as age, gender and comorbidities made no notable difference to the outcomes with volume having no significant relationship. The analysis was run with and without staff level details, this led to no change in the VOR results.

DISCUSSION

The principal finding of this study was that, based on clinical outcomes from the NACR data there is no evidence to support a VOR in routine CR. The study used hierarchical regression to investigate whether volume influences a range of patient outcomes reported by CR. No statistically significant associations were found for VOR. Model checking analysis showed the model was a good fit requiring no significant changes to the results.

In this study's population there were 48 476 patients who met the volume definition used for this study through starting outpatient CR. The participating population had a similar distribution of males to females as

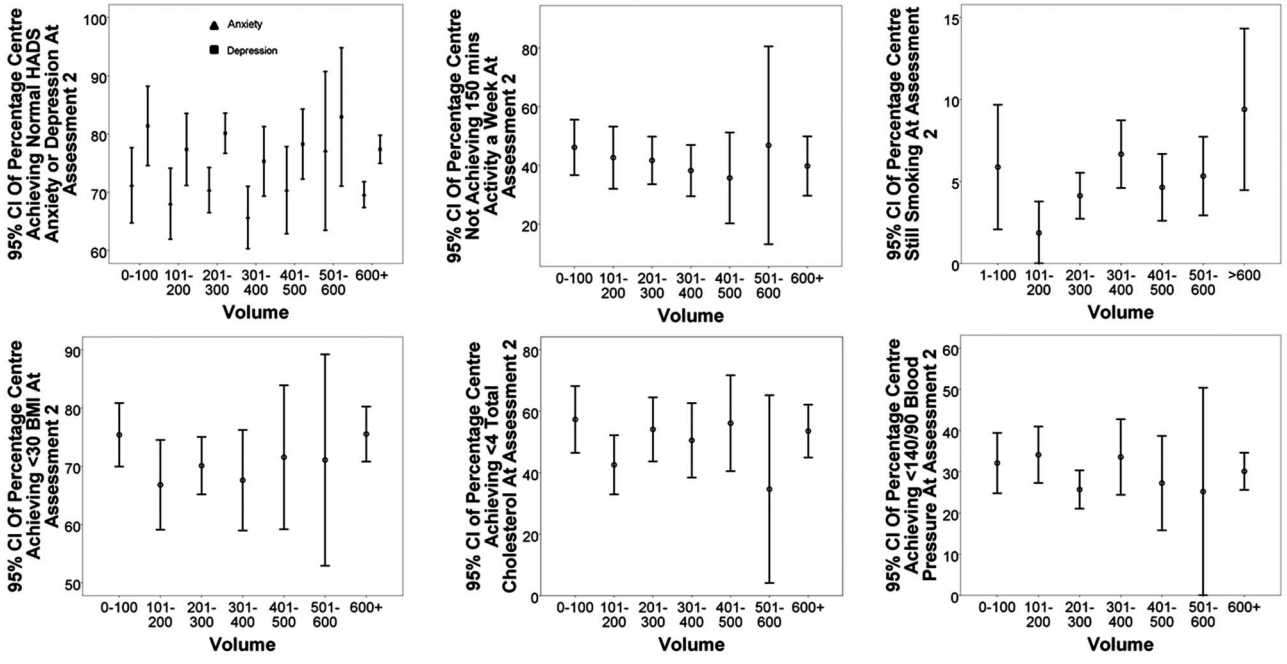

Figure 2 The volume per centre plotted against clinical outcomes which included Hospital Anxiety and Depression Scale (HADS) score, exercise 150 min, smoking, body mass index (BMI), blood pressure and total cholesterol. The measure of outcome is the percentage of participants reaching target boundaries. The error bars represent the 95% CI per volume category.

Table 3 Regression coefficients and OR for volume from the mixed model regression of the nine clinical outcomes

	Volume coefficient×10^{-3}	Significance*	95% CI×10^{-3}
BMI	0.1	0.820	–0.65 to 0.515
Systolic BP	0.242	0.929	–5.12 to 5.61
Diastolic BP	1.88	0.191	–0.94 to 4.69
Cholesterol	0.223	0.375	–0.27 to 0.715
HADS Anxiety	0.027	0.933	–0.66 to 0.609
HADS Depression	0.272	0.393	–0.35 to 0.895
ISWT (m)	–0.037	0.514	–1.15 to 0.075
	OR	**Significance**	**95% CI**
Smoking	1.001	0.276	0.998 to 1.002
Physical activity	1.001	0.994	0.999 to 1.001

*Analyses adjusted for age, gender, comorbidities, staffing profile and baseline measurement.
BMI, body mass index; BP, blood pressure; HADS, Hospital Anxiety and Depression Scale; ISWT, incremental shuttle walk test.

the most recent Cochrane review of clinical trials in CR with around 30% females. The age of patients was on average 10 years older in routine practice compared with the Cochrane review.[1] Our analysis accounted for the potential for age to impact on the outcome.

Our analysis which aimed to investigate volume and outcome is best interpreted in the context of the BACPR minimum standards which state that CR should be delivered by a MDT.[4] The staff details inputted in the analysis included the total number of hours worked and whether the centre had three or more MDT professionals. Despite having National and European guidelines defining the service specification for CR this study showed that the staffing hours and the MDT profile varies substantially.[4 12 19]

Much of the literature concerning volume, such as the work by Gammie *et al*[8] and Seperhripour and Athanasiou[9] in cardiac surgery showed a positive VOR. The only UK-specific study that included an aspect of volume (eg, exercise class sizes) found a non-significant but positive trend in favour of increased mortality with smaller volume.[5] The research undertaken by Lee and Lin[12] in Japan adds complexity to any conclusion by showing that tailored patient care (eg, low volume), such as that seen in psychiatric services, are beneficial at reducing hospital readmissions.

The evidence from our national study of routine CR, which accounted for known confounders, is unable to support either a negative or positive VOR. This study accounted for five well-understood covariates, known to influence cardiovascular outcomes, which boosts confidence in our findings but we cannot rule out interaction by other potential confounders such as patient case severity and the skills, experience and training of MDT staff.

One of the drivers for this research was that with increasing emphasis from policymakers to maximise throughput and efficiency, the volume within centres may need to increase. In many areas of cardiology a change has already been made to increase the number of high-volume centres. This has been proposed for CR as high volume is considered good practice.[10] There may be other benefits to increasing the number of high-volume centres such as reduced costs and improved patient access; however, improved clinical outcome is not supported as a high volume benefit in CR in the UK.

Clark *et al* argue that there is a severe problem with current CR programmes, which is poor accessibility. The article discusses how accessibility maximised through more accessible programmes would improve uptake to CR. The conclusion to their work and how exactly accessibility could be maximised is yet to be studied.[13] Currently only 44% of eligible patients receive CR meaning that over half of all patients are not taking up evidence-based CR.[10] Our findings suggests that size does not matter and smaller throughput programmes offer similar outcomes to larger ones. There may be unforeseen negative consequences, in terms of accessibility, when centralising programmes to improve productivity and clinical outcomes. Future research is required to evaluate innovation in clinical practice around a localised and centralised solutions aimed at increasing accessibility and outcomes.

Limitations

In contrast to the recommended national minimum standards there was significant under-reporting of the clinical outcomes. Standard 4 of BACPR standards, states that all patients undergoing CR should have 'Reassessment carried out upon completion of the CR programme to determine achievements of goals'. Based on NACR data, of all patients who completed CR, 32% did not have a post-CR assessment recorded. This shortfall will become less of an issue going forward as the BACPR and NACR have initiated a national certification scheme which has mandated post-CR assessment as a clinical standard.

Finally, the study used postrehabilitation assessment, after a median duration of 8 weeks of intervention, which albeit meets the minimum standards it may be insufficient time for certain risk factors to change.[17 19]

CONCLUSION

This study aimed to investigate whether there was an association between the volume of patients starting CR at a centre and clinical outcome.

Contrary to the literature this analysis showed no evidence to support any direction of a VOR within current UK CR.

This research has developed a robust approach to audit-based research and established a UK baseline from which future longitudinal audit-based research can be conducted. Future NACR research, involving data linkage with cardiology registries, aims to investigate the interaction between patient case severity and outcome in those attending and not attending CR.

Correction notice This article has been corrected since it was published Online. The Open Access license has been changed to CC BY.

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Relationship between employment and mental health outcomes following Cardiac Rehabilitation: an observational analysis from the National Audit of Cardiac Rehabilitation

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ABSTRACT

Background: Employment status has been shown to impact mental health state and intervention outcomes, yet still to be studied in a Cardiac Rehabilitation (CR) population. This observational study investigated the relationship between employment status and mental health outcomes following Cardiac Rehabilitation (CR).
Methods: All patients with an eligible cardiovascular incident entered into the National Audit of Cardiac Rehabilitation (NACR) 1 January 2013–31st December 2015. Logistic regression comparing the association between employment status and normal mental health categories.
Results: A total of 24,242 CR patients with completed post CR assessments were included and had representative age and gender distribution (mean 65 years, 73.2% male). At baseline the unemployed status had a lower proportion of patients in normal healthy categories than other groups (T-test and chi-squared $p = <0.05$). The regression analyses revealed no significant association between retired and employed groups and outcome. There was significant association between unemployed patients and all mental health outcomes except anxiety; all p values < 0.05 and odds ratios between 0.525 and 0.772 showing less likelihood of achieving the normal healthy category.
Conclusions: This is the first UK study, using routinely collected data, to investigate in coronary heart disease patients the impact of employment status on outcomes. The findings were that when weighted for baseline differences, unemployed patients mostly had poorer outcomes. Teams involved in CR delivery should take particular care when interpreting mental health baseline measures when setting CR goals, especially in relation to unemployed patients, and efforts should be made in providing more patient tailored interventions.

1. Introduction

Cardiac Rehabilitation (CR) is a highly evidenced based intervention for a variety of cardiac conditions, (1) significantly reducing cardiovascular mortality (RR 0.74, 95% CI 0.64–0.86) and hospital re-admission post CR (RR 0.82, 95% CI 0.70–0.96). [1,2] The modern United Kingdom (UK) CR population includes patients with conditions such as myocardial infarction, heart failure and angina, along with treatments such as percutaneous coronary intervention, coronary artery bypasses graft and valve surgery. [1] The benefits of CR are derived from modifications to lifestyle risk factors and the management of psychosocial factors associated with well-being. The approach is globally recognised as multi-disciplinary and comprehensive including structured education sessions, exercise based interventions and psychosocial support with agreed core components and minimum standards [3–5] yet less than 25% of programmes have access to psychosocial services. [6].

Current evidence in a post Percutaneous Coronary Intervention (PCI) population showed a link between employment, specifically unemployment, and lowered quality of life at baseline and 12 months post treatment [7]. This link between employment and health has scarcely been studied in CR, often only in uptake and participation [7–12]. The work by Strens et al. showed employment status at baseline was associated with reduced participation in CR post PCI (OR 0.54 CI 95% 0.44–0.68) or surgical intervention (OR 0.51 CI 95% 0.36–0.73) [8]. A study of patients following myocardial infarction found that unemployment was significantly associated with reduced intention to attend CR ($p = 0.007$) and increased drop out ($p = 0.044$) [9]. In a US study of underserved populations, patients were found to be less likely to attend CR if they were unemployed; however, conflict with work has also been identified as a common reason to not complete. [11] Although there is evidence of employment status affecting uptake and completion of CR, there is a dearth of evidence as to whether CR, as an intervention, is as

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effective in different employment statuses in terms of patient outcome. As such the aim of this study was to ascertain the general patient characteristics by employment status and investigate the association between employment status (employed, unemployed and retired) and patient outcome following CR; specifically mental health and quality of life (QoL).

2. Methods

This study was reported according to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines. [13].

2.1. Data

The analyses were performed using routinely collected patient level data from the UK NACR database from 1st January 2013 to 31st December 2015. According to the 2015 NACR report a total of 164 CR programmes across the UK enter into the NACR audit [6]. Information on patient's initiating event, treatment, individual risk factors, medication use, characteristics and outcomes of CR users is captured. Data is collected under 251 approvals which are reviewed annually by the Health and Social Care information Centre (HSCIC).

The analysis included all CR programmes in England, with valid patient data at both pre and post CR assessment including deprivation score as measured by the Index of Multiple Deprivation (IMD). Patients who had Myocardial Infarction with or without revascularisation were included to account for type of diagnosis/treatment. All patients with valid diagnosis/treatment entered were included, minimising selection bias.

2.2. Cardiac Rehabilitation

CR is conducted according to the British Association for Cardiovascular Prevention and Rehabilitation (BACPR) core components [3]. Typically programmes run for 8–12 weeks, twice weekly with structured education and exercise components.

2.3. Employment status

Employment status was categorised as employed, unemployed or retired. Being employed was classified as either full or part time employment, self-employed or as part of a government training scheme. Unemployed was defined as; unemployed, looking after family/home, permanently sick/disabled, temporarily sick or injured, student or other reasons for not working.

Employment status is often defined in a variety of ways, most commonly employed–unemployed comparisons are made sometimes including a third group; such as retired [14]. In the UK CR population the mean age of males is 66 years and females is 70 years, with approximately two thirds of population reported as being retired [6]. As such this study will include three employment groups; employed, unemployed and retired.

2.4. Outcome measures

Anxiety and depression symptoms were separately measured on the Hospital Anxiety and Depression Scale (HADS), licensed to NACR, (score range 0–21) with higher scores representing worse symptoms, patients were grouped as healthy normal category (<8) and unhealthy score (8+) [15]. Quality of life in relation to feelings and general quality of life were assessed on the Dartmouth COOP (score per item 1–5), responses were dichotomised (healthy normal score 1–3, unhealthy score 4–5) [16].

2.5. Statistical Analysis

The analyses were conducted in STATA 13.1. Baseline characteristics were compared across groups using Chi^2 or T-test as appropriate. Standardised differences were calculated for continuous variables, with >0.1 classified as meaningful. Unemployed and retired groups were compared to the baseline employed group [16]. Regression models were run comparing the unemployment and retired populations to the reference category employed. Relevant important covariates were included in the analysis. Age (years), gender (male/female) and number of comorbidities have both been shown to influence the outcomes following a variety of different interventions, including CR [17,18]. The duration of CR (length of core rehabilitation) was accounted for in analysis. The type of event/treatment prior to CR is likely to affect the patients' outcomes, to account for this variation patients were coded as medically managed or re-vascularised as shown in the NACR statistics report [6]. The IMD was calculated and ranked, from the most deprived to the least deprived regions, at for all 209 clinical commissioning groups and was included in this analysis [19]. Individual patients were assigned an IMD score according to where their General Practitioner (GP) was located within England. IMD was split into 10 equal sized groups 'deciles', with 1 being the most deprived group.

Logistic regressions were used to investigate the association between employment status, as an independent variable, and mental health outcomes as the dependent variable. Significance was set at the $p < 0.05$ level. Data model checking was performed to ensure that the models were a good fit through assumptions associated with the regressions.

3. Results

3.1. Study population

The study sample is summarised in Fig. 1 and the population characteristics are summarised in Table 1. A total of 24,242 patients were included in the analyses.

The population is representative of patients accessing CR [6], with an average age of 65 years (SD 11.9) and majority male participants (73.2% male). The average duration of CR for this study falls within the NICE guidelines of 8–12 weeks, with this population averaging 9 weeks. The distribution of the employment statuses is similar to the national level, which has stayed static at 58% retired for the past 6 years [6]. The patients were evenly distributed across the IMD deciles with the highest proportion in the 8th decile.

In terms of baseline scores by employment group, mean HADS were 2 points higher on average in the unemployed group (mean anxiety 7.7, depression 6.4) compared to the other two groups. Overall unemployed patients had the smallest proportion classified as normal on the HADS. The unemployed group also had the smallest proportions of patients reporting normal QoL readings in relation to feelings and general QoL, around 10% lower in comparison. The number of comorbidities was lowest in the employed group and duration of CR was greater, by 4 days, in the unemployed group. Naturally, the age was significantly different in the retired population with a 14 years greater average.

Table 1 also shows the proportion change from baseline to post rehabilitation into the normal group (HADS < 8 and Dartmouth ≤ 3) for the 4 mental health outcomes split by employment status. The results show that all groups had improvements across the four outcome measures, but the largest improvements were observed in the unemployed group.

3.2. Outcomes

The results from the regression analyses are presented in Table 2. The results consistently, apart from anxiety, showed that unemployed patients are significantly associated with worse mental health post

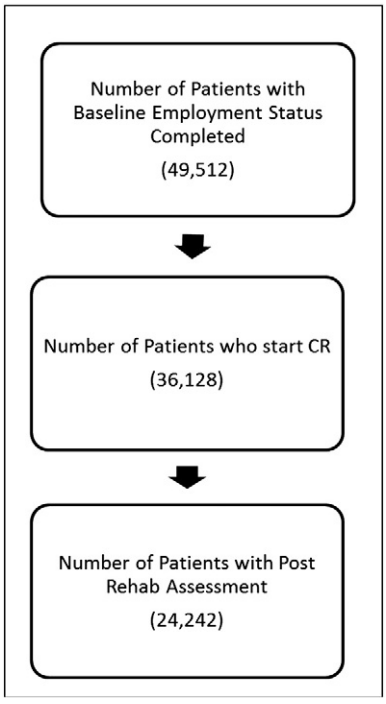

Fig. 1. Flow diagram showing patients' numbers from assessment 1 with a valid employment status field, starting core rehabilitation and then a valid assessment 2 post rehabilitation. Of the number with assessment 1 49% go on to have an assessment 2.

Table 1
Baseline and change in patient characteristics and outcome measures by employment status.

Baseline characteristics	Employment status groups			
	Employed	Unemployed	Retired	Total
Count n (%)	13,820 (27.9)	8253 (16.7)	27,439 (55.4)	49,512**
Male (%)	84.2	73.1	67.7	73.2**
Mean age (SD)	56.1 (9.1)	56.2 (10.3)	72.9 (7.5) [a]	65.5 (11.9)**
Number of comorbidities (median)	1	2[a]	2 [a]	2**
Duration of CR days (median)	63	67[a]	63	63**
% in Normal Category				
HADS anxiety mean (%)	69.7	57.9	77.4	72.3**
HADS depression mean (%)	83.8	69.0	83.9	81.7**
Dartmouth feelings (%)	85.0	76.8	88.1	85.4**
Dartmouth quality of life (%)	95.6	91.8	95.6	95.0**
Change from baseline in outcomes	% Change into Normal Category by Employment Status			
	Employed	Unemployed	Retired	Total
HADS anxiety (%)	7.1	8.0	4.6	6.1
HADS depression (%)	5.8	8.4	5.3	5.7
Dartmouth feelings (%)	5.9	6.4	4.3	5.3
Dartmouth quality of life (%)	2.6	3.6	2.4	2.6

Standardised differences [a] > 0.1 from employed group and Chi Squared * = $p < 0.05$ and ** = $p < 0.001$.

rehabilitation (all $p < 0.05$). The depression results showed unemployed patients were 26% less likely to be in the normal category ($p < 0.034$), and patients were 23–45% less likely to be in the normal category for Dartmouth feelings and QoL ($p < 0.001$). No significant associations were found between the retired population and mental health outcomes.

4. Discussion

The overriding result of this study is that although all employment groups show improvements in all post CR mental health outcomes, when compared to the employed group, unemployed patients were less likely to be in the normal category, post CR, for depression and Dartmouth feelings and QoL. Anxiety was inputted in a model as well, however, no significant association was found despite unemployed patients having a lower percentage in the baseline normal group. Interestingly work by Meyer et al. showed the complexity surrounding anxiety and outcome when they found that some level of anxiety, even as high as ≥10 on the HADS score, is associated with a beneficial reduction in cardiovascular events in a subset of cardiac patients undergoing PCI ($p = 0.014$) [20].

When compared at baseline, unemployed patients' mental health is consistently worse than the employed or retired population. Although the unemployed group make the greatest improvements pre to post CR this is likely due to worse pre CR starting point and some level of the other groups experiencing ceiling effects.

The unemployed patients' at follow-up were significantly (15–26%) less likely to be in the normal category for the HADS Depression and Dartmouth questions; this result was not significantly represented in the anxiety measure.

This seems consistent with the literature, in that unemployment has an association at baseline with poorer mental health [7,10,21]. The work by Waddell concluded a similar effect of employment status on mental health outcomes, in that unemployed status can be detrimental to mental health [21]. Additionally Brown and Jin's work also showed higher odds of poorer mental health in unemployed patients [12,22].

To date the literature investigating the effect of employment on CR, has only compared how patients differ at uptake and dropout [8–11]. This research has extended knowledge on the characteristics of those accessing CR from different employment groups and has identified an association between employment and outcome. In addition to existing research this current study has identified that from initiating event through to completion of CR there is a need for service tailoring to make sure all employment groups benefit from this intervention.

Overall this study enforces the importance of employment status on the CR population. Unemployed patients are less likely to attend CR and when they do attend they are less likely to be in three of the normal mental health outcome groups. This study's results, along with work on attendance and drop out suggest that commissioners may need to look at aligning the recruitment to and the delivery of CR by employment status [8–12].

Table 2
Results from the Multivariate Regression Analysis; association between employment status and mental health outcomes.

	Odds ratio	Sig.	95% CI		Observations
Effect of being unemployed in comparison to employed					
HADS anxiety	0.934	0.56	0.743	1.175	23,209
HADS depression	0.734	0.034	0.552	0.977	23,244
Feelings	0.772	<0.001	0.675	0.884	21,618
Quality of life	0.525	<0.001	0.406	0.678	21,530
Effect of being retired in comparison to employed					
HADS anxiety	0.992	0.98	0.513	1.915	23,244
HADS depression	0.978	0.892	0.711	1.346	23,209
Feelings	0.988	0.872	0.849	1.149	21,618
Quality of life	0.802	0.151	0.593	1.084	21,530

4.1. Limitations

One limitation of this study is the level of missing data. Although sufficiently powered for the purposes of this analysis, the inclusion of England only patients and ~31% missing data at the post rehab assessment may have limited the generalisability of the findings, although the population did appear to be representative of patients accessing CR in the UK. [13].

5. Conclusion

This study identified a strong association between employment status and mental health outcomes. The extent of benefit to patients is significantly influenced by employment status in that being unemployed led to reduced benefit in depression and QoL compared to patients who were employed or retired. Existing evidence has already established a link between employment and mental health at baseline; however, this is the first study to show this impact on patient outcomes. As recommended by national associations, CR teams need to assess patients,

based on the core components of CR, and consider employment status when tailoring care for individual patients. Future research should consider the staffing profile and types of tailored interventions that would enable unemployment patients to derive the same benefit.

Conflict of Interest

The authors report no relationships that could be construed as a conflict of interest.

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Does the mode of delivery in Cardiac Rehabilitation determine the extent of psychosocial health outcomes?

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ABSTRACT

Background: Cardiac Rehabilitation (CR) is a multicomponent tailored intervention aiming to reduce lifestyle risk factors and promote health in patients post cardiovascular disease. CR is delivered either as supervised or facilitated self-delivered yet little evidence exists evaluating the association between mode of delivery and outcomes.
Methods: This observational study used data routinely collected from the National Audit of Cardiac Rehabilitation from April 2012–March 2016. The analysis compared the populations receiving supervised and facilitated self-delivered modes for differences in baseline demographics, four psychosocial health measures pre and post CR and changes in anxiety, depression and quality of life following the intervention. The analysis also modelled the relationship between mode and outcomes, accounting for covariates such as age, gender, duration and staffing.
Results: The study contained 120,927 patients (age 65, 26.5 female) with 82.2% supervised and 17.8% self-delivered. The analysis showed greater proportion of females, employed and older patients in the self-delivered group. Following CR, patients in both groups demonstrated positive changes which were of comparable size. The regression model showed no significant association between mode of delivery and outcome in all four psychosocial outcomes when accounting for covariates (p-value > 0.0.5).
Conclusions: Patients benefited from attending both modes of CR showing improved psychosocial health outcomes with 3–76% change from baseline. Over half of CR programmes in the UK do not provide self-delivered CR yet this mode is known to reach older patients, female and employed patients. Facilitated self-delivered CR should be offered and supported as a genuine option, alongside supervised CR, by clinical teams.

1. Introduction

Cardiac Rehabilitation (CR) is a strongly evidenced intervention that is recognised as integral to comprehensive care for a range of cardiac conditions and treatments [1–3]. CR had, in 2007, a class one recommendation from the American Heart Association, American College of Cardiology and the European Society of Cardiology in the care of patients with heart disease [1,4].

The evidence for CR can be split into trial evidence and modern observational clinical registries [1–2]. The trial data, for the effectiveness of CR, summarised by the most recent Cochrane review shows that CR reduces cardiovascular mortality (RR 0.74, 95% CI 0.64–0.86) and hospital re-admissions post CR (RR 0.82, 95% CI 0.70–0.96) [1]. The registry data shows that CR could also significantly reduce all-cause mortality (HR 0.37, 95% CI 0.20–0.69) [3]. This disparity in conclusions highlights the differing populations that the studies/trials incorporate. In that Cochrane review average patient age was 56 years, whereas in the 2016 National Audit of Cardiac Rehabilitation (NACR) patients in the UK were shown to be 65 years, a 9 year increase in average age [1,5]. This issue of representativeness is a justification for increased use of observational registry based research.

Currently, the UK is world leading with 50% uptake across the four main diagnosis/treatment groups, Myocardial Infarction (MI), Percutaneous Coronary Intervention (PCI), MI + PCI, and Coronary Bypass Graft (CABG) [5]. Modern CR remains dominated by group-based approaches, with 82% of all patients taking up this mode of delivery as evidenced through the NACR 2016 report [5]. In 2017 a review concluded, based on 23 trials, that home based versus centre based rehabilitation was not associated with patients' outcomes, including physical capacity, mortality and health related quality of life. This strongly supports the utilisation of a diverse menu based approach to CR, which would include group based, home based and manual based CR [6]. However, in 2016 only ~60% of programmes in the UK did not have patients

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[1] This author takes responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation.

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receiving home-based in the 2016 audit [5]. Additionally, as shown in the review of CR effectiveness, evidence based on trial populations is often not representative of routine care. In the home vs. centre review 6 trials contained no female participants, when routine care shows around 30% female participation [1,6].

The traditional mode of CR delivery in Europe is supervised CR, with a median of 12 months with exercise as a predominant factor [1–2,5, 7–8]. Alternatively, facilitated self-delivered structured programmes such as the Heart Manual, Angina plan and home-based CR exist which are completed over a similar period [5–8]. The two forms of delivery, supervised versus facilitated self-delivered CR, are now forming modern CR. There is debate whether supervised delivery is better than its structured self-delivered counterpart containing facilitation from the CR team, as described in the heart manual [8]. A Danish study, from the CopenHeart research group, allocated patients into supervised group-based or self-care home-based; the findings were similar to that of the Cochrane Review and trial in favour of equivalence [9].

The British Association for Cardiovascular Prevention and Rehabilitation (BACPR) core components state that CR can be delivered in a variety of ways such as centre based and home-based along with the trial evidence that exists to suggest a comparable association with outcomes [10]. This study aims to investigate whether in a routine care population there is an association between patients receiving supervised or self-delivered CR and their psychosocial health outcomes post-CR. This will build upon the trial evidence, but in a more representative and diverse population.

2. Methods

This study was reported according to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines [11].

2.1. Data

The planned analyses used routinely collected patient-level data from the UK NACR database from 1st April 2012 to 31st March 2016. NACR collects electronic patient-level data from over 226 programmes each year [5].

NACR collects information about patients going through CR such as initiating event, treatment type, individual risk factors, medication use, patient characteristics and outcomes, along with centre level information; volume and staffing profiles [5]. Data is collected under NHS data requirements, reviewed annually by NHS Digital, which hosts and oversees the quality of audit data in the NHS. All data used in this study is anonymised by NHS Digital before reaching the NACR team.

CR is recommended for patients with a diagnosis of MI, heart failure, and angina; along with being eligible after having a treatment of CABG, PCI and Pacemaker [12–14]. All patients entered into the audit, within the time period, with an in scope diagnosis or treatment were included in the analysis [5].

The study includes CR programmes in the UK, with valid patient data at both pre and post CR assessment and completed data fields capturing staffing information. Inclusion was based on all patients with a valid diagnosis/treatment, started CR and a mode of delivery completed; this population was verified against the whole CR population without these measures completed (matching age, gender and baseline scores).

2.2. CR/Mode of delivery

Nationally CR is expected to be conducted according to the BACPR core components, which recommends a patient-tailored approach, based on the baseline assessment, defined needs and patient preference [10]. Patient specific CR means that mode of delivery is a patient-level variable, whereas staffing type is programme level.

For this study mode of delivery was coded from NACR variables, including group-based, home-based and web-based, into supervised (with staff present) and facilitated self-delivered (with contact but no staff required for the exercise component). Patients recorded as receiving delivery classified as 'other' were excluded from the study due to lack of descriptive information; this equalled 3% of patients, and were assessed for differences in demographics to ensure our final sample was representative.

2.3. Outcome measures

Psychosocial health status is a core area for CR, which in the UK includes assessment of the extent of anxiety, depression, self-perceived feelings and Quality of Life (QoL) at baseline and following CR as a measure of outcome improvement. Before starting, the 8–12 week CR programme all patients should receive a baseline assessment, which includes the Hospital Anxiety and Depression Scale (HADS) and Dartmouth questionnaire. This records their psychosocial well-being at baseline, which helps tailor the intervention. The patient is then provided a follow-up assessment post CR that assesses their improvement across the intervention. The outcomes included were HADS for anxiety and depression and the Dartmouth questions for Quality of Life (QoL) and feelings. HADS Anxiety and depression symptoms were separately measured (score range 0–21) with higher scores representing worse symptoms; patients were grouped by score as normal category (≤8) and at-risk group (8+) [15–16]. The Dartmouth feelings and QoL questions provide self-perceived psychosocial health scores. Responses were coded 1–5 and were dichotomised (normal score 1–3, at-risk score 4–5) [11].

2.4. Statistical analysis

The analyses were conducted in STATA 13.1. Baseline characteristics were compared across groups using Chi^2 and odds ratios for categorical variables or *t*-test for continuous variables. Regression models were built to investigate whether, accounting for covariates, the supervised and self-delivered methods for mode of delivery were associated with outcomes post CR.

Relevant important covariates were included in the analysis, where they were evidenced in the literature or significant in preliminary analysis. Age (years), gender (male/female), number of comorbidities and employment status have been shown to influence the outcomes following a variety of different interventions, including CR [16–18]. Employment status was coded as employed/retired or unemployed, this is because previous research found that employed and retired states have similar effects on outcomes [16]. The duration of CR (length of CR) was also included in the analysis along with staffing profile, total staff hours, Multi-Disciplinary Team (MDT) and total centre volume. The staffing information comes from the annual survey, performed routinely by the NACR to gain centre level information such as staff profile, hours and funding type. Because the mode of delivery was a patient-level variable, it was important to take into account the relative size and staffing profile of the centre where the patient received the CR.

Hierarchical logistic regressions were used to investigate the association between mode of delivery, as an independent variable, and psychosocial health outcomes as the dependent variable. A hierarchical design was used to account for different levels of patient and centre level data. Statistical level for significance was $p < 0.05$. Data model checking was performed to ensure that the models were a good fit through assumptions associated with the regressions.

3. Results

3.1. Study population

The study included 120,927 valid cases from across the UK that attended CR in the four-year period, this was from a sample of 385,002 patients entered in the time period, shown in Fig. 1. Within our eligible population, 82.3% received supervised CR whereas 17.7% received CR such as home-based or web-based coded as self-delivered.

The analysis in Table 1 shows increased odds for females and employed patients receiving self-delivered CR (1.26 and 1.24). The analysis also showed that older patients, lower mean comorbidity and longer

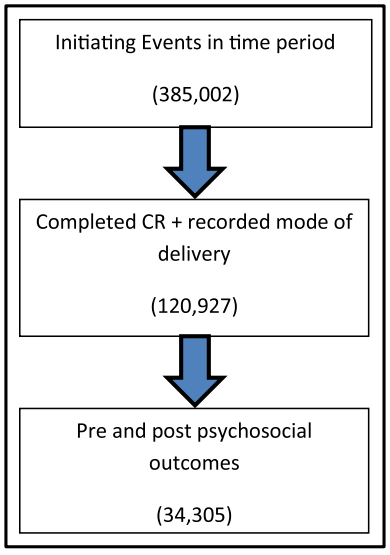

Fig. 1. Flow diagram showing total population in time period, those with valid mode of delivery and those with pre and post outcome measures resulting in them being included in regression analysis

Table 1
Showing the differences at baseline of patients when split by the mode of delivery they receive at CR.

	Supervised	Self-delivered	Total	Mean difference/Pearson Chi-square value	Odds ratio (CI 95%)
Number of patients (%)	99,491 (82.3%)	21,436 (17.7%)	120,927 (100.0%)		
Female (%)	25,190 (25.6%)	6565 (30.8%)	31,755 (26.5%)	258.356 (<0.001)	1.29 (1.26–1.32)
Mean age (SD)	64 (12)	67 (12)	65 (12)	2.282 (<0.001)	
Mean number of comorbidities (SD)	1.6 (1.6)	1.5 (1.5)	1.6 (1.6)	0.13089 (<0.001)	
Mean duration of CR days (SD)	68 (42.9)	87 (61.9)	69 (47.3)	19.310 (<0.001)	
Employed count (%)	42,012 (70.5%)	7940 (74.8%)	49,952 (71.2%)	143.29 (<0.001)	1.24 (1.19–1.28)

duration were significantly associated with patients receiving self-delivered CR.

Table 2 shows the baseline scores for psychosocial health measures across the two different modes of delivery. The Chi^2 analysis shows that there is significant difference between the two groups. The estimated odds ratio shows the size of the difference, which is 9–27% less likely to be in the target normal group at baseline if the patient attends self-delivered CR. This suggests that patients with poorer psychosocial health at baseline are receiving self-delivered CR compared to the supervised mode of delivery population. The patients are on average more anxious, depressed or have poorer psychosocial health in the self-delivered group.

The percentage change in Table 2 shows that all patients, in either delivery group, benefit from CR and demonstrated positive change. The self-delivered group actually improves more across all four outcomes measures, however, as seen in Table 2 this group also starts at a lower percentage at baseline.

3.2. Outcomes

Table 3 shows the results from the Logistic regression, comparing supervised delivery to self-delivered. In total 34,000 were eligible for the analysis with pre and post psychosocial measures recorded as shown in Fig. 1. The numbers included in each model are presented in Table 3. There was no significant association seen between any of the outcomes and the mode of delivery. The covariates that were included were justified. Employment status, age, sex and comorbidities, staffing hours and MDT were all seen to be significantly associated with likelihood of achieving the target health state post CR. All assumptions for the type of model used were met.

4. Discussion

The results from this study show that patients benefit irrespective of the mode of delivery in terms of psychosocial health outcomes following CR. This is the first large-scale routine population study to investigate whether the type of delivery influences the outcomes in a routine clinical setting. This study builds on the trial conclusions from Cochrane review by identifying in a real world setting that there is no significant association between different CR types and psychosocial health outcomes [6]. The results from the regression, that mode of delivery that a patient receives does not have an association with post CR psychosocial health outcome, is likely because CR is structured and patient-tailored, thus following the structure results in positive change.

The study's population consisted of 120,927 patients that were representative of modern UK CR. The population included in the valid case analysis was checked against the non-valid population; the valid population was deemed not significantly different in age, gender and baseline psychosocial health measures. The age, gender and comorbidity demographics were similar to the 2016 annual report [5]. However, the demographic profile shows stark contrast to the findings of the two recent Cochrane reviews which showed 15% female participation, as opposed to our ~26%, and 56 mean age where as this study had 65 (SD 12) [1,6]. This shows the difficulty between using trial evidence and the routine populations for generating service level advice. The recent CROS review, that utilised registry data from Europe, shows a similar population to this study, which supports the differences in routine clinical populations and those seen in trials [2].

The analysis investigated whether the patients receiving the two types of delivery differed at baseline; it showed that older, employed and female patients tended to be within the self-delivered programme. This is extremely important because female and older patients are often deemed in the evidence to be hard to reach and not taking up the offer of CR. If there is a preference in these demographics for self-delivered CR then a more diverse menu based approach to CR could influence uptake.

Patients were also investigated for differences pre and post CR in terms of psychosocial health. It was shown that patients in the self-delivered group were less likely to be in the normal group at baseline (0.91–0.73), however, they experienced a greater change post. This supports the idea that those with the most to gain experience the highest change and the supervised group was experiencing a ceiling effect. Regardless of this difference in change, the regression model shows no association between mode of delivery and post CR score.

This study's results emphasise the trend seen in recent literature that mode of delivery defined as supervised or self-delivered does not alter patient's outcomes. In the UK only 40% of centres supported patients receiving self-delivered CR which shows a lack of diversity in delivery [5]. This study shows that older and female patients may be more likely to attend self-delivered CR. The 65% uptake ambition set by NHS England [19] and 70% from the recent Road Map for CR [20], remains challenging and can only be achieved if CR programmes offer a greater choice to patients by offering more diverse CR options.

The regression analyses showed that there was no difference in psychosocial health outcomes post CR between the modes of delivery. There was positive change gained regardless of mode of delivery,

Table 2
The differences in percentage of patients in normal group at baseline and change post CR for the four outcome measures, HADS Anxiety and Depression, Dartmouth Feelings and Quality of Life.

	% in normal category for psychosocial health state			Odds ratio (Chi^2 *p*-value)	% Change into normal category by mode of delivery type the patient received		
	Supervised	Self-delivered	Total		Supervised	Self-delivered	Total
HADS Anxiety percentage in normal group	72.0%	70.2%	71.8%	0.91 (0.005)	6	7	6
HADS Depression percentage in normal group	82.1%	79.3%	81.8%	0.84 (<0.001)	6	7	6
Dartmouth Feelings percentage in normal group	84.9%	83.2%	84.7%	0.88 (0.004)	5	6	5
Dartmouth Quality of Life percentage in normal group	95.2%	93.5%	95.0%	0.73 (<0.001)	3	4	3

Table 3
Results from the hierarchical logistic regression analysis; association between mode of delivery and psychosocial health outcomes post CR.

Effect of self-delivered in comparison to supervised					
	Odds ratio	Sig.	95% CI		Observations
HADS Anxiety	0.981	0.744	0.878	1.098	33,748
HADS Depression	1.099	0.158	0.964	1.254	33.719
Dartmouth Feelings	0.882	0.086	0.764	1.018	28,982
Dartmouth Quality of Life	0.830	0.134	0.650	1.059	28,982

which shows that both methods of CR lead to improvements in psychosocial health.

In 2016, the NACR reports 50% uptake with 82% receiving supervised group-based CR, perhaps to further increase uptake the numbers receiving self-delivered programmes should increase [5]. The remaining patients not taking up the offer of CR, due to the offer not appealing, are branded harder to reach and are often female and older. This study suggests that the composition of facilitated self-delivery contained older patients with a higher proportion of females; this suggests that higher utilisation of this mode of delivery will improve the offer of CR and thus improve uptake.

4.1. Limitations

Our study population had a good size and is considered representative of modern routine CR. The study results, which reflect routine clinical practice, build on what was found in the Cochrane review of clinical trials in that mode of delivery is not a determinate of outcomes and that providing high quality tailored CR is associated with improved outcomes regardless of mode of delivery [6].

This study used four years of NACR accumulated data, which after including all the different variables such as age, gender, comorbidities and mode of delivery amounted to 120,927 patients. One limitation that is shared with the NACR 2016 national report is that only 56% of patients that start CR have a recorded post assessment. This reduces the number of valid patients substantially for the later analysis. The population is still representative and the analysis has enough patients. However, improvements in the recording of data such as mode of delivery, post assessments and baseline demographics would improve the power given to research such as this.

In addition to completeness of data, there are some issues around the use of questionnaires to capture patients' psychosocial health, firstly collecting questionnaires post an intervention may reduce completeness and secondly, honesty of patients recording psychosocial health may be questioned. These two issues could lead to recall and collection bias, however, the two questionnaires were validated in our CVD population and the authors feel confident of the accuracy of the outcomes.

Another limitation of this study is the level of contact that the CR team had with the self-delivered programme. The self-delivered programme was defined from modes such as home-based and web-based which are structured programmes facilitated by the CR, the exact nature of the facilitation specific to programmes was unknown.

5. Conclusion

This is the first investigation of the association between mode of delivery and psychosocial health outcomes in the UK clinical setting. This study aimed to investigate whether supervised or self-delivered CR differed in terms of four psychosocial health outcomes. This study concluded that there is no association between mode of delivery and psychosocial health outcomes post-CR. Currently, in the UK there are ~60% of programmes not providing self-delivered CR, with this study and the growing evidence there should be a wider menu of options in the delivery of CR including facilitated self-delivered programmes. This study suggests that facilitated self-delivered CR is appealing for older, female and employed patients who are traditionally harder to reach, through wider implementation of self-delivered uptake which may increase further from 2016.

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Conflict of interest

None.

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Are physical fitness outcomes in patients attending cardiac rehabilitation determined by the mode of delivery?

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ABSTRACT

Background Cardiac rehabilitation (CR) is a well-evidenced and effective secondary intervention proven to reduce mortality and readmission in patients with cardiovascular disease. Improving physical fitness outcomes is a key target for CR programmes, with supervised group-based exercise dominating the mode of the delivery. However, the method of traditional supervised CR fails to attract many patients and may not be the only way of improving physical fitness.

Methods Using real-world routine clinical data from the National Audit of Cardiac Rehabilitation across a 5-year period, this study evaluates the extent of association between physical fitness outcomes, incremental shuttle walk and 6 min walk test, and mode of delivery, delivered as traditional supervised versus facilitated self-delivered.

Results The proportion of patients receiving each mode were 80.6% supervised with 19.4% to self-delivered. The study analysis comprised of 10 142 patients who were included in the two models. The self-delivered group contained a greater proportion of females and older patients. The regression model showed no clinical or statistical significance between mode of delivery and post-CR physical fitness outcomes.

Conclusions This study is unique as it has identified through a routine clinical population that regardless of the mode of delivery of rehabilitation, patients improve their physical fitness outcomes at meaningful levels. This study provides a strong evidence base for patients to be offered greater choice in the mode of CR delivery as improvements in physical fitness are comparable.

Key questions

What is already known about this subject?

► Cardiac rehabilitation (CR) is a well-evidenced healthcare intervention that is successfully delivered to over 60 000 people in the UK each year. The intervention should be patient tailored and its mode of delivery varies from supervised to self-delivered. The evidence around the differences in outcome from these modes of delivery is lacking and has yet to look at physical fitness outcomes in routine populations. It has been shown in previous work that there is no statistical difference in patients' fitness, although this was in trial populations that are often not representative of routine populations. Additionally, for other outcomes such as psychosocial well-being in routine populations there was also no difference between modes. This will be the first study to investigate physical fitness outcomes, such as incremental shuttle walk test and 6-min walk test, with the mode of delivery.

What does this study add?

► This study adds to the growing evidence base of mode of delivery and its lack of association with patient's outcomes. For a long time, CR has thought to only be delivered in supervised gym-based sessions; however, with this study we know that not only are the outcomes of patients comparable but also that both groups of patients on average are exceeding meaningful clinical differences throughout their duration of the programme.

How might this impact on clinical practice?

► In the UK, CR is still predominantly delivered as supervised group-based rehabilitation, with it making up ~80% of the delivery type. Additionally, only 40% of programmes in 2017 record as using self-delivered CR. This study, along with others, that highlight the lack of differences in outcome for patients attending either type of rehabilitation can provide a strong evidence base for patients to be offered greater choice in the mode of CR delivery as improvements in physical fitness are comparable.

INTRODUCTION

Cardiac rehabilitation (CR) is a well-evidenced intervention that remains effective in the modern era of cardiology.[1 2] The aims of CR are to address and change lifestyle risk factors and promote physical fitness and mental health.[3 4]

The evidence for CR is from experimental and observational studies and shows that CR is effective at reducing mortality, both all-cause and cardiac along with readmissions.[1 2] However, the majority of this evidence is based on traditional supervised group-based CR as opposed to facilitated primarily self-delivered modes of delivery. In 2017, Cochrane reviewed randomised controlled trial evidence for the differences between home-based and group-based rehabilitation in terms of health-related quality of life, exercise capacity and readmissions.[5] They found

that in all outcomes there was no significant association between the mode of delivery and where the patients were post-CR. Historically, researchers and healthcare funders have separated rehabilitation into home-based and group-based; however, recently the literature has also considered the level of supervision to be an important factor in terms of the delivery of rehabilitation.[6 7]

Although there is growing evidence in the trial populations that mode of delivery is not significantly associated with a range of outcomes, there is in parallel an acknowledgement that trials may not be representative of routine populations. Notwithstanding the known benefits of Cochrane reviews of CR, there are concerns about the populations being representative of routine care (eg, average age of patients within the trials (56 years, range 48–70 years) and women accounting for less than 15% of the population).[1] In the most recent National Audit of Cardiac Rehabilitation (NACR) annual report, women made up 30% and the average age was 67 which is substantially older than the trials.[8] Moreover, the intervention within the trials may not contain the variety or nuances that are present in real-life/routine care. Due to the differences in population and potential intervention, it is important to address questions around association between mode and outcomes in routine populations as well as in trials.

The UK NACR showed that in 2016, 80% of rehabilitation was delivered as group-based, with other methods such as home-based, web-based and telephone making up the other 20%.[8] According to the British Association for Cardiovascular Rehabilitation and Prevention (BACPR) core components, the mode of delivery should be menu-based, with interventions centred on patients' needs and preferences.[3 4] The lack of choice in the CR offer shows that programmes are underusing modes of delivery proven to be effective at reducing risk factors and promoting lifestyle change.[5] In fact, many programmes in the UK still only offer group-based CR with ~60% of programmes not offering any form of self-delivered (home-based, web-based or telephone-based) rehabilitation to any patients.[8] The UK, Europe and the USA continue to aspire to challenging uptake ambitions in the region of 65% to 70%.[9 10] Recent findings from clinical data and clinical review identify a lack of choice in the menu of routine practice CR and make recommendations for more options appealing to patients' preferences and meeting their needs all of which will help overcome traditionally barriers to participation in CR such as older, female and non-native language speaking patients.[8 11]

British and European guidelines and core components suggest that CR is best delivered by a multidisciplinary team (MDT), through a variety of modes of delivery.[1 2] A study based in Denmark, using the CopenHeart data, found that patients assigned to supervised group-based or self-delivered home-based found no difference in their perceived exertion levels postintervention nor exercise effects.[6 7] A recent study conducted using data from the NACR showed that across the two delivery types, supervised versus self-delivery, there was no significant association with psychosocial health outcomes.[12] This provides the context for an emerging hypothesis testing the likelihood that physical fitness outcomes do not differ between the delivery type and that patients can benefit from either approach.

This study aimed to assess whether the mode of delivery, as supervised or self-delivered, is associated with improved physical fitness outcomes as measured through the 6 min walk test (6MWT) and the incremental shuttle walk test (ISWT).

METHODS

This study was reported according to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines.[13]

Data

The study used data from a routinely collected audit of CR, the NACR. The NACR collects data from CR programmes across the UK and has a 74% coverage through online data entry.[8] The electronic data come from 224 programmes, which collect data on patient's demographics, baseline risk factors and characteristics, the type of CR received and outcomes derived from pre-CR and post-CR assessment. Along with patient level characteristics, the audit also collects service level factors such as the number of patients seen (volume), staffing hours and the extent of staff in their MDT.

Patients were included if they had an initiating event between 1 April 2012 and 31 March 2017. The initiating event was the diagnosis or treatment that deemed the patient eligible for CR. All patient groups, except heart failure, were included in the main analysis, such as myocardial infarction (MI), percutaneous coronary intervention (PCI) and coronary artery bypass.[14 15]Patients with a primary diagnosis of heart failure were not included as this group were only recently added to the NACR dataset and at present there is insufficient sample for inclusion. To be included, patients needed to have (1) a completed CR and (2) a recorded mode of delivery. To account for reporting bias, the population without a recorded mode of delivery were compared for baseline demographics such as age and gender.

Mode of delivery

The NACR records the routine delivery CR in the UK, which includes core rehabilitation consisting of exercise sessions, education sessions and lifestyle advice as guided by the BACPR core components. The exercise sessions are supervised/facilitated by trained competent professionals to maximise patient benefit.[3] The modes of delivery recorded in the NACR, includes both supervised and self-delivered levels.[8] For this study, mode of delivery for each patient was coded from NACR variables, including group-based, home-based and web-based, into supervised (with staff present) and facilitated self-delivered (with contact but staff not required for the exercise

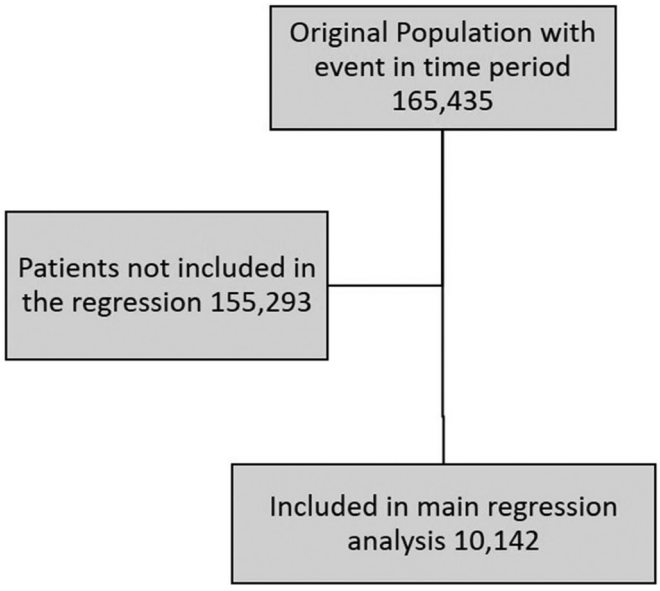

Figure 1 Flow diagram of the population included in the study based on having their event within April 2012–March 2017, having a recorded mode of delivery and completing cardiac rehabilitation. The population included in the analysis was compared with the full original population and were not significantly different.

component). Patients recorded as receiving delivery classified as 'other' were excluded from the study due to the lack of descriptive information; this equalled 3% of patients, and these were assessed for differences in demographics to test the extent by which our final sample was representative. Other factors about the service were included as covariates.

Outcome measures

The study, accounting for baseline assessment scores, explored predictors of post-CR outcomes for the ISWT and 6MWT expressed in metres walked.[16–18] The study used patients' final score which is collected on average 9 weeks after the initial baseline assessment.[8] The analysis also included the baseline walking score for all patients, to accurately account for their walking ability prior starting rehabilitation.

Statistical analysis

The analyses were conducted in STATA 13.1. Baseline characteristics were compared across groups using $\chi^2$for categorical variables or t-test for continuous variables.[19] Regression models were built to investigate whether, accounting for covariates, the supervised and self-delivered methods for mode of delivery were associated with outcomes post-CR.

Relevant important covariates were included in the analysis, where they were evidenced in the literature or significant in preliminary analysis. Age (years), gender (male/female), number of comorbidities and employment status have been shown to influence the outcomes following a variety of different rehabilitation interventions, including CR.[20–22] Employment status was coded as employed/retired or unemployed, and this is because previous research found that employed and retired states have similar effects on outcomes.[20] The duration of CR (length of CR) was also included in the analysis along with staffing profile, total staff hours, MDT and total centre volume after being evidenced in previous research.[20 21] The duration was calculated from the start to the end of core rehabilitation, which is advised by the BACPR to be at least 8 weeks.[3] Due to heterogeneity in the completion of sessions, the study was unable to include sessions and thus intensity of the intervention as a covariate. The staffing information comes from an annual survey, performed routinely by the NACR to gain centre level information such as staff profile, hours and funding type. Because the mode of delivery was a patient-level variable, it was important to take into account the relative size and staffing profile of the centre where the patient received the CR.

Hierarchical linear regressions were used to account for different levels of patient and centre level data as part of the investigation of association between mode of delivery, as an independent variable, and physical fitness outcomes as the dependent variable. Statistical level for significance was $p<0.05$. Data model checking was performed to ensure that the models were a good fit through assumptions associated with the regressions.

RESULTS

Study population

The overall study population comprised 165 435 patients from the full dataset with an initiating event within the time period. The flow diagram in figure 1 shows the total population and those included in the regressions models. The diagnosis/treatment split was 78.9% conventional CR population (MI 12.6%, MI+PCI 31.6%, PCI 18.1% and coronary artery bypass grafting (CABG) 16.7%) and the remainder 'Other', such as angina.

The mode of delivery distribution, seen in table 1, was similar to that of the wider CR population and that seen in the annual statistics report, with 80.6% receiving supervised and 19.4% in the self-delivered group. The proportion of females was lower in the supervised mode, which was significant ($p<0.001$). The self-delivered group also contained older, more employed, previous partnered and patients with 'other' treatments than the conventional PCI and CABG. These differences were all significant. Additionally, the length of CR in the self-delivered group was on average 10 days longer with a total mean duration of 73 days. Each mode of delivery population were deemed similar and representative of routine care when compared for age, gender and other demographics.

The two-population's physical baseline scores were also compared (table 2). The supervised group had, for both physical fitness measures, higher baseline scores by 30 m for 6MWT and 24 m for ISWT. The difference was also statistically significant ($p<0.001$).

Table 1 Patient characteristics across the two modes of delivery: supervised and self-delivered cardiac rehabilitation

	Supervised		Self-delivered		Total		
	Count	%	Count	%	Count	%	Pearson χ^2 value
No of patients (%)	133 386	80.6	32 049	19.4	165 435		
Gender							
Female	33 172	25.7	9474	30.7	42 646	26.6	321.4 (<0.001)
Body measurement							
>30 BMI	27 906	30.9	5439	30.8	33 345	30.9	0.075 (0.784)
Employment status							
Employed	67 765	84	12 850	78	80 615	83	373.5 (<0.001)
Marital status							
Partner	73 412	78.4	15 743	75.3	89 155	77.8	110.9 (<0.001)
Previous partner	12 377	13.2	3314	15.9	15 691	13.7	
Cardiac treatment							
PCI	65 098	48.8	14 721	45.9	79 819	48.2	534.3 (<0.001)
CABG	19 726	14.8	3750	11.7	23 476	14.2	
Other treatment	32 048	24.0	9465	29.5	41 513	25.1	
	Mean	SD	Mean	SD	Mean	SD	Mean difference
Mean age (years)	65	12	67	12	65	12	2.2 (<0.001)
Total no of comorbidities	1.70	1.69	1.56	1.72	1.67	1.70	0.14 (<0.001)
Core rehabilitation duration start to end including assessment (days)	69.70	43.21	89.53	59.33	73.25	47.13	19.8 (<0.001)

BMI, body mass index; CABG; coronary artery bypass grafting; PCI, percutaneous coronary intervention.

Table 3 shows the extent of change post-CR. At a first level of analysis, not accounting for covariates, the supervised group's ISWT change was statistically significantly higher in comparison to the self-delivered group, with a mean difference of 12.9 (p<0.001). However, the change seen for the 6MWT was greater in the self-delivered group, this was a 7 m greater change in the self-delivered group (p=0.007). Overall, the differences between the modes were not of clinical significance and patients attending either mode had meaningful clinical difference changes post - CR for this population.

Outcomes

The regression model (table 4) showed that there was no significant difference between the mode of delivery and the post-CR physical fitness outcomes for either measure (p>0.05). The inclusions of predictors such as age, gender, baseline physical fitness score and service quality were justified and were statistically significant. The models had an R^2 of 69%–85% and met the assumptions of uniform variance and linearity. The final population included in the regression model were compared with the wider study and routine care population and were deemed to be representative in terms of age, gender and other covariates. The full regression models for each outcome are included as online supplementary material which includes all covariates and the model descriptive.

DISCUSSION

This study set out to investigate whether patients attending supervised or self-delivered CR had different outcomes, in terms of physical fitness. The study's main analysis found that there was no significant difference in patient's physical fitness outcomes and the mode of delivery they received, either supervised or self-delivered. This is the first study of routine CR patients to investigate physical fitness outcomes and the mode of delivery.

Table 2 Baseline patients' physical outcome scores across the two modes of delivery: supervised and self-delivered

	Supervised		Self-delivered		Total		Mean difference (p values)
	Mean (SD)	Count	Mean (SD)	Count	Mean (SD)	Count	
Six minute walk test metres at assessment 1	332.8 (132.8)	12 708	302.9 (134)	1440	329.7 (133)	14 148	29.9 (<0.001)
Shuttle walk test metres at assessment 1	356.9 (176)	19 137	332.8 (201)	2644	354.0 (179)	21 781	24.1 (<0.001)

Table 3 Change in patients physical outcomes' post-cardiac rehabilitation across the two modes of delivery, supervised and self-delivered

	Supervised			Self-delivered			Total			
	Mean (SD)	% change from baseline	Count	Mean (SD)	% change from baseline	Count	Mean (SD)	% change from baseline	Count	Mean difference (p values)
Six minute walk test metres change	64.3 (65.8)	19.3	7215	57.4 (57.9)	19	732	63.7 (65.2)	19.3	7947	-6.9 (0.007)
Shuttle walk test metres change	102.7 (117.4)	28.8	11133	115.6 (139.1)	34.7	1486	104.2 (120.2)	29.4	12619	12.9 (<0.001)

This has been shown in trial populations to have similar relationship, Cochrane in a 2017 review found no association between home-based/group-based rehabilitation for patients post-CR exercise capacity.[5] Additionally, this conclusion builds on other research, investigating delivery mode and psychosocial health outcomes.[12] The combination of routine CR evidence and trial evidence results in a strong case for patients to have a menu-based approach offering supervised and facilitated self-delivered rehabilitation options.

The overall study population consisting of 165 435 patients and the regression population (n = 10 142), were representative of modern UK CR. The patient population in the analysis was checked against the population with no mode of delivery reported; the valid population were deemed as not significantly different in age, gender and baseline physical fitness measures. The age, gender and comorbidity demographics were similar to the national level data.[8]

This population had a high level of female participation. The total proportion of female was 26.6%, which is comparable with the overall NACR population (30%) and much higher than those recruited into the trials in the Cochrane 2017 review, where some studies had no female participants.[5] Additionally, our study looked at mode defined as supervised and facilitated self-delivered. The self-delivered modes included not only home-based as per Cochrane but also structured and facilitated web and e manual based approach which is increasingly being provided as an option in routine practice.

The population taking up the self-delivered mode is older, includes more females and a greater proportion of other cardiology treatments. Across the world, there are well-evidenced barriers to CR entry in females and older patients.[23–26] The current uptake for CR in the UK is 51%, which, although one of the top levels across the globe, falls short of targets such 65% set by NHS England. To meet these uptake targets and make CR more available to all eligible patients, greater utilisation of other modes, such as self-delivered should be considered. Having a menu-based approach, with the offer of CR being inclusive of more than just group-based, is essential for maximising patient participation.[11] This study indicates that two traditionally under-represented patient groups (females and older patients) attend self-delivered mode of delivery in greater proportions; wider adoption of this approach will reduce such inequalities and potentially increase uptake generally.

The change in physical fitness from baseline is for all modes, larger than the meaningful clinical difference.[17 18] This highlights that attending CR, through either mode, leads to a meaningful improvement in physical fitness for patients.

One possible reason for the lack of adoption for self-delivered rehabilitation is perhaps due to worry of safety surrounding non-supervised CR. This has been studied, and in 2014 a trial investigated the use of high-intensity interval training in CR patients.[27] Although this was in a younger trial population, the results found that home-based non-supervised group do comparably well. Additionally, the training in both settings was deemed safe.[27]

Limitations

One limitation that the study experienced was that although exercise testing is essential for setting objectives and assessing risk, the number of patients with pre-CR and post-CR physical fitness measurements was low. In 2016, NACR reported that less than one-third of patients had recorded physical fitness measurements either ISWT or 6MWT. This does limit the study results in that there may have been some reporting bias. However, the included population was verified against the wider

Table 4 Results from the hierarchical logistic regression analysis; association between mode of delivery and physical fitness outcomes post-CR

	Coefficient	Significance	95% CI	Snijders/Bosker R^2	Observations
Six minute walk test metres at assessment 2	–1.38	0.806	–12.383 to 0.778	0.846	3653
Shuttle walk test metres at assessment 2	0.31	0.957	–11.111 to 0.690	0.690	6175

eligible population in terms of demographics and characteristics, so the authors are confident in the regression model.

Another limitation with this study is that the study could not include intensity/dose of rehabilitation. The length of rehabilitation was included as a covariate as duration; however, the NACR currently has insufficient information regarding the number of sessions to calculate the dose. Although session data have just commenced as part of NACR data collection and will be available for further studies in 2019.

This study excluded patients with heart failure due to their difference in expected walking ability to the wider CR population such as re-vascularised patients. This strengthens our study as it reduces heterogeneity of our study population and additionally justifies future work into this subpopulation.

FUTURE WORK

This study's results show that either mode is beneficial for physical fitness. A finding in the 2017 Cochrane review was that the adherence rate was greater in home-based CR.[5] This study did not compare adherence rates between supervised and self-delivered CR. Future work will investigate whether the evidence shown in trials, in terms of adherence, is also true in routine CR.

CONCLUSION

This study finds, for the first time in a routine clinical population, that physical fitness post-CR improves to a clinically meaningful level independent of the mode of delivery. The population taking part in self-delivered CR is higher in proportion of female and older patients. With CR continuing to fail to appeal to many eligible patients, adopting a more menu-based approach which uses modes such as self-delivered is likely to reduce such inequalities in access to CR. The regression model which accounted for patient demographics and service level factors showed no difference, clinical or statistical between mode and post-CR outcomes. This is the first study to investigate the association between mode and physical fitness in routine patient populations. The results show that the population receiving self-delivered benefit as much as supervised group supporting the equivalence of these modes of delivery.

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Does the mode of delivery in routine cardiac rehabilitation have an association with cardiovascular risk factor outcomes?

Alex S Harrison and Patrick Doherty

Abstract

Aims: Cardiac rehabilitation is one of the most cost-effective interventions for patients with cardiovascular disease. Worldwide supervised group-based cardiac rehabilitation is the dominant mode of delivery followed by facilitated self-managed (FSM), which is emerging as part of a cardiac rehabilitation menu. Modern research evidence, using trials and well-resourced interventions, suggests FSM is comparable to supervised rehabilitation in its outcomes for patients; however, this is yet to be established using routine clinical practice data.

Methods: Including 81,626 patients from routine clinical data in the National Audit of Cardiac Rehabilitation, this observational study investigated whether mode of delivery, supervised or FSM, was associated with similar cardiac rehabilitation outcomes. Hierarchical regression models included patient and service covariates such as age, gender, cardiac rehabilitation duration and programme staff type.

Results: The results showed 85% of the population received supervised cardiac rehabilitation. The FSM group were significantly older, female and predominantly in lower socioeconomic groups. The results showed that all patients on average benefit from cardiac rehabilitation, independently of mode of delivery, across all risk factors. Additional benefit of 13% and 11.4% increased likelihood of achieving the target state for physical activity and body mass index respectively when using FSM approaches.

Conclusion: This is the first study to investigate traditional cardiovascular risk factors with cardiac rehabilitation mode of delivery using routine clinical data. Both modes of delivery were associated with comparable statistically significant positive outcomes. Despite having equivalent outcomes, FSM cardiac rehabilitation continues to be underutilised, with less than 20% of patients receiving this mode of delivery in the UK.

Keywords

Cardiac rehabilitation, risk factors, outcomes, secondary prevention

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Introduction

Cardiovascular diseases (CVDs) are the number one cause of death globally,[1] with an estimated 17.7 million related mortalities in 2015. It is estimated that in Europe more than 85 million people are living with CVD.[2] Cardiac rehabilitation is one of the most widely recognised and well evidenced treatments for CVD patients. Cardiac rehabilitation in the modern era of cardiology remains effective.[3,4] The evidence for effectiveness of cardiac rehabilitation includes reduction in re-admissions (risk ratio (RR) 0.82, 95% confidence interval (CI) 0.70–0.96) and cardiovascular mortality (RR 0.74, 95% CI 0.64–0.86) in trial populations and in observational studies a reduced overall mortality (hazard ratio 0.62 95% CI 0.54–0.70).[3,4] However, in updated reviews there has been a reduction in the strength of effectiveness, suggesting in meta-analysis of randomised controlled trials that there may no longer be an all-cause mortality effect.[5] This may be due to the ever improving routine care, or in the diversity of cardiac rehabilitation delivered.

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Cardiac rehabilitation is a multifaceted lifestyle intervention that aims to: influence favourably the causes of CVD, provide the best possible physical, mental and social conditions and result in the slowing or reverse of the progression of disease.[6] Cardiac rehabilitation is included in National Institute for Health and Care Excellence (NICE) guidelines for treatment of myocardial infraction patients.[7,8] Cardiac rehabilitation in the UK is widely adopted, with 51% of eligible patients participating in 2017, and is the most cost-effective intervention after aspirin.[9,10] In a recent cost-effectiveness systematic review, cardiac rehabilitation in a variety of countries and settings was seen to be significantly cost effective.[11]

Cardiac rehabilitation is best delivered by a multidisciplinary team in the form of a multi-component intervention that aims to reduce burden of disease, promote healthy lifestyle, improve risk factor management and facilitate optimal recovery.[6,12] The mode of delivery for cardiac rehabilitation has long been thought to be an influencing factor in terms of patient outcomes. Cochrane in 2017 reviewed the trial evidence for home-based versus centre-based cardiac rehabilitation modes of delivery, which concluded that; for total mortality (RR 1.19 95% CI 0.65–2.16), exercise capacity (standardised mean difference = –0.13, 95% CI –0.28 to 0.02) and health related quality of life (figure not estimated) there was no difference between modes.[13]

Additionally, two studies using routine data from the same clinical populations found no difference in the psychosocial outcomes (Hospital Anxiety and Depression Scale (HADS) and Dartmouth Cooperative Questionnaire [COOP]) and walking fitness (incremental shuttle walk test and 6 minute walk test) of patients attending supervised or self-managed rehabilitation in the UK.[14,15]

Currently, cardiac rehabilitation in 2017 is predominantly delivered in a supervised group-based mode and only a small proportion as other modes, which are often facilitated self-managed (FSM) modes.[9] The recent studies using the National Audit of Cardiac Rehabilitation (NACR) data indicated that one-fifth of the delivery is from FSM.[14,15] Tradition has been that supervised group-based has long been the assumed best approach for influencing outcomes; however, there is an emerging trend in recent years to offer modes such as the FSM alternatives.[14–16]

The aims of cardiac rehabilitation in all modes are to facilitate optimal recovery and reduce risk factors. According to the World Heart Federation, four of the highest associated risk factors for CVD are smoking, being overweight or obese, high blood pressure or hypertension, and physical inactivity.[17]

Smoking cessation is key to the British Association of Cardiovascular Prevention and Rehabilitation (BACPR) standards and core components are programmes to encourage smoking cessation supported by skilled and competent staff.[6] Based on the most recent UK data 6.4% of patients entering cardiac rehabilitation were smoking and one-fifth of this group had successfully quit by post assessment, which equated to over 300 patients.[10]

Patients who are physically inactive, defined by the Chief Medical Officer guidelines of <150 min of moderate activity per week, make up 58.4% of patients entering cardiac rehabilitation services.[18] On average 28.1% of patients (4448) had moved into the higher physically active group by the end of cardiac rehabilitation, which is a trend associated with reduced mortality.[9,19]

High blood pressure, defined in the CVD population as >140/90 (>130/80 for South Asians) is a major risk factor for CVD.[17] This study categorised the South Asians as >130/80 as evidence suggests that there are differences in risk associated with blood pressure and this group.[20] A reduction in systolic blood pressure by 5 mmHg can reduce cardiovascular mortality by as much as 20–40%. Through successful titration of drugs from the cardiac rehabilitation staff and increases in physical activity, 6% of previously high blood pressure patients move into <140/90 by the time they finish cardiac rehabilitation.[9] In the recent EUROSPIRE IV, it was found that ~60% of hypertensive patients were <140/90 after attending cardiac rehabilitation.[21]

The final risk factor to be considered is obesity, which is defined as body mass index (BMI) >30 (>25 for South Asian and Chinese populations). The different categorisation for South Asians is due to NICE guidance for increased risk in lower BMI score.[22] Obesity is an indicator of poor health and is associated with an increased likelihood of developing hypertension, diabetes and atherosclerosis.[6–17] According to recent statistics more than 400 million adults throughout the world are obese and ~30% of patients entering cardiac rehabilitation have a BMI higher than 30.[1,10] Evidence suggests that patients moving from obese and overweight to normal BMI have a reduction in risk of CVD and cancer.[23]

This study will incorporate all four major risk factors for CVD and investigate, using known predictors of outcome such as age, gender and deprivation score, whether mode of delivery, defined as supervised or FSM, has an association with patient outcome improvement.

Methods

This study was reported according to the Strengthening the Reporting of Observational Studies in Epidemiology guidelines.[24]

Data

The source of data for the study was the National Audit of Cardiac Rehabilitation.[9] The audit monitors and reports service quality, the patient profile and outcomes in patients that complete CR. The NACR covers cardiac rehabilitation programmes from the UK totalling over 200; with 74% coverage through online data entry; however, including the index of multiple deprivation (IMD), this study will look at cardiac rehabilitation programmes in England only.[9] The data collected includes patient characteristics such as age, gender and ethnicity along with services details such as staffing and number of patients seen.

Patients from England with an initiating event between 1 January 2012 and 30 April 2018 were eligible. The initiating event was the diagnosis or treatment that deemed the patient eligible for cardiac rehabilitation. All patient groups, such as myocardial infarction, percutaneous coronary intervention and coronary artery bypass, were included in the main analysis.[6,9] Patients needed to have 1) completed cardiac rehabilitation and 2) a recorded mode of delivery. To account for reporting bias, the population without a recorded mode of delivery was compared for baseline demographics such as age and gender.

Mode of delivery

The modes of delivery recorded in the NACR include both supervised and FSM levels.[9] For this study, mode of delivery for each patient was coded from NACR variables, including Group-Based into supervised (with staff present) and Home-Based and Web-Based into FSM delivery (contact with cardiac rehabilitation staff).

Patients recorded as receiving delivery classified as 'other' were excluded from the study due to lack of descriptive information; this equalled 3% of patients, and these were assessed for differences in demographics to test the extent to which our final sample was representative. If patients were recorded as receiving both supervised and FSM they were excluded. This is because the sample size to analyse this within the NACR is very small: <1%.

The cardiac rehabilitation in our sample is delivered according to the BACPR core components.[6] The UK guidelines according to which the cardiac rehabilitation is delivered closely resemble the European guidelines.[6,12] This is a multi-disciplinary team that delivers a comprehensive rehabilitation focusing on risk factor management and lifestyle change.

Outcome measures

The study's outcomes included four key CVD risk factors (physical activity, smoking status, blood pressure and obesity) in patients following a cardiac event or undergoing a related cardiac procedure. The patients were all assessed at baseline and followed up upon completion of the core stage of rehabilitation. The outcomes were all categorised into binary variables, such as self-reported achieving 150 min of physical activity per week, not smoking/smoking, having blood pressure greater than 140/90 (130/80 for South Asian populations) and having a BMI of >30 (>25 for South Asian and Chinese populations).

Statistical analysis

The analyses were conducted in SPSS 25. Baseline characteristics were compared across groups using chi-squared and odds ratios for categorical variables or *t*-test for continuous variables.[25] To account for missing variables, the data was manipulated using multiple imputation within SPSS. The valid patients needed to have a recorded age, gender, marital status, ethnicity and recorded IMD score. Imputed values for missing cases were in employment, comorbidities, baseline psychosocial health scores, waiting times, duration and staff at the programme. The imputation was run and 20 imputations were made as per guidance; the results presented are the pooled model results.[26]

Logistic regression models were built to investigate whether, in the fully imputed data, accounting for covariates, the supervised and FSM methods for mode of delivery were associated with outcomes post cardiac rehabilitation. Relevant important covariates were included in the analysis where they were evidenced in the literature or significant in preliminary analysis. Age (years), gender (male/female), number of comorbidities and employment status have been shown to influence the outcomes following a variety of different rehabilitation interventions, including cardiac rehabilitation.[27–29] Employment status was coded as employed/retired or unemployed; this is because previous research found that employed and retired states have similar effects on outcomes.[27] The duration (length) of cardiac rehabilitation was also included in the analysis along with staffing profile, total staff hours and Multi-Disciplinary Team (MDT) after being evidenced in previous research.[27,28] The staffing information was retrieved from an annual survey performed routinely by the NACR to gain centre-level information such as staff profile, hours and funding type. Because the mode of delivery was a patient-level variable, it was important to take into account the relative size and staffing profile of the centre where the patient received the cardiac rehabilitation.

The study also utilised the patient's IMD, based on where they live, as a predictor of outcome post cardiac rehabilitation. IMD score is a well evidenced

socio-economic factor influencing access to health care services and measures of patients' experience.[30] The IMD used ranked patients based on where they live; however, it is only available for England, and thus patients from Wales and Northern Ireland were excluded from the study population.[30]

Hierarchical logistic regressions were used to account for different levels of patient- and centre-level data as part of the investigation of association between mode of delivery, as an independent variable, and routine cardiac rehabilitation outcomes as the dependent variables. Statistical level for significance was $p < 0.05$. Data model checking was performed to ensure that the models were a good fit through assumptions associated with the regressions.

Results

The study included 81,626 patients categorised as 85% supervised and 15% FSM mode of delivery. Patient demographics and clinical status were, for most variables, significantly different between modes of delivery (Table 1). Patients in the FSM group were older (by one year), had shorter wait times (by 17 days) with longer duration of cardiac rehabilitation (by 17 days).

The FSM group had statistically higher proportions of female, White, unemployed, single and lower socio-demographic class ($p < 0.05$). Additionally, the FSM group had fewer overall comorbidities ($p < 0.001$); however, FSM also had more patients with a comorbid history of depression (p 0.032) and higher baseline depression measured by the HADS ($p < 0.001$).

The proportion of patients with BMI < 30 (0.9%) and blood pressure < 140/80 (1.7%) in FSM mode of delivery was larger, but there was a lower proportion of non-smokers (2.5%) and physical activity (3.6%) (Table 2).

The average BMI change was 0.3%, with FSM being 0.5% greater (Table 2). The change in smoking status was greater in the FSM group also (1.1%), although it should be noted that the FSM group started with a lower proportion of smokers at baseline. For patients who successfully quit smoking, their weight increased by, on average, 1.1 kg (±6.34) from baseline to post rehabilitation. When split by the mode of delivery, there was a slightly larger increase in the FSM group than supervised, of 0.22 kg; however, this did not reach significance ($p = 0.703$) (supervised mean 1.09 kg, SD 6.47; FSM mean 1.31 kg, SD 5.35).

Post cardiac rehabilitation blood pressure was 1.6% lower in the FSM group. The strongest association is seen in the physical activity outcome. Both modes had a large change in physical activity outcome: 25.7% and 30.8% in supervised and FSM respectively; however, after accounting for the lower starting point of 3.6% the difference in change for the FSM group is larger than the supervised group: a 5.1% difference between modes.

Figure 1 shows the flow chart for patients undergoing multiple imputation. If patients had missing data in non-mandatory variables, this was imputed. A total of 63% of the included patients had at least one of the non-mandatory variables missing. In the final model all patients appeared in at least one regression model due to having a pre and post assessment for the outcomes.

The regression model's independent variable, the mode of delivery, and its odds ratio and p value are presented for each outcome in Table 3. For two outcomes, smoking and blood pressure, the significance was larger than the threshold of 0.05; this means that there is no significant association between the type of delivery the patients received and the post cardiac rehabilitation outcome.

For the physical activity and BMI measures the p value was < 0.05 (p value 0.016 and < 0.001). This means that the association between mode of delivery and outcome post cardiac rehabilitation was statistically significant (p value < 0.001). The odds ratio indicates that there is a 13.7% increased likelihood of patients being physically active post cardiac rehabilitation in the FSM group and 11.4% for BMI < 30 (<25 for South Asian and Chinese populations).

The other variables included in the analysis, such as age, gender, IMD and MDT, were justified as many were statistically significant in their association with the four outcome measures. The model summaries show that the Nagelkerke R^2 was between 0.185 and 0.784, and the models accurately predicted between 67.5% and 97.1% of dependent variable.

Discussion

This study set out to investigate whether the mode of delivery, in routine cardiac rehabilitation practice settings, was associated with determining outcomes in four CVD risk factors: smoking, BMI, blood pressure and physical activity. Overall both modes of delivery were associated with statistically significant positive outcomes that were comparable.

The current literature on mode of delivery is a mixture of trial evidence, a robust Cochrane review,[13] and recent observational studies using routine patient populations in the UK and Europe.[14,15,31,32] The trials and previous observational studies have concluded that for psychosocial health, walking fitness, quality of life and total mortality there are no differences in association with the mode of delivery for cardiac rehabilitation.[13–15,31,32] A recent study conducted using Danish

Table 1. Patient demographics and clinical status by mode of delivery.

	Mode of delivery					
	Supervised		Facilitated self-managed			
	Mean	SD	Mean	SD	Mean difference	*p* value
Age (years)	65	11.06	66	11.67	1.309	<0.001
Duration (days)	68	37.83	83	49.38	14.88	<0.001
Wait time to start (days)	50.27	40.82	34.09	37.57	16.18	<0.001
	Count	%	Count	%	Chi^2 score	*p* value
Gender						
Male	52,533	75.6	8768	72.2	64.143	<0.001
Female	16,949	24.4	3376	27.8		
Ethnicity						
White	58,728	84.5	10,478	86.3	24.784	<0.001
Non-White	10,754	15.5	1666	13.7		
Employment status						
Employed	49,078	85.9	7936	79.1	314.799	<0.001
Unemployed	8038	14.1	2103	20.9		
Marital status						
Single	14,828	21.3	2701	22.2	4.973	0.026
Partnered	54,654	78.7	9443	77.8		
Comorbidity anxiety						
Not anxious	67,336	96.9	11,799	97.2	2.143	0.143
Anxious	2146	3.1	345	2.8		
Comorbidity depression						
Not depressed	51,422	93.7	7807	92.5	4.595	0.032
Depression	3468	6.3	630	7.5		
Comorbidities total						
No comorbidities	17,599	25.3	3876	31.9	260.972	<0.001
1–3 comorbidities	42,541	61.2	6989	57.6		
>3 comorbidities	9342	13.4	1279	10.5		
Pre-CR HADS-Anxiety						
Low anxiety (≤8)	48,312	88	7404	87.8	0.314	0.575
Mod.–high anxiety (>8)	6594	12	1031	12.2		
Pre-CR HADS-Depression						
Low depression (≤8)	67,432	97	11,742	96.7	15.952	<0.001
Mod.–high depression (>8)	2050	3	402	3.3		
Treatment						
None	6559	9.4	1698	14	342.26	<0.001
PCI	34,840	50.1	5770	47.5		
CABG	11,858	17.1	1591	13.1		
Other treatment	16,225	23.4	3085	25.4		
IMD						
Lowest quintile	7843	11.3	1170	14.6	237.059	<0.001
Second quintile	10,772	15.5	1978	16.3		
Third quintile	13,383	19.3	2653	21.8		
Fourth quintile	16,863	24.3	2756	22.7		
Fifth quintile	20,621	29.7	2987	24.6		

SD: standard deviation; CR: cardiac rehabilitation; HADS: Hospital Anxiety Depression Scale; Mod.: moderate; PCI: percutaneous coronary intervention; CABG: coronary artery bypass graft; IMD: index of multiple deprivation.

Table 2. Baseline measures and percentage change in cardiovascular disease risk factors.

	Supervised		Facilitated self-managed		Total	
	count	%	count	%	count	%
Baseline pre CR						
BMI <30[a]	36,411	67.8	6271	70.5	42,682	68.2
Not smoking	38,471	92.7	7063	90.2	45,534	92.3
Blood pressure <140/90 mmHg[b]	36,654	66.4	6152	68.1	21,392	33.3
Physical activity >150 min	20,595	36.3	2931	32.7	23,526	35.8
Change post CR						
BMI <30[a]	138	0.3	68	0.8	206	0.3
Not smoking	580	1.4	159	2.0	739	1.5
Blood pressure <140/90 mmHg[b]	1164	2.1	49	0.5	1213	1.9
Physical activity >150 min	14,588	25.7	2763	30.8	17,351	26.4

BMI: body mass index; CR: cardiac rehabilitation.
[a]BMI <25 for South Asian and Chinese populations.
[b]Blood pressure <130/80 for South Asians.

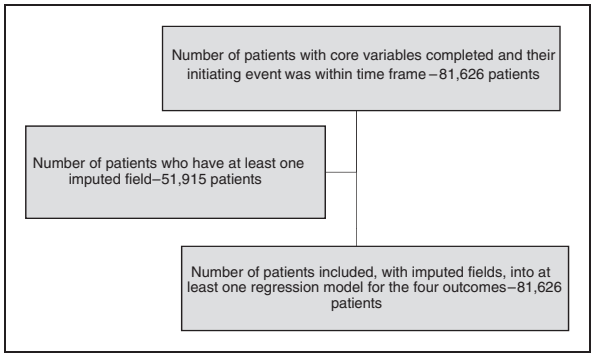

Figure 1. The study population, the missing cases within that population and the final population who were included in one of the four regression analyses.

Table 3. Results from the hierarchical logistic regression analysis; association between mode of delivery.

Effect of facilitated self-managed in comparison with supervised					
	Odds ratio	Significance	95% CI		Observations
BMI >30[a]	0.886	0.016	0.802	0.977	62,605
Physical activity >150 min	1.137	<0.001	1.081	1.197	65,693
Not smoking	1.026	0.745	0.877	1.202	49,331
Blood pressure <140/90[b]	0.982	0.492	0.931	1.035	64,198

CI: confidence interval; BMI: body mass index.
[a]BMI >30, or >25 for South Asian and Chinese populations.
[b]Blood pressure <140/90, or <130/80 for South Asians.

cardiac rehabilitation, comparing centre-based rehabilitation with home-based using tele-monitoring, found no differences in outcome, physical fitness, activity level and quality of life, after a year, and, moreover, identified that home-based is more cost effective.[32]

The results of this study are similar for smoking and blood pressure, which, after accounting for the patients' baseline score and relevant covariate measures, showed both modes had positive and comparable effects. The change is similar to that of the wider population in the 2017 NACR report, which identifies that the study population is representative of the wider cardiac rehabilitation population in the NACR and Wales and Northern Ireland.

The study, using a large clinical population recruited to cardiac rehabilitation from within routine practice, adds to the literature by showing that regardless of mode improvements are made in all outcomes, which further justifies the continued use of cardiac rehabilitation as an intervention for tackling CVD risk factors for all eligible patients. There was less change in patients from the FSM group for the blood pressure measure; however, in the baseline score these patients also started 2% higher in the target group. The changes experienced for the smoking and BMI outcomes were small; however, this is representative of routine change.[9] Additionally, there is an evidenced association between smoking cessation and weight gain; the interaction between outcomes will be addressed in future analysis.[33,34]

There was a greater likelihood of achieving physical activity status and target state for BMI in the FSM cardiac rehabilitation mode. This outcome was found to be significantly more likely in patients receiving FSM compared with supervised cardiac rehabilitation. The strength of this association was a greater likelihood of

13.7% of achieving the 150 min post cardiac rehabilitation and 11.4% for BMI in self-delivered mode than supervised (p value <0.001 and 0.016).

Within our study population, we found that for all four outcome measures, patients improved between pre and post cardiac rehabilitation measures in both modes; these changes were equivalent to the wider UK cardiac rehabilitation population.[9] This is similar to previous studies, indicating that patients improve regardless of the mode.[14,15] The most significant change was in physical activity, where the self-delivered group had a 3.1% greater proportional change post cardiac rehabilitation than the supervised group, which meant they had more patients active in the follow-up assessment.

The change in patients within the BMI target state was small for both groups (0.3–0.8%); however, the interesting result is that the supervised group started with a 2.7% lower proportion in the target state, thus a higher proportion of patients were obese at baseline. And at the post cardiac rehabilitation outcome stage the change was 0.5% larger in the FSM group. This signifies that even though the FSM had less change to make, a greater proportion did so when receiving this mode of delivery. Independent of mode of delivery, the extent of change in smoking was also significant, with more than 700 patients overall quitting smoking.

The proportion of patients in the FSM group is similar to recent observational studies and routine patients in that around 15% of the population receive this mode of delivery.[9,14] This highlights a lack of choice in the offer of cardiac rehabilitation, especially when the FSM mode is taken up more by females, older patients, those with single status and patients from lower socioeconomic areas. These sub-groups of CVD patients have been shown in routine care to not take up conventional group based cardiac rehabilitation with a mixture of patient and service factors that are inhibiting engagement and uptake to the offer of CR.[35] The BACPR core components state that CR should be delivered according to patients' needs; if some eligible patients' needs are met more by the FSM mode, then cardiac rehabilitation programmes need to include FSM as part of their offer.[6]

Limitations

The main limitation of this study is the lack of complete data entry. This study used multiple imputation to account for the large levels of missing data; however, the high number of cases having one or more missing fields in demographics or service levels variables is still an issue. The sample population used in the analysis was comparable to the original complete sample, with similar means in duration and waiting times (original duration 61 days, pooled 62 days; original waiting time 38 days, pooled 39). The categorical variables had similar proportions within groupings such as employment and MDT status (original employed 15.1%, pooled 15.2%; original MDT 83.9%, pooled 86.3%).

Increasing the data within the audit will improve the conclusions that can be made on what works in cardiac rehabilitation routine practice.

Another limitation is that the number of patients having a recorded mode of delivery and, moreover, receiving FSM rehabilitation is still very low and varied in terms of wait times and duration. Although our analysis took account of wait time and duration we were unable to take account of dose of cardiac rehabilitation, which is known to be a determinant of outcome following cardiac rehabilitation and adherence to medications.[31] This would have been calculated from the length of cardiac rehabilitation and number of sessions a patient received. However, the current recording of sessions in the NACR dataset reflects huge clinical variability and thus could not be included in the analysis. The BACPR and NACR have recently redefined sessions leading to the possibility of including sessions in future analysis.

Conclusion

This is the first observational study, using routine clinical data, to investigate whether outcomes from the four major CVD risk factor outcomes are associated with the mode of delivery of cardiac rehabilitation. The results show that patients benefit from cardiac rehabilitation through either mode of delivery. For physical activity and BMI, however, patients who received facilitated self-delivery were statistically shown to have a greater likelihood of achieving the target of 150 min per week and BMI < 30. The patients taking up the FSM option were on average older, more were female, with fewer comorbidities and a greater proportion in lower socioeconomic classes, all of which makes the FSM mode of delivery a valuable addition to the cardiac rehabilitation menu.

Author contribution

Both authors AH and PD were included in all aspects of the research from concept, design, analysis and write-up.

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