Evaluation of Cardiac Rehabilitation

Quality and Outcomes

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Abstract

Purpose: The beneficial effects of cardiac rehabilitation (CR) have been challenged in recent years and there is now a need to investigate whether current CR programmes, delivered in the context of modern cardiology, still benefit patients. Huge variability in quality of service delivery of CR in the UK and patient outcomes has consistently been reported. It is increasingly difficult to evaluate outcomes among CR programmes due to the interrelation of some measures such as smoking and body weight. The aims of this thesis are to assess the extent to which programmes meet standards for the delivery of CR and ascertain whether the variation in quality of CR delivery is determined by the CR attenders' characteristics as well as to determine predictors of quitting smoking and to ascertain whether CR is associated with helping patients quit smoking and avoid weight gain.

Methods: Observational studies using data extracted and validated from the UK's National Audit of Cardiac Rehabilitation (NACR). The quality of CR delivery was categorised into three groups: high, middle and low. Multinomial logistic regression models were used to test for predictors of high-quality delivery of CR. Binary logistic regression was performed to identify predictors of quitting smoking. Multiple linear regression models were constructed to understand the effect of quitting smoking on CR outcomes. An e-survey was administered to collect information about the smoking cessation support offered to patients attending CR.

Results: 30.6% programmes were assessed as high quality, 45.9% as middle quality, and 18.2% as low quality. Overall, 92.6% of CR programmes in the UK offer smoking cessation support for CR attenders. Quitting smoking during CR was associated with a mean increase in body weight of 0.4 kg.

Conclusion: This thesis revealed that high levels of quality delivery are achievable in the era of modern cardiology. CR programmes need to pay greater attention to recruitment of patients who are more representative of the broader CVD population than those with few comorbidities. The research highlights factors that determine smoking cessation outcomes, which could inform the delivery of CR to better help patients quit smoking. Future research is needed to investigate the extent to which patients meet outcomes targets among high-, middle- and low-quality CR programmes.

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Declaration

I declare that this thesis is a presentation of original work and I am the sole author. This work has not previously been presented for an award at this, or any other, University. All sources are acknowledged as References.

Publications arising from the thesis:

1. Doherty, P., Salman, A., Furze, G., Dalal, H.M.H.M. and Harrison, A. (2017) Does cardiac rehabilitation meet minimum standards: an observational study using UK national audit? Open Heart, 4 (e000519).
2. Salman, A. and Doherty, P. (2017) P2498 Do the demographic characteristics and baseline health state of patients vary in different cardiac rehabilitation performance programmes? European Heart Journal, 38 (suppl_1), pp. 518–519.

Chapter 1 Introduction

1.1. Title of the study

Evaluation of Cardiac Rehabilitation Quality and Outcomes

1.2. Background to cardiovascular disease

Cardiovascular disease (CVD), an umbrella term that describes all diseases of the heart and blood vessels, is the number one cause of death globally (WHO, 2016). Cardiovascular disease occurs in people of all ages and includes diseases that are diagnosed at birth or inherited through to conditions that develop later in life, such as coronary heart disease (CHD) and heart failure (HF).

Cardiovascular disease was the leading cause of noncommunicable diseases deaths (46% of all deaths from noncommunicable diseases in 2012) and was responsible for an estimated 17.5 million deaths, representing 31% of all global deaths (WHO, 2016, 2014, p.9). Cardiovascular disease is also the cause of 37% of all premature deaths (WHO, 2016).

Cardiovascular disease causes more than a quarter (26%) of all deaths in the United Kingdom (UK – that is nearly 160,000 deaths each year and an average of 435 deaths each day or one death every three minutes (BHF, 2016). About 42,000 people younger than 75 years in the UK die from CVD each year. About 7 million people are living with CVD in the UK: 3.5 million men and 3.5 million women (BHF, 2016). The ageing and growing population and improved survival rates from cardiovascular events could see these numbers rise still further. In 1961, more than half of all deaths in the UK were attributed to CVD (320,000 CVD deaths) (BHF, 2016). Since then, the death rate from

CVD in the UK has declined by more than three quarters. Death rates have fallen faster than the absolute number of deaths, because people in the UK are now living longer.

When premature death and disability are considered, CVD is estimated to cost the UK economy more than £15 billion each year (BHF, 2016; Cebr, 2014). Healthcare costs relating to CVD are estimated to be up to £11 billion each year (BHF, 2016; Cebr, 2014).

Cardiovascular disease is also a leading contributor to health inequalities; reducing excess deaths from CHD in the most deprived fifth of areas would have the greatest impact on the life expectancy gap in England (Public Health England Epidemiology and Surveillance team, 2016). Within England as a whole during 2012–14, male life expectancy at birth was 7.6 years higher in the least deprived fifth of areas than in the most deprived fifth (Public Health England Epidemiology and Surveillance team, 2016). For females, this gap was 5.9 years. More than a year of life would be gained if men in the most deprived areas had the same mortality from CHD as men in the least deprived areas. The segment tool shows considerable variation in the causes of death that drive the life expectancy gap, both within local authorities and between local authorities and England; however, excess deaths from CVD, cancer and respiratory diseases tend to contribute the most in the majority of areas (Public Health England Epidemiology and Surveillance team, 2016).

Cardiovascular disease is still the most common cause of death across Europe as a whole – accounting for 45% of all deaths, but rates have been falling by as much as 25–50% over the past 10 years (Townsend et al., 2015). A major review of European trends in CVD deaths published in the *European Heart Journal* found that cancer deaths in several European countries, including the UK, overtook CVD deaths in men in 2014 (Townsend et al., 2015). According to the World Health Organization (WHO), about 40% of all cancer deaths can be prevented by following a healthy lifestyle, with the remainder caused by genetics and other factors (WHO, 2007). While following a healthy lifestyle

may prevent more than 80% of cases of CHD (Chiuve et al., 2006; Stampfer et al., 2000), 80% of sudden cardiac deaths (Chiuve et al., 2011) and 72% of premature deaths (van Dam et al., 2008) are related to CVD. The vast improvements in the prevention and treatment of CVD seen in the UK over the past 50 years thus have had a much bigger impact than prevention and treatment of cancer, and this is reflected in the reduced number of cardiovascular deaths.

The reductions in cardiovascular mortality and morbidity are hypothesised to be due to advances in treatment or therapy in patients with CVD. These reductions result has been enhanced by efficacious, non- pharmacological treatments such as cardiac rehabilitation (CR).

Cardiac rehabilitation is a clinically effective and cost-effective multifaceted secondary prevention programme that aims to improve outcomes for people with CVD (Shields et al., 2018; Sumner, Harrison and Doherty, 2017; Anderson et al., 2016; Rauch et al., 2016). It includes components of health education, advice on cardiovascular risk reduction and physical activity, as well as stress management to prevent further deterioration of the condition. A recent systematic review reported that more than 60 randomised controlled trials (RCTs) showed that exercise-based CR reduces cardiovascular mortality and hospital admissions and improves quality of life among patients with CVD (Anderson et al., 2016).

1.3. Cardiac rehabilitation

Cardiac rehabilitation programmes are recognised to be integral to comprehensive intervention offered to patients with CVD and have been given a Class I recommendation by international guidelines from organisations such as the American Heart Association (AHA), American College of Cardiology (ACC), European Society of Cardiology (ESC) and British Association for Cardiovascular Prevention and Rehabilitation (BACPR)

(BACPR, 2017; Piepoli et al., 2016; Balady et al., 2011; Smith et al., 2011; Wenger et al., 1995). These bodies have consistently identified exercise therapy as a central element of a comprehensive approach. Evidence that CR reduces mortality, morbidity and unplanned hospital admissions in addition to improving exercise capacity, quality of life and psychological wellbeing is increasing (Sumner, Harrison and Doherty, 2017; Anderson et al., 2016; Rauch et al., 2016).

Nearly two decades ago, the 1995 clinical practice guideline on CR from the United States (U.S.) Department of Health and Human Services, Agency for Healthcare Policy and Research, and National Heart, Lung, and Blood Institute characterised CR as the provision of comprehensive, long-term programmes involving medical evaluation, prescribed exercise, modification of cardiovascular risk factors, education, and counselling (Wenger et al., 1995). These programmes are designed to limit the physiological and psychological effects of cardiac illness, reduce the risk for sudden death or reinfarction, control cardiac symptoms, stabilise or reverse the atherosclerotic process, and enhance the psychosocial and vocational status of some patients (Wenger et al., 1995). In spite of the fact that exercise is a core component of CR, current guidelines reliably recommend that ‘comprehensive rehabilitation’ programmes ought to include other components to enhance cardiovascular risk reduction, cultivate healthy behaviours and compliance with these behaviours, decrease disability, and promote an active lifestyle (Balady et al., 2007).

The National Institute for Health and Care Excellence (NICE), Department of Health, BACPR, AHA and European guidelines agree that the following patients benefit from CR (BACPR, 2017; Piepoli et al., 2016; JBS3, 2014; NICE, 2013a, 2013c, 2010c, 2010d, Balady et al., 2011, 2007; Leon et al., 2005):

- acute coronary syndrome – including ST elevation myocardial infarction, non-ST elevation myocardial infarction, and unstable angina – and all patients undergoing reperfusion (such as coronary artery bypass surgery (CABG), percutaneous coronary intervention (PCI))
- newly diagnosed chronic HF and chronic HF with a step change in clinical presentation
- heart transplant or ventricular assist device
- surgery for implantation of intracardiac defibrillator or cardiac resynchronisation therapy for reasons other than acute coronary syndrome and HF
- heart valve replacements
- confirmed diagnosis of exertional angina.

Historically, CR in the UK, US, and most European countries has been delivered to groups of patients in healthcare or community centres (Mampuya, 2012; Bethell, Lewin and Dalal, 2009). The Department of Health (NICE, 2013a) refers to a six-stage pathway that begins with diagnosis and is followed by an assessment, referral, clinical assessment, and core delivery of CR before progressing to long-term management (Figure 1.1). The UK has led the world in the uptake of CR, with an average of 51% of patients accessing CR (NACR, 2017).

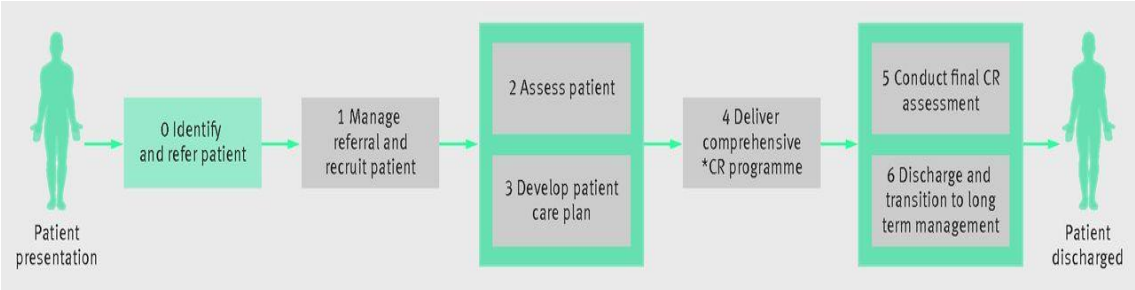


Figure 1.1 Department of Health's commissioning guide six-stage patient pathway of care. Figure adapted courtesy of BACPR (2012)

Formal CR programmes vary in their prescription of intensity and duration of exercise. The European guide for patients with established CVD provides a full review of the impact of the mode and dose of exercise-based CR (Vanhees et al., 2012). The European Association of Cardiovascular Prevention and Rehabilitation has formulated recommendations regarding frequency, intensity, time (duration), type (mode) and volume (dose: intensity × duration) of exercise, along with safety aspects during exercise in patients with CVD (Vanhees et al., 2012). Exercise training programmes for patients with CHD or HF need to be tailored to the individual's exercise capacity and risk profile, with the aim of reaching and maintaining that individual's highest possible fitness level and performing endurance exercise training 30–60 minutes daily for 3–5 days per week in combination with resistance training 2–3 times a week. In the UK, formal CR is predominantly provided to supervised groups in outpatient hospital clinics or community centres, starting 2–4 weeks after PCI or myocardial infarction (MI) and usually 4–6 weeks after CABG (Bethell, Lewin and Dalal, 2009). Most CR programmes comprise weekly attendance at group sessions for an average of 63 days or 9 weeks (NACR, 2017). Centre-based sessions include graduated exercise training, education (covering coronary risk factors and diet), common cardiac misconceptions, preventative medications, and stress management (Bethell, Lewin and Dalal, 2009). Ideally, patients ought to be given information about the cardiac event and lifestyle advice, including the importance of smoking cessation, a healthy diet, and physical activity that encourages progressive mobilisation (BACPR, 2017). Good communication between secondary and primary care after discharge can improve uptake of CR and optimise secondary prevention (Dalal and Evans, 2003).

In the US and Europe, CR programmes tend to be more intensive than those in the UK and are delivered from outpatient departments over 3–6 months (Menezes et al., 2014; Mampuya, 2012). Some European countries offer residential programmes lasting 3–4

weeks. The focus is mainly on ‘monitored exercise and aggressive risk factor reduction’ in medically supervised sessions.

The evidence-based service standards for CR delivery include centre-based programmes and home-based programmes for those who have difficulty accessing centre-based CR programmes (BACPR, 2017; NICE, 2013a; Wingham et al., 2006; Dalal and Evans, 2003). Home-based programmes administered by a multidisciplinary team and supported by community services (such as smoking cessation) are equally as effective as centre-based programmes (Taylor et al., 2015). The most widely used home-based programme in the UK is the Heart Manual (Lewin et al., 1992) – a six-week intervention that uses written material and a relaxation CD and is delivered by a trained healthcare facilitator who makes home visits and provides telephone support – which has been appeared to be just as effective as centre-based programmes (Jolly et al., 2009; Dalal et al., 2007).

1.4. British Association for Cardiovascular Prevention and Rehabilitation

The British Association for Cardiovascular Prevention and Rehabilitation (BACPR) is an affiliated group of the British Cardiovascular Society. In 2017, the BACPR defined, recommended six standards that promote high quality in the provision of CR programmes and aim to ensure that all service providers, health professionals and service users, together with service commissioners, where relevant, understand the requirements for providing CR that is both clinically and cost effective and that can achieve sustainable health outcomes for patients (BACPR, 2017). These six standards are:

1. delivery of six core components by a qualified and competent multidisciplinary team, led by a clinical coordinator
2. prompt identification, referral and recruitment of eligible patient populations
3. early initial assessment of individual patient needs, which informs agreed personalised goals that are reviewed regularly
4. early provision of a structured cardiovascular prevention and rehabilitation programme, with a defined pathway of care, which meets the individual's goals and is aligned with patient preference and choice
5. a final assessment of individual patient needs and demonstration of sustainable health outcomes upon programme completion
6. registration and submission of data to NACR and participation in the National Certification Programme for Cardiovascular Rehabilitation (NCP_CR).

To ensure delivery of a quality-assured, high-standard CR programme, BACPR also recommends that CR programmes should include six components that have health behaviour change and education at their core (Figure 1.2) (BACPR, 2017).

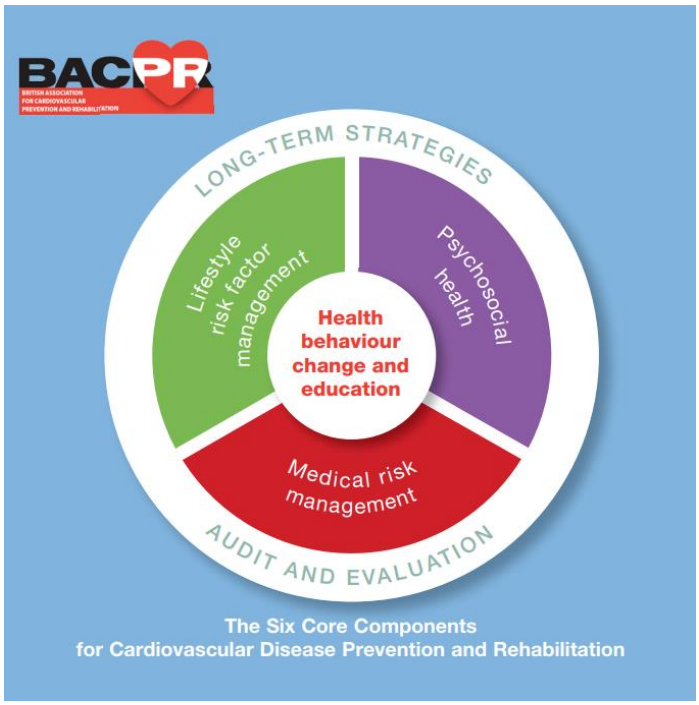


Figure 1.2 Core components of cardiac rehabilitation (BACPR, 2017)

Programmes are should ideally be delivered by an integrated multidisciplinary team led by an qualified clinician with a special interest in CR (BACPR standard 1) (BACPR, 2017).

Delivery of the core components requires expertise from a range of different professionals. The team may include:

- cardiologist, community cardiologist, physician, or general practitioner with a special interest in cardiovascular prevention and rehabilitation
- nurse specialist
- physiotherapist
- dietitian
- practitioner psychologist
- exercise specialist
- occupational therapist
- pharmacist.

1.5. National Audit of Cardiac Rehabilitation

The National Audit of Cardiac Rehabilitation (NACR) based at the University of York and funded by the British Heart Foundation monitors and assesses the quality of CR delivery annually, with findings published in an annual report (NACR, 2017). The NACR collects programme- and patient-level data from most CR programmes across the UK (except Scotland). To ensure data security and quality, NACR data are hosted by NHS Digital (NACR, 2017).

Most CR programmes in the UK (74%) provide data to the NACR via patient-level data submitted to the online database or via an annual survey of all CR programmes in the UK (NACR, 2017). The NACR highlights the gap in respect of previous BACPR standards and delivery, which demonstrates that BACPR service standards are clearly

aspirational for most services in the UK (BACPR, 2017; NACR, 2017); although there are examples of excellent practice in the UK, many CR programmes do not meet the BACPR's standards. In addition, it is difficult for service managers, patients and commissioners to assess how a particular CR programme meets standards of service delivery. For example, BACPR's standard 1 recommends that CR should be delivered by a multidisciplinary team drawn from any of 10 or more professions, but the minimum requirement to demonstrate this is not clear.

1.6. UK National Certification Programme for Cardiac Rehabilitation

Concerns about the quality of delivery of some CR programmes have led to the collaboration of the BACPR and NACR in developing a UK National Certification Programme for CR (NCP_CR) that is mainly based on assessment of quality-assured patient-level NACR data and certification of whether CR programmes meet service standards for CR delivery (Furze, Doherty and Grant-Pearce, 2016).

Furze, Doherty and Grant-Pearce undertook a three-stage process that involved: (1) capturing the views of commissioners, service staff and patients on whether a certification programme was needed and what would be included in the process; (2) developing standards for certification; and (3) piloting the certification processes (Furze, Doherty and Grant-Pearce, 2016). The standards were developed by a group of academic and clinical experts in CR based on the BACPR standards (BACPR, 2017) – which are uprated each year after new NACR data are published – and, where possible, on median data for the UK from the NACR annual report (Furze, Doherty and Grant-Pearce, 2016; NACR, 2015). Following a successful pilot, the NCP_CR was launched in the UK in July 2015, enabling CR programmes to apply voluntarily for assessment against the standards at a small administration cost for all CR programmes that submit

data to NACR. The BACPR webpages (education@bacpr.com) show how programmes can apply. In a two-year period after the NCP_CR started, fewer than 40 programmes applied for certification through the formal BACPR panel review (BACPR/NACR, 2018b). At this rate, it would take 15 years to certify all programmes. In May 2018, the NCP_CR's steering group decided to run certification annually as part of the NACR report (BACPR/NACR, 2018a). Information on the extent to which programmes achieve or come close to being certified will be shared with each programme, as part of a quality assurance check, prior to the publication of the report. This new approach to certification allows providers and commissioners of CR services to obtain an up-to-date assessment of the quality of CR delivery.

1.7. Inequity in delivery of cardiac rehabilitation

Although the UK has a track record of driving excellence in CR, service inequality remains one of the challenges of contemporary healthcare (Furze, Doherty and Grant-Pearce, 2016). Despite the strong evidence base for CR and existing standards for service delivery, it has become apparent from NACR reports in recent years that CR is not delivered equitably across the UK (NACR, 2017). Although there are examples of excellent practice in the UK, NACR reports have shown that many CR programmes do not meet the BACPR standards for CR delivery and also clearly find the BACPR standards to be aspirational (Furze, Doherty and Grant-Pearce, 2016). The NACR reports provide many examples of suboptimal delivery, which has been the topic of much debate (Lewin and Doherty, 2013; West and Jones, 2013; West, Jones and Henderson, 2012). For instance, NICE and the BACPR recommend that CR should start within 28 days after MI and/or PCI (BACPR, 2017; NICE, 2013c), yet the median time for starting CR across the UK is 28 days, varying from a swift six days to a greatly delayed 78 days (NACR, 2017). Concerns have also been raised about other aspects of CR delivery in the UK that do not meet the standards recommended by BACPR, including omissions in

undertaking pre- and post-CR assessment and reduction of length and frequency of CR programmes, resulting in ‘too small a dose’ of CR being delivered (NACR, 2017).

Figure 1.3 shows that waiting times vary substantially among CR programmes within each country covered by the NACR audit (permission to use figures form the NACR authors is shown in Appendix 1) (NACR, 2017). Published research using NACR data has shown that timely CR is associated with greater patient benefit in terms of physical and psychosocial outcomes compared with CR offered late (Sumner, Böhnke and Doherty, 2018; Fell, Dale and Doherty, 2016). Despite emerging research that showed patients following CABG can safely start CR earlier than existing guidelines recommend (Eder et al., 2010), they are waiting 50 days (national average) before starting CR (NACR, 2015).

Figure 1.3 National Audit of Cardiac Rehabilitation (NACR) 2017: time from referral to start of cardiac rehabilitation by programme and country. Figure reproduced with permission of NACR (2017) (see Appendix 1)

In the 2017 NACR, 83% of patients who started CR had a pre-CR assessment and 62% had a post-CR assessment, which means that 38% of patients cannot be assessed for improved outcomes and will not have had quantifiable notification of their progress, which is important as part of successful health behaviour change (Table 1.1) (NACR, 2017).

Table 1.1 National Audit of Cardiac Rehabilitation (NACR) 2017: percentage of patients who started cardiac rehabilitation (CR) and had pre- and post-CR assessments. Table reproduced with permission of NACR (2017) (see Appendix 1)

COUNTRY	HEALTH REGION	STARTING REHABILITATION (N)	% WITH PRE (ASSESSMENT 1)	% WITH POST (ASSESSMENT 2)
England	C & M	2,845	83	62
	EM	3,733	86	64
	E o E	4,067	83	65
	GM, L & SC	5,872	73	56
	L	4,970	90	62
	SEC	4,304	86	65
	SW	4,303	93	60
	TV	1,732	80	69
	W	2,366	89	71
	WM	2,983	63	53
	Y & TH	3,407	90	73
Total		**40,582**	**83**	**63**
Northern Ireland	BHSCT	573	98	62
	NHSCT	593	90	61
	SEHSCT	610	88	67
	SHSCT	327	83	39
	WHSCT	114	74	68
Total		**2,217**	**90**	**60**
Wales	ABM	684	94	81
	AB	860	95	64
	BC	1,867	60	38
	C & V	299	92	73
	CT	421	78	54
	HD	363	82	52
Total		**4,494**	**78**	**54**
Other	Other	107	99	89
TOTAL		**47,520**	**83**	**62**

England N=40,582, Northern Ireland N=2,217, Wales N=4,494, Total N=47,520 (includes Other)
NE has been removed due to insufficient NACR data

The most recent Cochrane review of the effectiveness of CR in 63 clinical trials found that the median duration of CR was six (range 1–48) months (Anderson et al., 2016). In routine clinical practice, where funding is more likely to be a determinant of the duration of CR, the duration is three months in the USA, five months in Canada, and a recommended minimum of 12 weeks across Europe. In all of these countries, the preferred frequency is 2–3 formal sessions per week (Vanhees et al., 2012; Suaya et al., 2007). One of the principal components of effective CR is successful behaviour change

as applied to exercise training, physical activity, risk factor management, and psychosocial wellbeing interventions, and this requires sufficient time to achieve desired lifestyle changes. However, the median duration of CR in the UK according to the 2017 NACR is 63 days (nine weeks), and Figure 1.4 shows that the duration of CR vary substantially among CR programmes within each country that contributes to the audit.

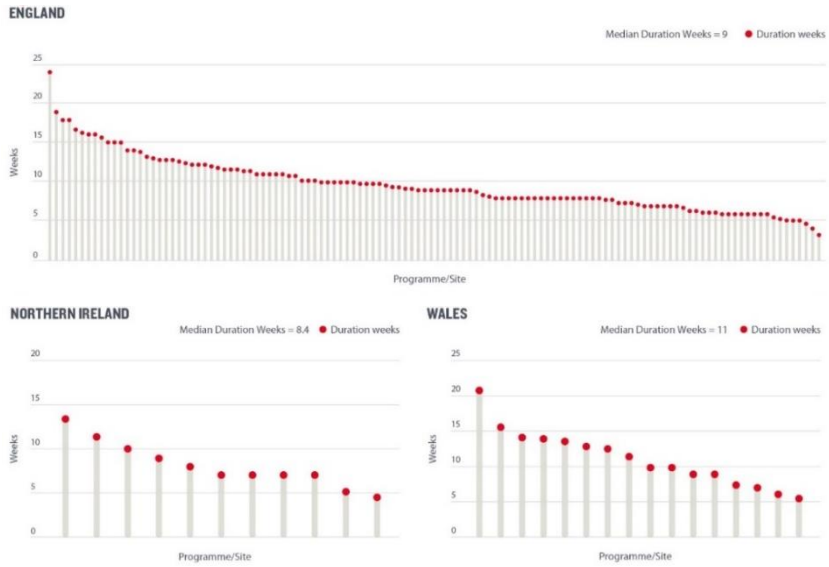


Figure 1.4 National Audit of Cardiac Rehabilitation (NACR) 2017 report: duration of cardiac rehabilitation. Figure reproduced with permission of NACR (2017) (see Appendix 1)

1.8. Inequity in cardiac rehabilitation outcomes

It is increasingly difficult to evaluate outcomes among CR programmes due to the complexity of reporting the extent of change, as the scale in terms of clinical presentation and potential for change at the point patients start CR is very different from programme to programme. For example, the average proportion of patients who started CR as non-smokers among the 24 health regions of the UK was 93.6% (range 85.9% to 98.8%) (NACR, 2017), but the profile of smoking status when patients start CR differs greatly among programmes (Table 1.2). In 25 CR programmes, 100% of patients were not smoking before CR compared with about 25% of patients in one other programme (NACR, 2017). These differences make comparisons of change at a programme level

difficult to judge, as the potential for change is non-existent in programmes with initially low levels of smoking and much greater in programmes with initially high levels of smoking.

Table 1.2 National Audit of Cardiac Rehabilitation (NACR) 2017: percentage of non-smokers starting cardiac rehabilitation (CR). Table reproduced with permission of NACR (2017) (see Appendix 1)

PERCENTAGE OF NON-SMOKERS

COUNTRY	HEALTH REGION	PRE %	POST %	POINT CHANGE %
England	C & M	93.6	94.5	0.8
	EM	93.5	93.8	0.4
	E o E	95.9	96.0	0.1
	GM, L & SC	94.9	95.6	0.7
	L	93.7	95.2	1.5
	SEC	95.8	96.3	0.6
	SW	94.6	96.6	2.0
	TV	96.0	95.5	-0.5
	W	94.5	96.4	1.9
	WM	91.6	96.0	4.4
	Y & TH	85.9	90.7	4.8
Total		**93.5**	**95.0**	**1.5**
Northern Ireland	BHSCT	92.3	92.6	0.2
	NHSCT	88.1	97.2	9.1
	SEHSCT	94.7	94.7	0.0
	SHSCT	98.8	100.0	1.2
	WHSCT	87.5	100.0	12.5
Total		**92.3**	**95.2**	**2.9**
Wales	ABM	96.2	95.3	-0.9
	AB	94.0	94.0	0.0
	BC	96.1	94.8	-1.3
	C & V	96.8	96.8	0.0
	CT	88.1	88.1	0.0
	HD	95.8	97.9	2.1
Total		**95.4**	**95.2**	**-0.2**
Other	Other	97.7	94.3	-3.4
TOTAL		**93.6**	**95.0**	**1.4**

Another challenge when evaluating patient outcomes is that some measures are inter-related, such as smoking and obesity (Tian et al., 2015; Aubin et al., 2012). Thus, although smoking cessation results in considerable improvements in health, it is often accompanied by weight gain, with patients trying to quit smoking more likely to put on weight in the first three months to a year after quitting (Tian et al., 2015; Aubin et al., 2012). This substantial effect may mask the success of some weight-loss programmes. With such an interaction, it would be wrong to assess the success of weight management and smoking cessation associated with CR programmes at a named local level without taking this relationship into account. Moreover, numerous studies have not measured

changes in physical activity to examine whether that influenced weight gain after quitting smoking, and a level of positive association also exists between obesity and anxiety and depression.

1.9. Summary of the justification for this research

Numerous clinical trials and systematic reviews over the past 20 years have shown that CR is effective (Sumner, Harrison and Doherty, 2017; Anderson et al., 2016; Rauch et al., 2016; Dalal, Doherty and Taylor, 2015). For example, an updated Cochrane review in 2016 reported that CR reduces cardiovascular mortality and hospital admissions in addition to improving health-related quality of life (Anderson et al., 2016). On the other hand, the conclusion of 'Rehabilitation After Myocardial Infarction Trial (RAMIT)' – the largest UK-based RCT – was that comprehensive CR in the modern era of medical management does not reduce mortality or morbidity and has no beneficial effect on psychosocial wellbeing or lifestyle (West, Jones and Henderson, 2012). The 2016 Cochrane review by Anderson et al. included RAMIT alongside 62 other trials, but its inclusion did not alter the overall benefit in cardiovascular mortality (Anderson et al., 2016) despite the negative results of RAMIT clearly differing from those of the latest Cochrane reviews (Anderson et al., 2016; Heran et al., 2011). Anderson et al.'s Cochrane review revealed a neutral effect, concluding that some CR programmes may not be delivering CR in an effective way in routine clinical practice (Anderson et al., 2016). The negative findings of RAMIT have also led to scepticism about the delivery of CR programmes in the UK (West and Jones, 2013; Wood, 2012). Furthermore, a clinical review published in the *British Medical Journal* highlighted CR as highly effective but warned that not all programmes are working to the recommended standards (Dalal, Doherty and Taylor, 2015). Continued debate in the research literature suggests that routine clinical practice might be suboptimal and may not be resulting in expected outcomes (Doherty and Lewin, 2012; West, Jones and Henderson, 2012). The regular

NACR reports show huge variability in the quality of CR service delivery and patient outcomes in routine clinical practice in the UK (NACR, 2017, 2016, 2015), with CR (1) being delivered later than recommended, (2) not underpinned by pre- and post-CR assessment, and (3) shorter in duration than evidence suggests is needed (BACPR, 2017; NACR, 2017, 2016; Piepoli et al., 2016; NACR, 2015; NICE, 2013c; Vanhees et al., 2012). It therefore is important to assess the extent to which programmes meet national standards for the delivery of CR. The role played by patient characteristics in determining whether delivery of CR services is high, medium, or low quality remains unclear (Doherty et al., 2017). It therefore is important to assess whether patients who attend CR programmes are the same across the three categories of delivery quality, which is the aim of the first study reported in this thesis.

Smoking and body weight are closely related, and this link poses significant challenges for researchers investigating the effect of interventions in smokers. Most patients who quit smoking put on weight (Tian et al., 2015; Aubin et al., 2012), and many smokers report concern about this and say it may put them off trying to quit (Bush et al., 2016; Farley et al., 2012; Filozof, Fernández Pinilla and Fernández-Cruz, 2004). Several exercises programmes aimed at limiting post-smoking cessation weight gain have been tested and suggest that exercise as an intervention reduced post-cessation weight gain significantly in the long term but not in the short term (Farley et al., 2012). However, CR has not been evaluated to control weight gain after smoking cessation, and little is known about the predictors of quitting smoking in CR, with limited research to date on the determinants of likelihood of quitting smoking among CR participants. A thorough investigation is required to identify the predictors of quitting smoking in CR, specifically influencing factors that could inform tailored interventions to increase quitting smoking. As little is known about how routinely CR programmes support smoking cessation, an investigation of smoking cessation support services provided in CR to help patients quit

smoking could encourage knowledge exchange and discussion, which is the aim of the second study reported in this thesis.

This thesis is based on an observational research design as an RCT design was not appropriate for this thesis. Observational designs are used to measure the effectiveness of an intervention in real-world settings at the population level (Anglemyer, Horvath and Bero, 2014; Centre for Reviews and Dissemination, 2009). Observational studies play a vital role in building clinical evidence, identifying best practices, and understanding variations of delivery of services (Anglemyer, Horvath and Bero, 2014; Carlson and Morrison, 2009). The selective process of RCTs in terms of choosing participants may make the study population less representative of the whole population, which raises questions about the generalisability of its findings (Noordzij et al., 2009). The age of patients attending CR in the NACR ranges from 18 to 108 years – a much broader population than studied in clinical trials of CR (NACR, 2017). Anderson et al.'s Cochrane review of the effectiveness of CR is based on patients with a mean age of 56 (range 49 to 71) years, whereas the patient population seen in routine practice, as captured by the NACR, has an average age of 67 (18 to 108) years (NACR, 2017; Anderson et al., 2016). The number of patients older than 75 years in the NACR was 12,248, which once again reiterates the difference from the research population in clinical trials, where virtually no patients older than 71 years were recruited. The percentage of patients completing CR is 77% (NACR, 2017), which is equivalent to the completion rates seen in well-resourced clinical trials. The populations studied by reviews and clinical trials were predominantly male, middle aged (mean age 56 years) and low risk (most studies excluded patients who had comorbidities or HF). The NACR is representative of the eligible population, suggesting that findings from the NACR annual report are more likely to reflect the reality of routine clinical practice. In addition, the amount of time, cost, restrictive recruitment of population and inadequate statistical power of RCTs mean that RCTs may lead to invalid conclusions (Hannan, 2008). However, observational studies that use large databases,

through the use of larger and more varied populations with comorbidities and longer follow-up periods, can complement findings from RCTs by assessing the effectiveness of interventions in routine clinical services (Silverman, 2009). However, it should be noted that the selection bias is the most serious shortcoming of observational designs due to the absence of randomisation, which is exacerbated when the observational data derive from an administrative database rather than a clinical database (Hannan, 2008).

The research reported in this thesis is based on a research design that incorporated two main observational studies and is based on the following gaps in the research literature that have led to the evaluation of CR quality and outcomes is listed below:

- Results differ between RAMIT and the latest Cochrane reviews (Sumner, Harrison and Doherty, 2017; Anderson et al., 2016; Rauch et al., 2016; West, Jones and Henderson, 2012).
- CR is highly effective but not all programmes are working to the standards
- Routine clinical practice might be suboptimal and may not be resulting in expected outcomes
- Annual NACR reports consistently show huge variability in quality of CR service delivery and patient outcomes in the UK
- Little is known about CR attenders' characteristics and the role of these characteristics in determining the quality of CR programmes in routine clinical practice
- The role played by patient characteristics in classification of CR delivery quality as high and low remains unclear
- Interrelation of smoking and body weight present a challenge in reporting the extent of patient outcomes per measure, as most patients who try to quit smoking will gain weight
- Little is known about whether weight gain associated with smoking cessation in patients attending CR

- Little is known about the predictors of quitting smoking in CR
- Little is known about actual smoking cessation services provided by CR programmes.

1.10. Research aims for the thesis

The approach of this thesis, structured by the scientific paradigm, is to critically explore the literature regarding existing practices to establish scientific rigor in proclaiming the evaluation of CR quality and outcomes. The aims are:

- to critically review the existing literature to better evaluate CR quality and outcomes and further shape research methods
- to assess the extent to which programmes meet national standards for the delivery of CR by evaluating quality of CR delivery against national averages in service delivery in the UK according to the NCP_CR
- to assess whether the quality of CR delivery and any variability are associated with the participating patients' characteristics, while also addressing whether these differences are associated with better CR delivery quality
- to investigate and determine sociodemographic and clinical factors associated with the likelihood of quitting smoking among CR attenders
- to ascertain whether weight gain is associated with smoking cessation in patients attending CR and whether CR, as delivered in routine practice, is associated with helping patients quit smoking and avoid weight gain
- to evaluate the smoking cessation support offered to patients attending CR using an e-survey.

1.11. Structure of the thesis

This thesis is organised into six chapters that provide background information according to the literature, the methods used for the study, the results from the study, and a discussion of the findings.

Following this Introduction, which described what is known about CR, gaps in knowledge, why the research reported in this thesis is needed and its aims, Chapter 2 offers a review of literature that more deeply explores the current evidence base for CR, offers criticism of this evidence, and collates the clinical guidance, quality assurance of services, and high-quality indicators for CR and related provision of CR.

Chapter 3 covers the main methods relating to the methods underlying the NACR, data access, verification, validation, and analytical approaches used in planned observational studies.

Chapter 4 investigates the extent to which the delivery of CR programmes in the UK meets national standards as part of the NCP_CR, as well as evaluating the role of patient characteristics in the quality of CR delivery.

Chapter 5 focuses on sociodemographic and clinical factors associated with the likelihood of quitting smoking among CR attenders and investigates whether CR is an effective strategy to help patients who are quitting smoking to avoid excess weight gain. In addition, this chapter describes a survey that investigated how many CR programmes provide smoking cessation services.

Finally, Chapter 6 provides an overall conclusion for the research, including recommendations for future studies and the potential impact of this research.

Chapter 2 Literature review

2.1 Introduction

Cardiac rehabilitation (CR) is a complex intervention that is an integral part of the modern standard of care offered to patients diagnosed with cardiovascular disease (CVD). Over the past four decades, the focus has shifted from an emphasis on exercise therapy to comprehensive secondary prevention strategies to manage risk factors, nutritional, psychological, behavioural and social factors that can affect patients' CVD outcomes (Anderson et al., 2016; Dalal, Doherty and Taylor, 2015; Sagar et al., 2015). Cardiac rehabilitation has been proved to be an effective tool with an important role in the overall clinical management and care of patients with CVD. Over the past 40 years, research in CR has demonstrated tremendous benefits from optimal use of CR in patients with various cardiac pathologies, including ischaemic heart disease, heart failure (HF) and post-heart surgery. The modern-day benefits of CR are recognised to include reductions in cardiac morbidity and mortality, relief of symptoms, reduction in smoking, improved exercise tolerance, risk-factor modification and improvements in overall psychosocial health (Sumner, Harrison and Doherty, 2017; Anderson et al., 2016; Rauch et al., 2016; Sagar et al., 2015).

Although the importance of primary prevention measures aimed at delaying or preventing the onset of CVD is obvious and cannot be emphasised enough, CR is mainly involved with secondary prevention. This relies on early detection of the disease process and its impact on health followed by application of interventions – including education, counselling and behavioural strategies to promote lifestyle change and modify risk factors – to prevent progression of disease and manage psychosocial health, particularly depression, which many studies have shown impacts on outcomes (Hare et al., 2014) Clinical trials have proved that strategies for the detection and modification of risk factors

can slow, stabilise or even modestly reverse the progression of atherosclerosis and reduce cardiovascular events (Mampuya, 2012). Current guidelines from international cardiovascular societies consider CR as useful and effective for patients diagnosed with CVD based on Class I evidence (Anderson et al., 2016; Piepoli et al., 2016; Sagar et al., 2015; NICE, 2013c; Smith et al., 2011).

On the other hand, the 'Rehabilitation After Myocardial Infarction Trial' (RAMIT) – the latest and largest UK-based randomised controlled trial (RCT) of comprehensive CR in the modern era of medical management – showed that CR is not effective (West, Jones and Henderson, 2012). The negative results of RAMIT seem to differ from those of the latest reviews (Sumner, Harrison and Doherty, 2017; Rauch et al., 2016; Sagar et al., 2015), and the negative findings of RAMIT have also led to scepticism about the delivery of UK-based CR programmes (West and Jones, 2013; Wood, 2012). Moreover, a recent clinical review of CR published in the British Medical Journal highlights that CR is highly effective but warns that not all programmes are working to recommended standards (Dalal, Doherty and Taylor, 2015). Continued debate in the research literature suggests that routine clinical practice might be suboptimal and may not be producing the expected outcomes (Rauch et al., 2016; Doherty and Lewin, 2012; West, Jones and Henderson, 2012). Data from routine clinical practice assessed through the National Audit of Cardiac Rehabilitation (NACR) (NACR 2017) showed that CR is: (1) being delivered later than recommended, (2) not underpinned by pre- and post-assessment, and (3) shorter in duration than the evidence recommends (NACR, 2017; Anderson et al., 2016; Piepoli et al., 2016; NICE, 2013c; Vanhees et al., 2012).

2.2 Rationale and methods of review

This chapter provides an overall review of the current evidence for CR, including a critical review of this evidence and an evaluation of clinical guidance and quality assurance of services.

Given the emphasis on developments within the past 20 years, usual care cardiology has improved massively, including the use of interventional therapies, surgery and medications, and the fact that stents and statins have become part of routine practice since 1995 has had a large impact on the quality of care delivered to patients participating in modern CR (Rauch et al., 2016; Montalescot et al., 2004; Johannesson et al., 1997). On this basis, older studies evaluating the effect of CR are no longer suitable for estimating the effectiveness of CR, as it was easier for trials 40 years ago to show that CR was effective when usual care was so poor compared with the post-1995 stents and statins era, and there is therefore a distortion of the perceived benefits when based on older evidence (Rauch et al., 2016). The NSF for CHD was published in the UK, detailing modern standards of care, including CR services (Department of Health, 2000). The AHA published position statements on CR programmes and CR core components in 2000 (Balady et al., 2000), a position paper by the European Society of Cardiology in 2003 provided recommendations on the design and development of CR programmes (Giannuzzi et al., 2003), and in 2001 Cochrane published the first review to define exercise-based CR (Jolliffe et al., 2001).

Much of the evidence was produced before the era of modern cardiological treatments and therefore may not be relevant. In line with the establishment of international modern standards of care in CR, the period for this literature review was restricted to publications from 1995 to present day. The review was carried out using the following bibliographic databases: PubMed, Embase, Medline, Cochrane Central Register of Controlled Trials, Ovid databases, Science Citation Index (Web of Science), Science Direct and Wiley

resources. The search period for articles was between 1995 and 2017 (including only studies that recruited patients in 1995 or later), and the review was carried out between 2015 and 2017. Interlibrary loans were used to acquire unavailable full texts. The search sought key study techniques such as systematic reviews, meta-analyses, randomised controlled trials (RCTs), observational studies, cross-sectional studies, and cohort studies. Keywords used for this review included cardiovascular diseases (CVD), coronary heart disease (CHD), cardiac rehabilitation (CR), exercise rehabilitation, cardiac prevention, secondary prevention, prevention, cardiovascular risk factor, smoking, predictors and weight gain.

Critical appraisal is a systematic essential evaluation of research of different types of medical evidence, which aims to identify gaps in the literature reviewed in order to provide research evidence (CAT, 2017). In addition, this approach gives information on the quality of research evidence. It aims to identify flaws in methods used in studies reported in the literature and provide the opportunity to make informed decisions about the quality of research evidence. Critical appraisal tools (CATs) are used to appraise various types of study, such as RCTs, case studies, qualitative research, systematic reviews and clinical guidelines (CAT, 2017). However, most of these types of study involve evaluation and investigation of intervention programmes.

The Physiotherapy Evidence Database (PEDro) is one of the available methods for rating trials such as RCTs but not reviews or guidelines (PEDro, 1999; Verhagen et al., 1998). The PEDro scale is based on the Delphi list of criteria for assessing the quality of RCTs for conducting systematic reviews, which was developed by Verhagen and colleagues at the Department of Epidemiology, University of Maastricht (Verhagen et al., 1998). PEDro is used to assess two aspects of trial quality: internal validity (believability) and whether the trial has full statistical information to make the data interpretable (PEDro, 2017, 1999). Online tutorials are available to develop the skills to use PEDro. Trials are

scored from poor (one) to high (10) quality. This review assessed studies without PEDro scores or CATs using the following criteria:

1. Study design
2. Data sources
3. Sample size
4. Representativeness of the population
5. Methods
6. Advantages and disadvantages of the methods
7. Presentation of outcomes and handling of bias.

2.3 Cardiac rehabilitation

The World Health Organization (WHO)'s definition of CR from 1993 very well summarises its objectives: 'The sum of activities required to influence favourably the underlying cause of the disease, as well as to ensure the patient the best possible physical, mental and social conditions, so that they may, by their own efforts, preserve or resume when lost, as normal a place as possible in the life of the community' (WHO, 1993). Cardiac rehabilitation is recognised as integral to comprehensive intervention offered to patients with CVD and has been given a Class I recommendation in international guidelines from organisations such as the American Heart Association, American College of Cardiology, European Society of Cardiology, and British Association for Cardiovascular Prevention and Rehabilitation (BACPR), with exercise therapy consistently identified as a central element (BACPR, 2017; Piepoli et al., 2016; Balady et al., 2011; Smith et al., 2011; Wenger et al., 1995). Although exercise training remains a cornerstone intervention, international guidelines consistently recommend the provision of comprehensive CR that includes education and psychological input focusing on health and lifestyle behaviour change, risk-factor modification, and psychosocial wellbeing (BACPR, 2017; Piepoli et al., 2016; Balady et al., 2011; Smith et al., 2011).

Cardiac rehabilitation has been proved to have morbidity and mortality benefits and has been recommended as an important therapeutic tool in modern cardiology by most cardiovascular professional societies (BACPR, 2017; Sumner, Harrison and Doherty, 2017; Piepoli et al., 2016; Anderson et al., 2016; Rauch et al., 2016; Sagar et al., 2015). The benefits of CR for individuals after myocardial infarction (MI) and percutaneous coronary intervention (PCI) and for those with HF have been reviewed comprehensively in several meta-analyses, including two Cochrane reviews, one review each in the *Journal of the European Journal of Preventive Cardiology*, *PLOS One* and *BMJ Open Heart*, and a recent clinical review from the United States (Sumner, Harrison and Doherty, 2017; Anderson et al., 2016; Rauch et al., 2016; Sagar et al., 2015; Menezes et al., 2014; Taylor et al., 2014).

2.4 Evidence for modern cardiac rehabilitation

Many systematic reviews included older RCTs where almost half of the studies were performed in the pre-statin era (Sumner, Harrison and Doherty, 2017; Anderson et al., 2016; Rauch et al., 2016; Heran et al., 2011). During this earlier period, treatment and medications were very different compared with clinical practice from 1995 onwards, and the impact of participation in CR on the long-term clinical course have been attenuated through modern treatment options. Although there have been multiple trials and systematic reviews, there is concern that inclusion of older trials may be distorting the effect of CR shown by these studies. However, the benefits of CR, as delivered in the context of the present day, have been challenged.

2.4.1. Reviews of cardiac rehabilitation after myocardial infarction

A 2011 Cochrane review and meta-analysis carried out by Heran et al. included 47 RCTs with 10,794 patients and a follow-up period of at least six months to determine the effectiveness of exercise-based CR (exercise training alone or in combination with psychosocial or educational interventions) compared with usual care on mortality, morbidity and health-related quality of life in patients with CHD (Heran et al., 2011). This showed that exercise-based CR is effective in reducing total mortality (relative risk (RR) 0.87 (95% confidence interval (CI) 0.75 to 0.99), absolute risk reduction (ARR) 3.2%, number needed to treat (NNT) 32) and cardiovascular mortality (RR 0.74 (95% CI 0.63 to 0.87), ARR 1.6%, NNT 63) in medium- to long-term studies (i.e. with ≥12 months follow-up) in addition to hospital admissions (RR 0.69 (95% CI 0.51 to 0.93)) in short-term studies (<12 months follow-up). Statistically significantly differences were not observed for total mortality and cardiovascular mortality in short-term studies; total MI or revascularisation (coronary artery bypass graft (CABG) or percutaneous transluminal coronary angioplasty (PTCA)) in medium- to long-term or short-term studies; or total hospitalisations in medium- to long-term studies. There was evidence of a significantly higher level of quality of life with exercise-based CR than usual care in seven of 10 RCTs that reported health-related quality of life using validated outcome measures, but Heran et al. were not able to pool the data to quantify the effect because of the heterogeneity of outcome measures and methods of reporting findings. The population studied by Heran et al. was predominantly male (number of women participants was low), middle aged (mean age of participants was 56 years) and low risk (most studies excluded patients with comorbidities or HF). Overall, Heran et al. (2011) found that the mortality benefit was limited to medium- to long-term studies (with follow-up ≥12 months). Participation in CR may reduce the rate of hospital readmissions in studies with up to 12

months' follow-up (based on four trials with 54/254 versus 73/225 events) but not with long-term follow-up.

Concerns have been raised about the applicability of the meta-analyses of results of exercise-based CR to the provision of CR services; about the inclusion of small, poor-quality RCTs, which may have resulted in overestimation of the benefits of CR; and about the almost exclusive recruitment of low-risk, middle-aged, post-MI men in early trials, thereby reducing the generalisability of their findings to the broader population of patients with CHD (Doherty and Rauch, 2013; West and Jones, 2013; West, Jones and Henderson, 2012; Heran et al., 2011). It has also been argued that major advances in medical management of CHD may have led to a reduction in the incremental effect of exercise-based CR on mortality compared with usual care alone.

Anderson et al. updated the Cochrane systematic review and meta-analysis of exercise-based CR for CHD to reassess the effects of exercise-based CR compared with usual care in terms of mortality, morbidity, health-related quality of life and cost-effectiveness (Anderson et al., 2016). A total of 63 RCTs conducted between 1974 and 2014 with 14,486 participants and median follow-up of 12 months were included to compare exercise-based CR with usual care in patients after MI or revascularisation and in those with a diagnosis of angina pectoris or CHD confirmed by angiography. The study showed reductions in cardiovascular mortality (RR 0.74 (95% CI 0.64 to 0.86)) and the risk of hospital admissions (RR 0.82 (95% CI 0.70 to 0.96)) with exercise-based CR compared with usual care. No statistically significant reductions were seen in total mortality (RR 0.96 (95% CI 0.88 to 1.04)) or in the risk of fatal or non-fatal MI, CABG or PCI between exercise-based CR and usual care. Most studies (14/20) showed higher levels of health-related quality of life in one or more domains after exercise-based CR compared with usual care. Anderson et al. (2016), which summarises the results of RCTs in >14,000 patients, is the most comprehensive review of evidence to date and confirmed that exercise-based CR reduces cardiovascular mortality and, importantly, reduces hospital

admissions and improves quality of life, which seems to be consistent across patients and intervention types (i.e. exercise only or comprehensive CR, dose of exercise training, and centre- or home-based settings) and independent of study quality, setting and publication date. Although Anderson et al. (2016) reported no reductions in total mortality or the risks of fatal or non-fatal MI or coronary revascularisation (CABG or PCI), pooled cardiovascular mortality (10.4% to 7.6%, NNT 37) and hospital admissions (30.7% to 26.1%, NNT 22) were reduced with exercise-based CR compared with usual care.

In contrast with the Cochrane review and meta-analysis by Heran et al. (2011) and findings from observational studies that support a mortality benefit (Doherty and Lewin, 2012), Anderson et al. (2016) found no statistically significant reduction in total mortality with exercise-based CR. The Heran et al. review of 2011 included 47 randomised controlled trials with 10,794 patients, while Anderson et al.'s review of 2016 included 16 new RCTs, giving a total of 63 studies with 14,486 participants. Although Heran et al. and Anderson et al. applied the same methods in their reviews, which were performed just five years apart, the findings for total mortality differ because Anderson et al. included results from RAMIT, which was conducted in the era of major advances in medical management of CHD, such as the increased use of statins, and showed little effect of CR on mortality at two years (RR 0.98 (0.74 to 1.30)) (West, Jones and Henderson, 2012). The meta-regression analysis in Anderson et al. showed a trend towards a linear reduction in the total mortality effect of CR over time (i.e., by study publication date). Anderson et al. did not show a reduction of total mortality in the subgroup of studies published after 1995; however, cardiovascular mortality was significantly reduced both before and after 1995.

Anderson et al. included eight effective trials, two borderline effective and three not effective trials for total mortality; five effective and one not effective for cardiovascular mortality; and six effective, two borderline effective and one not effective for

hospitalisation. Heran et al. included one effective, one borderline effective and two not effective trials for total mortality; one effective and one not effective for cardiovascular mortality; and three effective and two borderline effective for hospitalisation.

The finding that exercise-based CR reduces the risk of cardiovascular mortality compared with usual care but does not reduce the risk of MI or revascularisation suggests that, although CR does not improve coronary vascular function or integrity, it does confer improved survival in patients after MI.

On the other hand, Powell et al's systematic review and meta-analysis of 22 RCTs with 4,834 participants recruited after the year 2000 concluded that there was no effect on on total mortality or cardiovascular mortality outcomes between exercise-based CR and a no-exercise control (Powell et al., 2018). They did find a small reduction in hospital admissions after exercise-based CR, but this is unlikely to be clinically important. They did not include health-related quality of life as an outcome measure. Although 16 of the 22 trials reviewed by Powell et al specified inclusion of additional components of a comprehensive CR programme, the review remains focused on exercise. Anderson et al's Cochrane review acknowledged a linear reduction in total mortality effect over time (i.e., with publication date) and demonstrated an extremely positive effect of CR overall (Anderson et al., 2016; Lavie, Arena and Franklin, 2016). Moreover, Powell et al included studies where recruitment periods are unconfirmed (Powell et al., 2018). They also included patients with stable angina – a group for which CR is not currently recommended in NICE guidance (Powell et al., 2018; NICE, 2011b). This thesis has not put emphasis on this review due to the poor quality of this study and the extremely wide definition of possible CR interventions.

2.4.2. Review of cardiac rehabilitation in heart failure

Similar to Anderson et al.'s Cochrane review update, Sagar et al. updated the Cochrane systematic review and meta-analysis of exercise-based CR for patients with HF, including 33 RCTs and 4,740 participants predominantly with a reduced ejection fraction (<40%) and New York Heart Association class II and III with ≥6 months of follow-up (Sagar et al., 2015). Although there was no difference in pooled total mortality between exercise-based CR alone or as a component of comprehensive CR programme compared with the usual care in trials with follow-up to 12 months (RR 0.93 (95% CI 0.69 to 1.27)), there was a trend towards a reduction in trials with follow-up beyond 12 months (RR 0.88 (95% CI 0.75 to 1.02)). Exercise CR reduced the risk of overall hospitalisations (RR 0.75 (95% CI 0.62 to 0.92), ARR 7.1%, NNT 15) and HF-specific hospitalisations (RR 0.61 (95% CI 0.46 to 0.80), ARR 5.8%, NNT 18) and led to improvements in health-related quality of life. In 13 RCTs that used the Minnesota Living with Heart Failure questionnaire – a validated quality-of-life measure – an average 5.8-point increase was seen in those undertaking exercise as part of their CR compared with those who did not exercise (mean difference −5.8 points (95% CI −9.2 to −2.4, p=0.0007). A difference of ≥4 points on the Minnesota Living with Heart Failure questionnaire has been shown to represent a clinically important, meaningful difference for patients (McAlister et al., 2004).

Sagar et al.'s updated review showed that the benefits of CR seem to be consistent across patients regardless of type of CR programme characteristics (i.e. exercise only vs comprehensive CR, aerobic exercise only vs aerobic and resistance exercise) and trial characteristics (i.e. length of follow-up and publication date) and may reduce mortality in the longer term. Many trials included in this review were conducted in the era of modern medical therapy for HF. For example, in the large multicentre Heart Failure: A Controlled Trial Investigating Outcomes of Exercise Training (HF-ACTION), 94% of patients were receiving β-blockers combined with angiotensin-receptor blockers or

angiotensin-converting enzyme (ACE) inhibitors, and 45% had an implantable cardioverter defibrillator or implanted biventricular pacemaker at the time of enrolment (Connor et al., 2009). Many included trials were relatively small and with short-term follow-up, so the number of deaths and hospitalisations reported by most trials was small (26 trials <100 participants) and single centre (30 trials), with the large HF-ACTION contributing about 50% (2,331 participants) of all patients included in the review.

2.4.3. Cardiac Rehabilitation Outcome Study (CROS)

The Cardiac Rehabilitation Outcome Study (CROS) is the first published systematic review and meta-analysis of RCTs and non-randomised studies (retrospective controlled cohort and prospective controlled cohort studies) to investigate the efficacy of structured and multi-component CR compared with the usual care in the post-statin and acute revascularisation era in a mixed CR population (Rauch et al., 2016). The review only included studies that recruited patients in 1995 or later (n=25): one RCT, seven prospective controlled cohort studies, and 17 retrospective controlled cohort studies, which included a total of 219,702 patients (46,338 after acute coronary syndrome, 14,583 after CABG, and 158,781 from mixed populations) with mean follow-up of 40 months. As CROS only included one RCT and the other trials were systematically evaluated large, controlled, cohort studies, it makes an important independent contribution that more closely reflects the conditions in routine clinical practice. This study showed that participation in CR after acute coronary syndrome or CABG and in mixed populations with stable CHD is associated with reduced mortality, even in the era of acute revascularisation and routine medication with statins.

Controlled cohort studies evaluating patients with acute coronary syndrome showed significantly reduced mortality for patients participating in CR by a factor of 0.37 in all prospective controlled cohort studies (four studies; hazard ratio (HR) 0.37 (95% CI 0.20 to 0.69); heterogeneity was low (I^2=17.8%)) and by a factor of 0.64 in retrospective

controlled cohort studies (three studies; HR 0.64 (95% CI 0.49 to 0.84), odds ratio (OR) 0.20 (95% CI 0.08 to 0.48); heterogeneity was moderate to substantial). The only RCT included yielded a neutral result (HR 1.01 (95% CI 0.85 to 1.21)) (West, Jones and Henderson, 2012).

After CABG, all retrospective controlled cohort studies consistently showed reduced mortality in patients participating in CR (four studies; HR 0.62 (95% CI 0.54 to 0.70); heterogeneity was absent (I^2=0%)). One additional prospective controlled cohort study supported this result (Hansen et al., 2009).

In 'mixed populations', participation in CR was associated with a significant reduction in mortality on the basis of five retrospective controlled cohort studies (HR 0.52 (95% CI 0.36 to 0.77); heterogeneity was high I^2=84%) and one prospective controlled cohort study (HR 0.67 (95% CI 0.55 to 0.82)). Analysis of two retrospective controlled cohort studies that reported ORs yielded a neutral result (OR 0.56 (95% CI 0.26 to 1.22); heterogeneity was high (I^2=81%)) (Schwaab et al., 2011; Suaya et al., 2009). Although the study of Suaya et al. showed a significant reduction in mortality (OR 0.42 (95% CI 0.40 to 0.45)) (Suaya et al., 2009), the results of Schwaab et al. were neutral (OR 0.91 (95% CI 0.45 to 1.81)) (Schwaab et al., 2011).

The major finding of CROS is that CR in the modern era of cardiology is associated with significantly reduced total mortality after acute coronary syndrome and after CABG. However, in patients after acute coronary syndrome, this positive result of controlled cohort studies does not concur with the neutral result of RAMIT, the only RCT included (West, Jones and Henderson, 2012), which indicates that the results from RAMIT may not be generalisable to a wider population. Although the primary outcome in CROS – total mortality following CR – was confirmed, the secondary outcomes of cardiac mortality and rehospitalisation were not evident in CROS, which is contrary to the findings of the most recent Cochrane review of RCT evidence in patients with CHD or

after MI (Anderson et al., 2016). On the basis of CROS findings from 24 controlled cohort studies including 217,889 patients and reflecting routine clinical care in nine countries worldwide, participation in structured multi-component CR is associated with reduced mortality after an acute coronary event, even in the era of statins and acute revascularisation. The CROS showed a trend in favour to CR participation regarding cardiovascular mortality and major cardiovascular and cerebrovascular events. Although CROS did not show any trends regarding non-fatal MI or non-fatal stroke, it also did not show a consistent and clear effect of CR on hospital readmissions after acute coronary syndrome, after CABG or in mixed populations.

The variation in type of mortality benefit between CROS (total mortality) and the Cochrane review (cardiac mortality) (Anderson et al., 2016) is not clear, but it may be the result of differences in populations under investigation and the type of CR delivered – for instance, the Cochrane analysis included 'exercise-only' interventions while CROS exclusively evaluated 'multi-component' CR.

Participation in CR was associated with significantly reduced mortality in all but three studies by Kim et al., West et al. and Schwaab et al (West, Jones and Henderson, 2012; Kim, Kim and Moon, 2011; Schwaab et al., 2011), which are discussed below.

Kim et al. assessed the prognostic influences of a CR programme in Korean patients with acute MI during the first year after an episode of the event (Kim, Kim and Moon, 2011). A total of 141 patients with acute MI who underwent PCI were recruited consecutively and divided into a CR group and a control group. The CR group completed a phase 2 CR programme in hospital for a period of 6–8 weeks after strict management of risk factors followed by self-exercise in their community by exercise prescription for a year after acute MI. Patients in the CR group had a greater reduction in recurrence rate (14%) and 38 more disease-free days than patients in the control group. In this study, the CR and control groups were not chosen randomly and a monitoring period of one

year was too short for sufficient monitoring of progress. In addition, one death in each group in one year does not support comparison of the mortality rates.

Schwaab et al. reported on a non-randomised study that compared outcomes in patients who attended a three-week inpatient CR programme or received usual care (Schwaab et al., 2011). The results of this multicentre cohort study reflect current management of CR in a large and unselected population in Germany. All patients had acute coronary angiography, 679 were discharged from hospital receiving usual care, and 795 completed a comprehensive CR programme. After 12 months of follow-up, 16 patients from the usual care group had died compared with 17 patients in the CR group (p=0.78; RR reduction 9%; NNT 455). The primary combined endpoint of mortality, MI, revascularisation and hospitalisation occurred in 32.6% of patients who attended CR and 38.7% of those who received usual care (p=0.01; RR reduction 16%; NNT 17). Although patients who attended CR were sicker at entry than patients who received usual care, their outcome was substantially improved within 12 months. This study suggests a significant reduction of clinical endpoints by 3–4 weeks with inpatient CR in patients with CHD.

The largest pragmatic RCT of modern day CR in the UK, the RAMIT trial, found no significant beneficial effects on mortality, cardiac or psychological morbidity, risk factors, health-related quality of life or activity level from CR (West, Jones and Henderson, 2012). The findings of RAMIT have been included in the latest systematic reviews (Anderson et al., 2016; Rauch et al., 2016). Since RAMIT, the two most recent 2016 reviews on CR effectiveness identified no current RCTs that have been conducted with sufficient sample sizes to investigate efficacy (Anderson et al., 2016; Rauch et al., 2016).

2.4.4. Effectiveness of modern cardiac rehabilitation in real-life settings

Recent observational evidence draws different conclusions to the most current reviews of trial data with respect to total mortality and rehospitalisation, questioning the representativeness of historic data in the modern cardiology era. A systematic review of observational studies investigated the effects of modern day CR in routine practice when recruitment occurred from 2000 onwards in non-attenders versus attenders (Sumner, Harrison and Doherty, 2017). Eight studies conducted in six countries involving 9,836 patients with acute MI were included in the analyses. Overall, CR was found to reduce the risk of total and cardiac-related mortality and improve health-related quality of life significantly in at least one domain. The benefits of CR in terms of recurrent MI were inconsistent, and no significant effects were found regarding revascularisation or rehospitalisation following acute MI. Four studies showed that CR was related to a decreased total mortality: unadjusted OR 0.25 (95% CI 0.16 to 0.40; I^2=66%) and adjusted OR 0.47 (95% CI 0.38 to 0.59; I^2=0%). Two studies showed that CR was related to a decreased risk of cardiac-related mortality; unadjusted OR 0.21 (95% CI 0.12 to 0.37; I^2=0%) and adjusted OR 0.43 (95% CI 0.23 to 0.79). Data could not be pooled from the two identified studies assessing the impact of multi-component CR on readmission due to the methods by which findings were reported. One study reported an adjusted effect, finding no significant effect from CR (OR 0.96 (95% CI 0.81 to 1.13)). Three studies showed that CR was associated with a decreased risk of recurrent MI in unadjusted analysis only (OR 0.31 (95% CI 0.13 to 0.74); I^2=61%) while adjusted analysis found no significant effect (OR 0.72 (95% CI 0.43 to1.21)). In two studies, CR was not significantly related to a reduction in revascularisation in either unadjusted or adjusted effect measures (OR 1.07 (95% CI 0.86 to 1.38); I^2=0%, and OR 1.00 (95% CI 0.78 to 1.28), respectively). Heterogeneity prevented date from being pooled from the two identified studies that reported health-related quality of life.

Sumner et al. looked to extend the findings of the CROS review of observational CR data by exploring a homogeneous patient sample (acute MI only) and including health-related quality of life outcomes (Sumner, Harrison and Doherty, 2017). In an era where the existing RCT evidence base is aged and non-representative and there are ethical challenges with conducting a new effectiveness trial when standard care is established as CR, this study has provided an important perspective on current day effectiveness of CR in routine practice.

In comparison with the most recent review of RCT evidence (Anderson et al., 2016), the findings from Sumner et al.'s study (Sumner, Harrison and Doherty, 2017) and CROS (Rauch et al., 2016) drew differing conclusions. Specifically, opposite effects in total mortality and rehospitalisation were found between observational and trial data, with a reduction in total mortality and no effect on rehospitalisation found in observational studies. Anderson et al. included historic RCT trials that used exercise-only CR formats, as well as patients who had different care and treatment options historically versus modern-day counterparts, and there are inherently different characteristics for RCT populations compared with those receiving routine care (Anderson et al., 2016). However, there were some similarities between trial and observational data: no reductions in recurrent MI were found, and health-related quality of life improved. The positive effects on health-related quality of life were found in Sumner's review of patients with acute MI (Sumner, Harrison and Doherty, 2017), as CROS did not consider health-related quality of life (Rauch et al., 2016).

2.5 Rehabilitation After Myocardial Infarction Trial (RAMIT)

Systemic reviews and meta-analyses of the effect of CR have had to rely on mostly small and older trials undertaken over several decades. As clinical management has transformed over the past 30–40 years, West et al. believed that the findings of historic trials may have little relevance now in the modern era of early thrombolysis, short hospital stays and extensive medication (West, Jones and Henderson, 2012). They therefore commissioned a multicentre RCT to evaluate the effect of CR for secondary prevention on mortality, morbidity, health-related quality of life, risk factors and activity in patients following acute MI (West, Jones and Henderson, 2012). This study compared 1,813 patients referred to comprehensive CR programmes (n=903) or discharged to 'usual care' without referral to CR (n=910) in 14 representative hospitals in England and Wales during 1997–2000 (West, Jones and Henderson, 2012). A parallel 'elective' study compared 331 patients in matched elective CR (n=197) and elective usual care without CR (n=134) in hospitals.

The CR programmes reportedly conformed to guidelines issued by the BACPR for phase 3 rehabilitation and comprised exercise training; health education about heart disease, risk factors and treatment; counselling for recovery; and advice for long-term secondary prevention. Exercise training, which used equipment in physiotherapy gyms, was described as the largest component. Programmes were led by nurses with previous acute cardiac care experience in most centres and by occupational therapists or physiotherapists in a few. All programmes involved at least one other discipline. Sessions took place weekly or twice a week and averaged 20 hours over 6–8 weeks. All patients in the trial (and in the 'elective' comparison trial) had similar care in all respects.

The primary outcome measure was total mortality at two years. Secondary measures were morbidity, health service use, health-related quality of life, psychological general

wellbeing and lifestyle and cardiovascular risk factors at one year. Patient entry ran from 1997 to 2000, and secondary outcomes were followed up to 2001 and vital status up to 2006.

Baseline characteristics were almost identical. No significant differences between patients referred to CR and usual care were seen in mortality at two years (RR 0.98 (95% CI 0.74 to 1.30)), mortality after 7–9 years (RR 0.99 (95% CI 0.85 to 1.15)), cardiac events, seven of eight domains of the health-related quality of life scale (36-item short-form survey (SF36)) or the Psychological General Wellbeing Index. Cardiovascular morbidity at one-year follow-up did not differ between CR and usual care, and readmissions to hospital among surviving patients for any cardiovascular condition during the first year were similar for CR and usual care. No significant differences at one year were seen in smoking, alcohol consumption or any of the dietary measures between CR and usual care. Patients who participated in CR reported slightly less physical activity. Data from the elective hospitals comparison concurred with these findings. The trial showed no benefit of CR on total mortality at one year, two years or after 7–9 years and no major effect on morbidity, psychological morbidity, risk factors, health-related quality of life or physical activity at one year.

The RAMIT is the largest study of CR since the WHO's European collaborative of 1971–6 (West, 2012; WHO European Collaborative Group, 1986). It was funded to randomise 8,000 patients to CR or usual care, which was the sample size required to detect a 20% RR reduction compared with usual care, but it enrolled fewer hospitals and recruited fewer patients than planned because the study sponsor (the NHS Research and Development Programme) requested early closure due to initial low recruitment (West, Jones and Henderson, 2012). Only 1,813 patients were randomised between 1997 and 2000 before funding support was withdrawn, with 903 allocated to rehabilitation and 910 to usual care, and the usual 'CONSORT diagram' showing recruitment and losses is missing from the published paper (Boutron et al., 2008). With fewer than a quarter of the

total planned patients recruited, the trial was far too small and weak to assess the primary outcome and only exceeded the required sample size for quality of life measures. Given the level of total mortality in the control group (84/910, 9.2%), the trial would have needed about 3,100 patients in each arm to detect a 20% reduction at 80% power, but each arm had fewer than 1,000 patients.

It therefore is hardly surprising that there was no difference in total mortality, as these 'comprehensive' programmes did not achieve any benefit whatsoever at one year compared with usual care. The prevalence of smoking was almost identical, diet in terms of fresh fruit consumption was similar, and, paradoxically, physical exercise (>100 kcal/day) was significantly lower in the CR arm. Alcohol consumption in terms of moderate and heavy drinking was identical. The management of blood pressure, lipids and glucose was not reported despite the emphasis on secondary prevention. This was all delivered in the name of CR and yet was insufficient to reduce the prevalence of smoking, improve dietary habits, or increase physical activity. However, the findings of the National Heart Failure Audit run by the National Institute for Cardiovascular Outcomes Research (NICOR) suggested that survival analysis of patients with HF who were referred to CR demonstrated improvements of 12% compared with patients not referred to CR (Donkor, McDonagh and Hardman, 2017).

In the RAMIT study, patients were generally not old, were not afflicted by anxiety and depression, and were not greatly at risk given mortality of 6% and 17% at one and five years, respectively. There was no short-term analysis of the 6–8-week rehabilitation programme until 12 months, at which time the assessments identified similar health outcomes in both groups.

In terms of the CR intervention in RAMIT, its effectiveness could be questioned when usual care resulted in a significant increase in exercise at 12 months. A common theme of all CR programmes in RAMIT was the emphasis they placed on physical exercise. It

therefore is surprising that physical activity levels were significantly lower in patients who participated in CR despite exercise being the cornerstone of these programmes. However, RAMIT did not involve a standard exercise training component: patients only trained once or twice a week, which is nowhere near the general recommendations for physical activity in primary or secondary prevention. The study publication did not describe the intensity, modality and duration of training sessions, and exercise testing was not performed before and after CR to assess the treatment effect. In addition, significantly fewer patients were exercising after one year, which suggests underdosing of exercise. There are significant discrepancies between these study results and the findings of the NACR: in RAMIT, people who attended CR were exercising less at 12 months than they had been at the start of the programme, but year on year the NACR consistently reports that patients are doing significantly more exercise 12 months after being referred for CR (NACR, 2017, 2016, 2015).

However, RAMIT did not include Heran et al.'s update to the review of exercise-based CR published in 2011 by the Cochrane Heart Group, which included 47 trials randomising more than 10,500 patients with CHD to exercise-based CR or usual care between 1975 and 2008 and clearly showed that CR reduces total mortality by 13% and cardiac mortality by 26% (Heran et al., 2011). In addition, it is essential for a pragmatic trial to capture a representative sample of clinical practices and patients and to accurately describe them when publishing findings (Clark et al., 2012), but, unfortunately, some conventions of trial reporting were not observed in the writing of the RAMIT paper (Clark et al., 2012; Boutron et al., 2008). The RAMIT paper also failed to mention two studies that found that participation in CR after PCI was associated with a significant reduction in mortality rates and acute coronary syndrome patients, who extremely well treated in terms of pharmacological prevention, and not comply to diet and exercise recommendations were associated with increased risk of adverse cardiovascular events (Goel et al., 2011; Chow et al., 2010).

A retrospective analysis of data from a prospectively collected registry of 2,395 consecutive patients who underwent PCI in Olmsted County, Minnesota, USA, from 1994 to 2008 found that CR led to a 45% reduction in long-term mortality (Goel et al., 2011). In a three-month landmark analysis in this study, the association of CR with total mortality, cardiac mortality, MI or revascularisation was assessed through three statistical techniques: propensity score-matched analysis (n=1,438), propensity score stratification (n=2,351) and regression adjustment with propensity score (n=2009). During a median follow-up of 6.3 years, 503 deaths (199 cardiac), 394 MIs and 755 revascularisation procedures occurred in the study subjects. Participation in CR, noted in 40% (964/2,395) of the cohort, was associated with a significant decrease in total mortality according to all three statistical techniques (HR 0.53 to 0.55, $p<0.001$). A trend toward decreased cardiac mortality was also observed in participants of CR; however, no effect was observed for subsequent MI or revascularisation. The associations between CR participation and reduced mortality rates were similar for men and women, for older and younger patients, and for patients undergoing elective and non-elective PCI.

A registry of 18,809 patients with acute coronary syndrome from 41 countries enrolled in the Organization to Assess Strategies in Acute Ischemic Syndromes (OASIS)-5 RCT examined the influence of adherence to lifestyle and exercise recommendations on the risk of repeat MI (Chow et al., 2010). At 30-day follow-up, patients reported adherence to diet, physical activity and smoking cessation. Cardiovascular events (MI, stroke, cardiovascular death) and total mortality were documented to six months. About one third of smokers continued to smoke. Adherence to both diet and exercise recommendations was reported by 29.9%, adherence to either diet or exercise by 41.6%, and adherence to neither diet nor exercise by 28.5%. Quitting smoking was associated with a decreased risk of MI compared with continued smoking (OR 0.57 (95% CI 0.36 to 0.89)). Adherence with both diet and exercise was associated with a decreased risk of

MI compared with non-adherence with both (odds ratio, 0.52; 95% confidence interval, 0.4 to 0.69). Patients who reported persistent smoking and non-adherence to diet and exercise had a 3.8-fold (95% CI 2.5 to 5.9) increased risk of MI/stroke/death compared with never smokers who modified diet and exercise. Failure to comply with lifestyle and exercise recommendations was associated with an early, almost fourfold increased risk of adverse cardiovascular events.

The RAMIT researchers concluded that CR had no effect on psychological morbidity or quality of life (West, Jones and Henderson, 2012), but a non-randomised clinical trial showed that CR has a significant beneficial effect on psychological morbidity (Denollet and Brutsaert, 2001). In this study, 150 men with CHD involved in CR (n=78) or received standard care (n=72). There were no differences between CR and control patients with regard to left ventricular ejection fraction (LVEF) or standard care. Endpoints were reduction in distress after three months and mortality after nine years. At the end of the three-month trial, 64 (43%) patients conveyed improvement and 22 (15%) conveyed deterioration in negative affect. Patients who taken part in CR improved more (p=0.004) and deteriorated less (p=0.001) than patients who received usual care, so CR was effective in reducing distress. After nine years of follow-up, 15 patients had died (13 cardiac and two cancer deaths). Mortality was associated with LVEF ≤50% (p=0.038) and deterioration in negative affect (p=0.007). Mortality was 17% (12/72) for control patients versus 4% (3/78) for CR patients (p=0.009), so CR was effective in reducing mortality. Both LVEF ≤50% (OR 3.2 (95% CI 1.1 to 9.8), p=0.041) and CR (OR 0.2 (95% CI 0.1 to 0.7), p=0.016) were independent predictors of mortality. Cardiac rehabilitation thus warded off the deleterious effect of deterioration in negative affect on prognosis.

A matched, cluster-randomised, controlled trial (EUROACTION) in eight European countries, six pairs of hospitals and six pairs of general practices assigned patients with or at high risk of developing CVD to a nurse-coordinated, multidisciplinary, family-based preventive cardiology intervention programme or usual care (Wood et al., 2008). Overall,

1,589 and 1,499 patients with CHD and 1,189 and 1,128 at high risk were assigned to intervention programme and usual care, respectively. The primary endpoints were family-based lifestyle change and management of blood pressure, lipids, and blood glucose measured at one year. The EUROACTION programme prevented relapse in some smokers who had stopped smoking after their coronary event: 136 (58%) in the intervention programme and 154 (47%) in the usual care groups did not smoke one year after their event (difference between intervention and usual care groups in change from baseline to one year: 10.4% (95% CI −0.3 to 21.2, p=0.06). For all patients, there was a significant reduction in saturated fat consumption (196 (55%) vs 168 (40%); 17.3% (95% CI 6.4% to 28.2%); p=0.009), a substantial increase in intake of fresh fruit and vegetables (680 (72%) vs 349 (35%); 37.3% (95% CI 18.1% to 56.5%); p=0.004), and an increase in the frequency of consumption of oily fish at one year (156 (17%) vs 81 (8%); 8.9% (95% CI 0.3% to 17.5%); p=0.04) with the intervention compared with usual care. More patients with CHD (615 (65%) vs 547 (55%); 10.4%, 0.6 to 20.2, p=0.04) and patients at high risk of CHD (586 [58%] vs 407 [41%]; 16.9% (95% CI 2.0% to 31.8%), p=0.03) achieved blood pressure target <140/90 mm Hg with the intervention than with usual care. The proportion of patients who achieved total cholesterol <5 mmol/l did not differ between groups, but the difference in change from baseline to one year in high-risk patients was 12.7% (95% CI 2.4% to 23.0%); p=0·02) in favour of intervention. A considerably higher proportion of patients achieved the physical activity target, an absolute difference of 34% between intervention and usual care, and the same direction of lifestyle change for diet and physical activity was seen in partners of the patients. The EUROACTION trial included a really comprehensive CR programme with corresponding one-year outcomes, unlike RAMIT, and the principles of EUROACTION are now epitomised in the MyAction community-based preventive cardiology programme for the NHS (Connolly et al., 2011).

The effectiveness of CR, as suggested by the above critical review of RCTs and observational studies, requires routine practice be delivered in a way that closely reflects the evidence base. Table 2.1 summarising the key details of each of the above studies.

Table 2.1 Summary of results

Study 1st author, year	Study design	Number of studies	Number of patients	Follow-up	Types of interventions	Outcome measures			
						Total mortality	Cardiovascular mortality	Hospital admissions	Health-related quality of life
Heran, 2011	Cochrane systematic review and meta-analysis	47 RCTs	10,794	≥6 months	Exercise-based CR versus usual care for CHD	Effective	Effective	Effective	Effective
Anderson, 2016	Cochrane systematic review and meta-analysis	63 RCTs	14,486	≥6 months	Exercise-based CR versus usual care for CHD	No effect	Effective	Effective	Effective
Sagar, 2015	Cochrane systematic review and meta-analysis	33 RCTs	4,740	≥6 months	Exercise-based CR versus usual care for HF	No effect	–	effective	effective

Rauch (CROS), 2016	Systematic review and meta-analysis	25 studies: 1 RCT 7 pCCS 17 rCCS	219,702	≥6 months	Multi-component CR versus usual care for CHD	Effective	No effect	No effect	–
Sumner, 2017	Systematic review of observational studies	8 observational studies	9,836	≤12 months	Multi-component CR attenders versus non-attenders for CHD	Effective	effective	No effect	effective
West, 2012	RCT	–	1,813	≥12 months	Comprehensive CR versus usual care for CHD	No effect	–	No effect	No effect

–, not available; CHD, coronary heart disease; CR, cardiac rehabilitation; HF, heart failure; pCCS, prospective controlled cohort studies; rCCS, retrospective controlled cohort studies; RCTs, randomised controlled trials.

2.6 Quality of delivery of cardiac rehabilitation

The results of the most recent systematic reviews of evidence on CR support the Class I recommendation of current international clinical guidelines that CR should be offered to patients with CVD (Sumner, Harrison and Doherty, 2017; Anderson et al., 2016; Rauch et al., 2016; Sagar et al., 2015). Provision of exercise-based CR among patients with established CHD provides important health benefits that include reductions in cardiovascular mortality and hospitalisation, which are associated with reduced healthcare costs and improvements in health-related quality of life (Anderson et al., 2016).

Wood argued that RAMIT demonstrated that CR programmes were not fit for purpose, explaining that if all 8,000 patients had been randomised, total and cardiovascular mortality would still have been the same in both arms, because these programmes achieved no added benefit in terms of lifestyle, risk-factor and therapeutic management compared with usual care (Wood, 2012). The central question raised by the results of RAMIT is the quality of participating CR programmes (Wood, 2012), as RAMIT showed that CR as delivered did not provide any added value over usual care. The reports of the NACR reveal daunting challenges every year for current NHS programmes, most of which are inadequately staffed and resourced (NACR, 2017, 2016, 2015; NICE, 2013a).

Only 38% of patients after MI access CR programmes, and those with angina or other atherosclerotic vascular disease are largely ignored (NACR, 2015). Median waiting time to joining a programme after MI is an astounding five weeks – and even longer after CABG (seven weeks) – so early opportunities following diagnosis to help patients understand their disease and its treatment, address anxiety and depression, and reduce their overall cardiovascular risk are being missed (NACR, 2015).

The range of disciplines in the UK has significantly declined over the past 3 years, specifically dieticians, physiotherapists and psychologists, making these programmes less multidisciplinary and comprehensive (Wood, 2012). Group-based interventions, rather than individualised care, are still the norm, and this is one explanation for poorer outcomes from CR –, both in terms of lifestyle change and the totality of risk factor management.

The suggestion that some CR programmes in the UK are not providing all of the benefits shown in RCTs is not new (Sumner, Harrison and Doherty, 2017; Rauch et al., 2016; Dalal, Doherty and Taylor, 2015; Wood, 2012; NACR, 2015). Others have pointed out that some programmes bear little resemblance to the treatment protocols used in some of the RCTs and have questioned the assumption that these programmes are delivering effective treatment (Brodie, Bethell and Breen, 2006). This was one reason that the British Heart Foundation (BHF) provided funding to establish the NACR, which, for five years, has documented in its annual report the huge variation among the CR programmes in England, Wales and Northern Ireland in terms of staffing levels, multidisciplinary involvement (i.e., dietetics, physiotherapy, psychology, occupational therapy), duration (i.e., four to 20 weeks) and method of delivery (i.e., individual, group-based, group-based with 'home exercise', outpatient, self-management at home, home-based and menu-based) (NACR, 2017, 2016, 2015). The uptake rates, refusal rates, dropout rates and time on the waiting list – all proxy indicators of quality – also vary widely (NACR, 2017, 2016, 2015). It therefore would be surprising if there was no variation in outcomes.

The outcomes reported by NACR at one year offer substantial scope for improvement in terms of smoking cessation, diet and weight management, risk factor reduction and so on, and these results from the UK are entirely consistent with results from the EUROASPIRE III survey, a European-wide audit of one-year outcomes of CR across 22 countries in 2008 – almost a decade after RAMIT started (NACR, 2017, 2016, 2015;

Kotseva et al., 2013). The cross-sectional EUROASPIRE III survey was conducted in 76 centres to describe lifestyle and risk-factor management in patients attending CR programmes compared to those who do not (Kotseva et al., 2013). Consecutive patients who had a coronary event or revascularisation before the age of 80 years were identified and interviewed at least six months after hospital admission. In total, 13,935 medical records were reviewed and 8,845 patients interviewed (participation rate 73%); 44.8% of patients reported being advised to attend a CR programme and 81.4% of these did so (36.5% of all patients). Wide variations were seen in participation in CR programmes between countries and diagnostic categories – ranging from 15.9% of those who had a coronary event to 68.1% in those who underwent revascularisation. Characteristics associated with participation in a CR programme included younger age, male gender, higher educational level and CABG as a recruiting index event, while smokers were less likely to attend a CR programmes. Cardiac rehabilitation programmes in Europe are underused, with poor referral, low participation rate and wide variations between countries. The EUROASPIRE III survey showed that cardiovascular prevention is still poorly implemented in daily practice.

Given insufficient patient uptake to CR programmes, protracted delays in patients joining CR programmes, and the decline in participating disciplines, which is making programmes less comprehensive, the NACR findings should be a wake-up call to all CR programmes in the UK to look at themselves, the service they provide and the quantitative outcomes they achieve, as well as their ability to deliver all aspects of secondary prevention of CVD.

2.7 Conclusion of the literature

Although several recent studies, meta-analyses (Sumner, Harrison and Doherty, 2017; Anderson et al., 2016; Rauch et al., 2016; Sagar et al., 2015) and recommendations of international guidelines (BACPR, 2017; Piepoli et al., 2016; Smith et al., 2011) suggest a beneficial effect of CR in patients with CVD, considerable scientific doubt is still apparent. The BHF research group led on a series of observational studies using NACR data. The NACR collects electronic audit data at the patient level, which, when pooled across all programmes, has shown that the key outcome targets for CR defined in the service framework for CHD are being met or exceeded, with the exception of referral, which, on average, is less than half that advocated. These improvements in outcomes are evident after CR. One of the most striking outcomes for patients is the reduction in those who were sedentary before and after CR (63% vs 33%) and the 30% increase in the proportion of patients who met the UK's recommended guidelines for physical activity after CR (NACR, 2017).

The type of CR offered varies considerably between and within countries with respect to content, duration, intensity and volume, and worldwide there are no accepted standards for judging the quality of CR delivery, thereby leaving doubt as to the effectiveness of CR as delivered in routine clinical practice (Zwisler et al., 2012; Bjarnason-Wehrens et al., 2010). Such differences in outcomes from the latest three recent meta-analyses highlight the ongoing need for well-designed studies with specified standards in CR delivery and study reporting (Sumner, Harrison and Doherty, 2017; Anderson et al., 2016; Rauch et al., 2016). Moreover, these problems underscore the need for RCTs to prove efficacy under controlled (experimental) conditions and for controlled and well-designed observational studies to prove the effectiveness of clinical interventions as complex as CR in clinical practice.

Current observational evidence from Sumner et al.'s review of patients after acute MI and the mixed CR populations in CROS seems to contradict the findings of the most recent Cochrane review with respect to total mortality and rehospitalisation (Sumner, Harrison and Doherty, 2017; Anderson et al., 2016; Rauch et al., 2016). These differences highlight that analysis of data that is closer to clinical practice yields different findings to analysis of data from clinical trials, which are known to recruit populations less representative of the general patient population. However, Sumner et al.'s recent review of observational data shows that CR reduces total mortality and improves health-related quality of life (Sumner, Harrison and Doherty, 2017). There is a fundamental need to evaluate the quality of routine practice CR and clarify the extent by which it reflects the evidence base.

Chapter 3 Methods

3.1. Introduction

This chapter describes the dataset of the National Audit of Cardiac Rehabilitation (NACR), which was used to obtain cohort data for the research described in this thesis, as well detailing the methods used for this research. The chapter begins by describing the NACR data source, including the methods for collecting NACR data, as well as ethical approval for the NACR audit and the research described by this thesis. This chapter then explains the design and variable definitions used in the research, as well as the cardiac rehabilitation (CR) service standards, statistical methods, and how missing data and outliers were handled. It also describes a short survey used to add CR programme-level details to evaluate the impact of CR on smoking cessation, which is a key part of secondary prevention and rehabilitation and a British Association for Cardiovascular Prevention and Rehabilitation (BACPR) core component of lifestyle risk-factor management (BACPR, 2017). More details on the statistical methods used for each substudy of this research are given in the relevant chapters. Permission to use figures from the NACR authors is shown in Appendix 1.

3.2. Data source

The NACR is a British Heart Foundation (BHF) strategic project established in 2005 and hosted and managed by a team based in the Department of Health Sciences at the University of York in collaboration with NHS Digital (NACR, 2017; NHS, 2012). The NACR collects comprehensive audit data to support monitoring and improvement of cardiovascular prevention and rehabilitation services in terms of access, equity in provision, and quality and clinical outcomes. It aims to establish the extent of accessibility

and uptake of CR services, promote best practice, and improve service quality in cardiovascular prevention and rehabilitation services by (NACR, 2017; NHS, 2012):

- monitoring and supporting CR teams and commissioners to deliver high-quality and effective services to evidence-based standards for the benefit of all eligible patients
- informing local and national planners, providers and commissioners where services are not reaching expected standards defined in key national guidance
- mapping the extent of provision and highlighting inequitable provision and insufficiencies in delivery compared with key service indicators at strategic clinical network, clinical commissioning group, health board and cardiac network levels for more than 300 programmes in the United Kingdom (UK), so that local providers of CR can formulate appropriate business plans and work towards all patients having an equal opportunity to benefit
- describing the typical gains on agreed outcomes, cardiovascular disease (CVD) risk profiles, and healthcare and social care utilisation that a patient can expect from CR, by which the effectiveness of routinely delivered CR programmes can be judged
- examining reasons for variation in patient outcomes between programmes, so that services can be helped to improve
- using and sharing audit and research data generated through the NACR to inform appropriate national bodies including:
    - Department of Health, NHS England, and NHS healthcare commissioning processes and decision making
    - development of National Institute for Health and Care Excellence (NICE) clinical guidance and service specification
    - Cardiovascular Care Partnership UK
    - BACPR
    - clinical practice standards from national associations
    - public and cardiac patient groups about how local services are performing.

The NACR is the only source of information on CR services across the UK. Data for the NACR are collected by NHS Digital (formerly the Health and Social Care Information Centre (HSCIC)), which holds data and information relating to health and social care (http://content.digital.nhs.uk/).

The UK has the potential to lead the world in CR uptake and is in the top 2% of countries in Europe (Bjarnason-Wehrens et al., 2010). In the NACR in 2017, overall mean uptake to CR in the UK achieved a significant milestone by reaching 51% (NACR, 2017). The total number of CR programmes entering data electronically to the NACR is 224 (that is, 74% of all 303 programmes), and the average number of patients starting CR per programme in the UK is 290 (NACR, 2017). Note that Scottish programmes do not participate in the NACR.

Registration and input of data to the NACR is one of the six BACPR standards, which aims to use audit data to quality assure CR delivery and drive service improvement (BACPR, 2017). The NACR data entry pathway is shown in Figure 3.1.

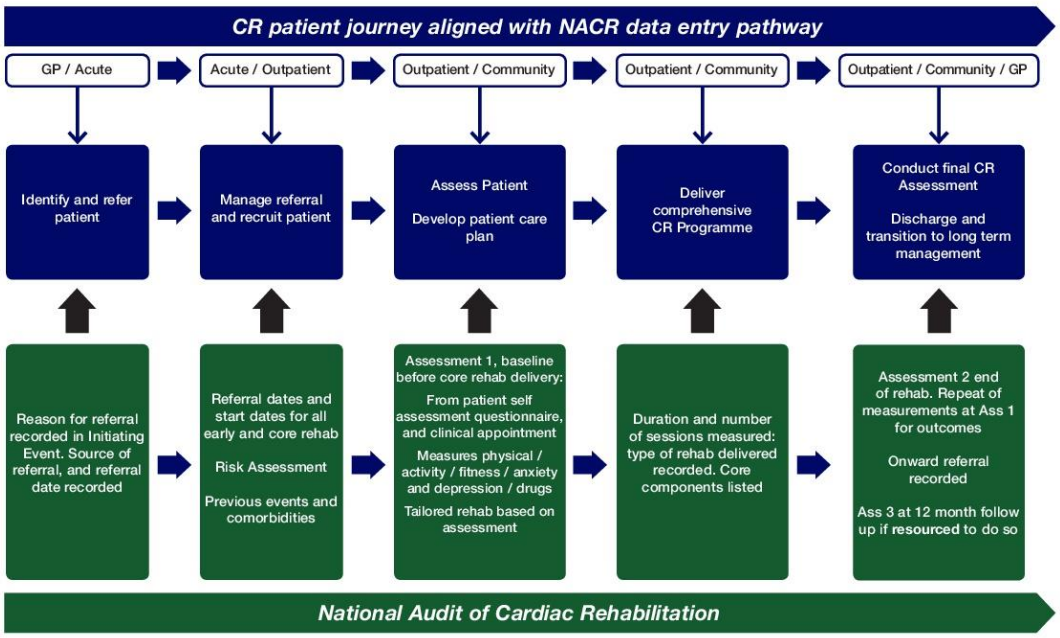


Figure 3.1. National Audit of Cardiac Rehabilitation (NACR) and the cardiac rehabilitation pathway. Figure reproduced with permission of NACR (2017) (see Appendix 1)

3.2.1. Methods for collecting data for the NACR

The NACR database captures a wide range of information on clinical and other expected outcomes of CR, as well as patient demographics and process data. The dataset is contained within a national (electronic) database linked to NHS Digital (NACR, 2017; NHS, 2012). The NACR uses a quality approach, with extensive data checking and validating, which has reduced the burden of matching and cleaning audit data. The NACR has developed a comprehensive dataset that consists of numerous data fields collected either via CR programmes or by annual postal survey or e-survey.

3.2.1.1. Submission of data by programmes on individual patients

Data for the NACR are gathered by clinicians using purpose-designed questionnaires. Patient-level data are collected via the administration of patient questionnaires before, immediately after, and 12 months after a patient starts to attend a CR programme. The staff of the CR programmes distribute the questionnaires, receive the replies, and submit the data to the NACR database. Information from these questionnaires, which includes medical history, demographics, smoking, physical activity, and mental and physical wellbeing, is entered directly into the NACR database either manually through a secure online portal provided by NHS Digital or indirectly by importing data into the system from other third-party applications or a bespoke local database (NACR, 2017; NACR and NHS Improvement, 2012). Pseudonymised data are passed to the NACR team at the University of York, which uses the data to produce annual reports and ad-hoc reports for individual programmes on request. Cardiac rehabilitation programmes can also view and download data for local analysis, as well as requesting bespoke reports from the NACR. Participation in the NACR is voluntary and not all CR services use the electronic database.

3.2.1.2. Annual postal survey of programmes

The NACR team at York sends questionnaires out to the coordinators of every CR service on the register they maintain, receive the responses, collate the results, and include them in annual reports. An annual postal survey collects information on organisational elements such as staffing and activity and for programmes that are not yet linked up to the electronic database.

3.2.1.3. e-survey

The NACR team at York also collects information by sending out e-survey questionnaires aimed at addressing key service delivery issues.

3.2.2. NACR dataset

The NACR dataset consists of numerous data fields, and data are collected via a set of questionnaires completed by patients themselves or by the CR programme team at clinical appointments/rehabilitation sessions with the patient (NACR, 2017). The data collected includes:

- demographics (age, gender, marital status, ethnicity)
- initiating event, which can be a diagnosis such as myocardial infarction (MI), a treatment such as percutaneous coronary intervention (PCI) or a combination of MI and PCI; additional information includes comorbidities, acute events during CR, previous cardiac events, and the reason for CR
- waiting time (date of initiating event, date referred to CR, date started CR, date completed CR)
- clinical information (blood pressure, weight, height, cholesterol, drugs)
- lifestyle information (smoking status, level of physical activity, physical fitness)
- health-related quality of life (scored via Dartmouth Primary Care Cooperative Information Project (COOP) questionnaire)

- mental health (anxiety and depression as scored via the Hospital Anxiety and Depression Scale)
- duration of CR (length of programme and number of sessions)
- dropout rates (reason for not completing CR)
- CR information (each phase has a separate record, which includes type of CR received, start and end dates, reasons for not taking part or not completing CR)
- assessment records (three assessments in total: assessment 1 is completed before the core CR programme begins, assessment 2 is after CR is completed, usually after the last session, and assessment 3 is 12 months after CR is completed; these assessments include drugs that the patient is taking at each assessment, cardiovascular risk factors (weight, body mass index (BMI), blood pressure, cholesterol, physical activity level, smoking status), Hospital Anxiety and Depression Scale scores, Dartmouth COOP score, and employment status.

3.3. Ethics approval

The NACR has approval to collect patient-identifiable data without explicit consent from individual patients from the Health Research Authority's Confidentiality Advisory Group through NHS Digital (under Section 251 of the NHS Act 2006) (NACR, 2017). The NHS has in place an 'exemption from consent' process, by which clinical and personal data are entered into NHS systems without explicit consent. Patients are informed about the purposes of the audit, how the information will be used through face-to-face communication, and about the assessment questionnaires that are used to collect data for the audit. Information on the front of these questionnaires provides patients with details of why the data are being collected, how they are used, who can see them, and their right to opt out without any effect on their treatment. Section 251 approval covers the roles of the BHF, NHS Digital, and NACR team and ensures the highest quality procedures for collecting, sharing, and using only agreed data about a patient's CR

experience. This ethical approval and the role of the national audit are reviewed each year by the Health Research Authority's Confidentiality Advisory Group.

Ethics approval was not specifically required for the cohort studies undertaken for the research reported in this doctor of philosophy (PhD) thesis, because the research only used pseudonymised data.

3.4. National Certification Programme for Cardiac Rehabilitation in the UK

In July 2015, the NACR and BACPR, as the UK's national body for CR, launched a National Certification Programme for CR (NCP_CR) for the UK, which would be based mainly on assessment of quality-assured patient-level NACR data and certification of whether CR programmes meet service standards for CR delivery (Furze, Doherty and Grant-Pearce, 2016). The standards for certification were developed by a group of academic and clinical experts in CR and based on the published BACPR standards (BACPR, 2017). The standards are developed from median UK data in the NACR annual report and are updated every other year when new NACR data are published (NACR, 2017).

3.5. Study design

All studies for this PhD research involved a retrospective observational study design using data derived from the NACR, with an additional prospective e-survey questionnaire in order to gain insights into the quitting smoking support offered to patients participating in CR in the UK.

Data from 1 April 2013 to 31 March 2014 (the first year of the NCP_CR standards), which have been validated, were extracted and used to support analysis of the studies reported in Chapter 4. The latest three years of NACR data from 1 April 2013 to 31 March 2016 were also extracted and validated and used for the studies in Chapter 5.

This PhD research included patients who:

a) started CR
b) were assessed at baseline
c) had follow-up data at an assessment after CR.

All of the research studies reported in this thesis follow the guidelines of the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) (von Elm et al., 2008), which were developed to provide recommendations on what should be included in an accurate and complete report of an observational study.

3.6. Variable definitions

The variables used in this research were collected as part of the NACR routine data and are defined below (Figure 3.2). A variety of baseline characteristic variables were recorded in the assessment before starting CR (pre-CR) and outcome variables were recorded in the assessment immediately after CR (post-CR). This research included pre- and post-CR variables in the database. From information provided, new variables that could be used in this research were created, which are described in greater detail in Chapters 4 and 5. The NACR assessment questionnaire on which variables were collected and used is given in

Appendix 2. Further detail on how the new variables were developed from the information available in the NACR dataset is given below.

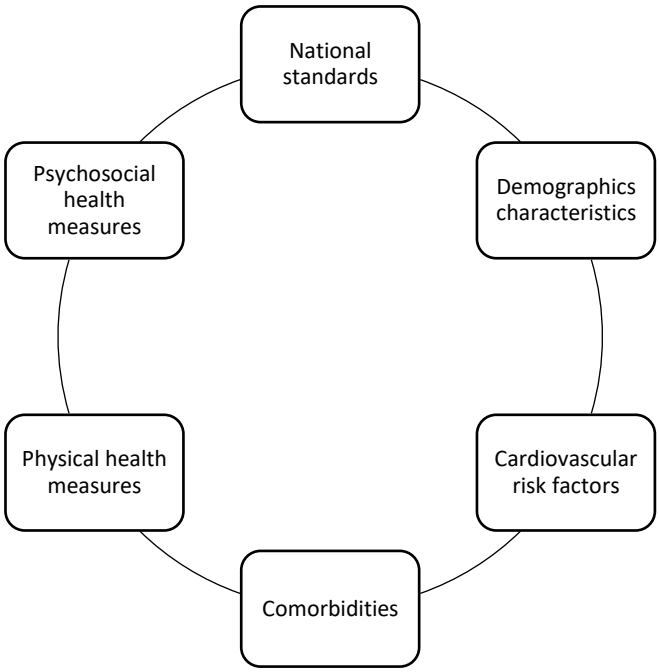


Figure 3.2. Study variables

3.6.1. National standards

The BACPR has developed standards and core components required for delivery of CR within the UK (BACPR, 2017). The standards defined by BACPR are an achievable level for CR programmes to aim for while still delivering a good quality standard of CR service and are derived from the national averages in the latest published version of the NACR annual report (BACPR, 2017; Furze, Doherty and Grant-Pearce, 2016; NACR, 2015). The BACPR/NACR's NCP_CR is used to assess whether a CR programme meets the recommended quality of service delivery standards across the UK (Furze, Doherty and Grant-Pearce, 2016). Within the NCP_CR report (see Appendix 3), quality of service delivery is compared with six standards that are deemed important to define the delivery of high-quality CR programmes, and these are used alongside 95% confidence intervals (CIs) as part of the certification criteria derived from all three countries that participate in the audit (England, Wales, and Northern Ireland). The NCP_CR's quality service delivery criteria to define high-quality CR programmes were based on NICE clinical guidance and

national CR statistics for the UK from the NACR 2015 report, which was the first year of the NCP_CR (NACR, 2015; NICE, 2013c, 2010c).

The BACPR (2017), NICE (clinical guideline (CG) 172 and CG108) and Scottish Intercollegiate Guidelines Network (SIGN) (2017) recommend that CR programmes should be offered early and should be underpinned by assessment before starting and on completion of the programme (BACPR, 2017; SIGN, 2017; NICE, 2013c, 2010c). The duration and frequency of CR, based on NICE guidance (NICE CG172) and a Cochrane review by Anderson et al., should ideally be 12 weeks (or no less than eight weeks as recommended by BACPR) at a frequency of twice per week (BACPR, 2017; Anderson et al., 2016; NICE, 2013c). Consequently, it is possible to compare the available data in the NACR database with recommended standards.

An example of using the national average to set a standard is Standard 4 of the BACPR's standards published in 2017, which states that provision of CR "…shall occur within 10 working days of receipt of referral"; however, most CR programmes are not yet delivering early CR (BACPR, 2017; NACR, 2015). The national average (median) figure from the 2015 NACR report from referral to start of CR was 38 days for people after MI or PCI, so this was the figure used as the standard for this aspect of certification in 2015 (NACR, 2015).

3.6.1.1. Quality of cardiac rehabilitation

The NCP_CR report includes six measures deemed to be important to define the delivery of high-quality CR programmes. A CR programme was given a score of 1 for each standard that it achieved, with a total score that ranged from 1 to 6. The quality of delivery of CR programmes was categorised into three groups: scores of 5–6 represented high quality, scores of 3–4 represented middle quality, and scores of 1–2 represented low quality. If a programme did not meet any of the six criteria, they were considered to have failed.

3.6.1.2. Confidence interval

Within the six standards used in this research to define high-quality CR programmes, five standards were assessed by the 95% CI of the mean/median value, which is the range of values within which the mean/median resides. The five standards assessed in this way are:

- mean percent of patients attending CR with recorded assessment before starting formal CR programme (Ax1)
- mean percent of patients attending CR with a recorded assessment after completing CR programme (Ax2)
- median waiting time from referral to start (TRS) of CR after MI/PCI (TRS_CR/MIPCI)
- median TRS of CR after CABG (TRS_CR/CABG)
- median duration of CR programmes.

3.6.1.3. Priority groups

The BACPR and NACR highlight and recommend offering CR to at least four priority groups in which there is a need to improve uptake: those who have had MI, PCI, CABG and those with HF (BACPR, 2017; Furze et al., 2016; NACR, 2015).

3.6.1.4. Timing of cardiac rehabilitation

Time from referral to start of CR, delivered soon after discharge from acute services or as part of a step change in clinical treatment for CVD, is a key recommendation of NICE CG172 and SIGN guidelines and forms one of the BACPR's standards (BACPR, 2017; SIGN, 2017; NICE, 2013c).

3.6.1.5. Pre- and post-cardiac rehabilitation assessment

Assessment is another key recommendation of NICE CG172 and SIGN guidelines and also forms one of the BACPR's standards (BACPR, 2017; SIGN, 2017; NICE, 2013c).

The BACPR and numerous clinical guidance and position statements stress the importance of pre- and post-CR assessment, and these are seen as essential if patients are to experience a tailored intervention and achieve the expected outcomes.

3.6.1.6. Duration of cardiac rehabilitation

The BACPR and NACR's recommended duration of CR is eight weeks (BACPR, 2017; NACR, 2015).

3.6.2. Demographics characteristics

This section describes the demographic variables collected in the NACR and how some were used and adapted for the research reported in this thesis.

3.6.2.1. Patients who started cardiac rehabilitation

To calculate the number of patients who started CR in a programme in a period of time by the NACR database, the number who started were counted using date starting participation. This is the date of first active participation in an agreed plan of CR – that is, when the patient does something observable such as a structured home exercise plan (NACR, 2015). For a group-based programme, it is the date of the first attendance at the group, and for a home-based or individualised programme, it is the date on which the patient undertook their supported activity at home. The patient may have been seen on the ward, in a clinic, or given general advice at a home visit.

3.6.2.2. Delivery of CR by a multidisciplinary team

The BACPR/NACR recommends that the six core components of CR are delivered by a qualified multidisciplinary team (MDT) of skilled and experienced staff who aim to support a multi-morbid patient population to achieve optimal outcomes from CR (BACPR, 2017; NACR, 2015). The BACPR/NACR state that a CR programme needs to include at least

three different professions in the team (BACPR, 2017; NACR, 2015). Staffing information in the NACR dataset include the number and total hours of the following staff:

- Nurse specialist
- Physiotherapist
- Dietician
- Practitioner psychologist
- Social worker
- Counsellor
- Physician with special interest in prevention and rehabilitation
- Healthcare assistant
- Secretary
- Administrator
- Exercise specialist
- Occupational therapist
- Pharmacist
- Physiotherapy assistant.

Using the staffing data information provided, two new variables were created: total staff hours and a dichotomous MDT variable (MDT with more than or equal three member of staff and other).

3.6.2.3. Age at initiating event

Age is derived from the year of birth recorded in the NACR (NACR, 2015). Age at initiating event (years) is calculated from date of birth difference to initiating event date.

3.6.2.4. Gender

The NACR 2015 audit divided gender into two categories (NACR, 2015):

- Male
- Female.

3.6.2.5. Marital status

The NACR 2015 audit divided marital status into six categories (NACR, 2015):

- Single
- Married
- Permanent partnership
- Divorced
- Widowed
- Separated.

At 70%, married was the dominant social status in the NACR 2015 report, with the other forms of marital status ranging from 1% to 11%. The six categories of marital status were used to create a new dichotomous marital status variable ‘partnered’ or ‘single’, with patients who were single, divorced, widowed, or separated recorded as single and those who were married or in a permanent partnership recorded as partnered.

3.6.2.6. Ethnic group

Ethnic group is a self-reported category in the NACR database (NACR, 2015). In the 2015 NACR report, the ethnicity of patients attending CR was predominately White British (81%).

To simplify analyses, the ethnicity information provided was used to create a new dichotomous ethnicity status variable ‘White’ or ‘Other’, with patients who were white

British, Irish, or any other white background recorded as white and all other ethnicities recorded as ‘Other’.

3.6.2.7. Work and employment

Employment status is a self-reported category in the NACR database (NACR, 2015). The dominant employment status in the 2015 report was retired (56%), followed by employed (27%) when part-time and full-time employment were combined.

The NACR 2015 audit divided employment status into the following status (NACR, 2015):

- Employed full time
- Employed part time
- Self-employed full time
- Self-employed part time
- Unemployed/looking for work
- Government training scheme
- Looking after family/home
- Retired
- Permanently sick/disabled
- Temporarily sick/injured
- Student
- Other reason not working.

The employment status variables were used to create a new dichotomous employment status variable ‘employed’ or ‘unemployed’. Patients who were employed full- or part-time or self-employed full- or part-time were recorded as employed, and all other employment statuses were recorded as unemployed.

3.6.2.8. Social deprivation

The English Index of Multiple Deprivation (IMD), the official measure of relative deprivation for small areas (or neighbourhoods) in England, is used to evaluate the role of social deprivation, which is linked to the NACR database (Department for Communities and Local Government, 2015). The IMD combines scores across seven diverse domains of deprivation – income; employment; education, skills, and training; health and disability; crime; barriers to housing and services; and living environment – with each domain having its own weight (Department for Communities and Local Government, 2015). The IMD ranks every small area in England, known as lower-layer super output areas (LSOAs), from 1 (most deprived area) to 32,844 (least deprived area) and publishes deprivation 'deciles,' calculated by dividing the 32,844 ranked subareas into 10 equal groups, alongside the ranks (Department for Communities and Local Government, 2015). The groups are ranked from 1 to 10, so an LSOA in group 1 is among the most deprived 10% of LSOAs nationally and an LSOA in group 10 is among the least deprived 10%. The IMD has been criticised as a measure of individual deprivation (Shaw et al., 2007), and it is undoubtedly cruder than individual measures of social class, such as those used in the Whitehall II (Hemingway et al., 2000); however, it has been found to be strongly associated with CHD and mortality (Hippisley-Cox et al., 2010; O'Flaherty et al., 2009).

3.6.3. Comorbidities

The 2015 NACR defined comorbidities as any of 19 conditions commonly associated with CR conditions that make them eligible for CR, such as angina, diabetes and cancer, and these are routinely collected by the NACR and reported in the national report (NACR, 2015). The comorbidity profile for CR patients include the following:

- Angina
- Arthritis
- Cancer
- Diabetes
- Rheumatism
- Stroke
- Osteoporosis
- Hypertension
- Chronic bronchitis
- Emphysema
- Asthma
- Claudication
- Chronic back problems
- Anxiety
- Depression
- Family history of CVD
- Erectile dysfunction
- Hypercholesterolaemia/dyslipidaemia
- Other comorbidity.

The profile of patients eligible for CR is becoming increasingly multimorbid across a range of different conditions. Multimorbid presentation is an important consideration when carrying out baseline assessments and tailoring an intervention for patients. According to the NACR 2015 report, hypertension was the most dominant comorbidity, affecting 64% of patients participating in CR, followed by hypercholesterolaemia and diabetes (NACR, 2015). Previous analysis of NACR data for 2013 has shown that the benefit for patients following CR decreases as the number of comorbidities increases (NACR, 2013).

The comorbidity profile for each CR patient was used to create a new variable that is the sum of a patient's comorbidity conditions. A percentage of each comorbidity in a programme was also calculated by diving the number of patients with a comorbidity by the total number of patients who started a CR programme.

3.6.4. Risk stratification

Risk stratification is a multifactorial measure used to establish prognosis of future major cardiac events or exercise complications by using all relevant patient information, e.g. left ventricular ejection fraction, history of arrhythmia, symptoms, and functional capacity (BACPR, 2017; ACPICR, 2015; AACVPR, 2013; BACR, 2006). Mortality risk within the first year is 2% for an individual assessed as low risk, 10–25% for an individual assessed as moderate risk, and >25% for those assessed as high risk (see Appendix 4) (BACPR, 2017; ACPICR, 2015; AACVPR, 2013; BACR, 2006).

3.6.5. Anthropometric measurements

Anthropometric measurements that are available in the NACR database (NACR, 2015) include:

- Weight (kg)
- Height (m)
- BMI (kg/m^2)
- Waist (cm).

If BMI is ≥30 kg/m^2, a person is considered to be obese (Centers for Disease Control and Prevention, 2016).

3.6.6. Smoking

Smoking status in the NACR database is recorded using information obtained from patient self-report questionnaires (NACR, 2015). The patient was allocated to the relevant category based on their status:

- Never smoked
- Ex-smoker
- Stopped smoking since event
- Currently smoking.

The smoking status recorded before and after CR for each patient in the NACR was used to create a new dichotomous variable ‘continued smokers’ or ‘quitters’, which was used for the smoking outcome study (Chapter 5). Patients were defined as continued smokers if they were current smokers in the pre-and post-CR assessments or quitters if they were current smokers at the pre-CR assessment but had no smoking status at the post-CR assessment. Figure 3.3 gives a graphic representation of this variable definition; the findings are given in Chapter 5.

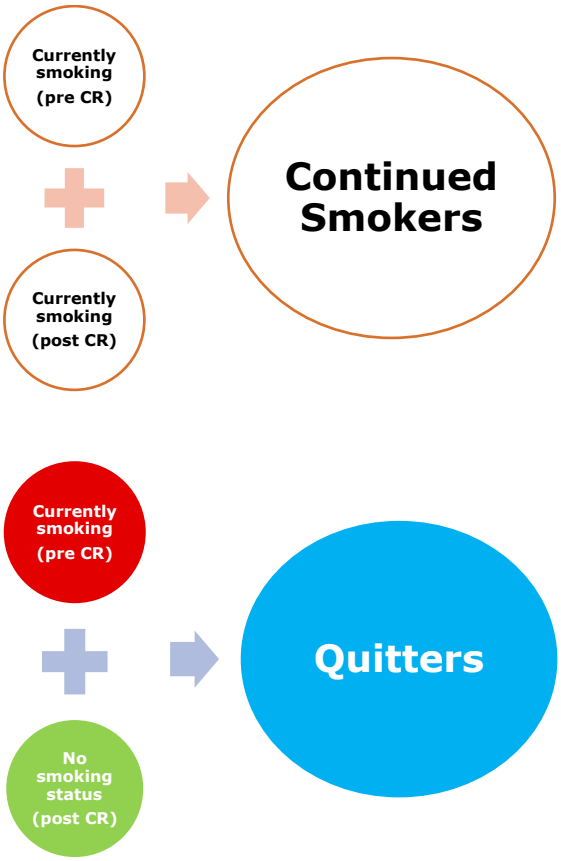


Figure 3.3 Graphic representation of smoking groups

3.6.7. Blood pressure

Blood pressure (BP) measurements were included in the NACR (NACR, 2015):

- Systolic blood pressure (SBP)
- Diastolic blood pressure (DBP).

If BP is ≥140/90 mmHg, a patient is considered to have hypertension (NICE, 2013b). The pre- and post-BP measurements for each CR patient were used to create a new variable, in which hypertension (BP ≥140/90) was categorised as Yes or No.

3.6.8. Alcohol

Alcohol consumption status in the NACR database is recorded using information obtained from patient self-report questionnaires about weekly alcohol consumption (NACR, 2015). Where a weekly unit amount was recorded, the patient was allocated to the relevant category based on their gender and the recommended weekly units.

The NICE guidelines recommend that men should not regularly drink more than 21 units of alcohol per week and women should not regularly drink more than 14 units of alcohol per week (NICE, 2010a).

3.6.9. Physical fitness and activity

Physical activity status in the NACR database is recorded using information obtained from patient self-report questionnaires about weekly physical activity (NACR, 2015). Where a weekly type and time of activity were recorded using the Chief Medical Officer's Physical Activity Questionnaire (

Appendix 2), the patient was allocated to the relevant category based on the recommended UK physical activity guidelines, which recommend regular moderate physical activity of at least 30 minutes duration on average five times a week or equivalent – e.g. 150 minutes over seven days and 75 minutes of vigorous exercise a week (Bull et al., 2010). Exercise tests such as the incremental shuttle walking test and six-minute walk test are used to assess physical fitness in patients attending CR (Gremeaux et al., 2011).

3.6.9.1. Incremental shuttle walking test

The incremental shuttle walking test (ISWT) is an externally paced maximal exercise test that evaluates physical fitness based on the distance walked around a 10-metre course according to different speeds dictated by an audio signal (Singh et al., 1992). The ISWT

involves walking on the flat between two markers 10 metres apart; at the end of each minute, the speed is increased through a series of pre-recorded signals until the participant can no longer continue. The maximum duration of the test is 20 minutes. Each stage of the test is related to a particular metabolic equivalent, with 1 MET equivalent to oxygen uptake (VO_2) of 3.5 ml/kg/min (Pescatello et al., 2014). The primary outcome of the ISWT is distance measured to the nearest 10 metres. The information is entered into the NACR as the number of metres walked and the number of minutes walking.

3.6.9.2. Six-minute walk test

The six-minute walk test (6MWT) is a widely used validated assessment of physical fitness and prognosis in patients with cardiorespiratory diseases, because it is reproducible, well tolerated in patients with CVD, and can be used to assess CR programmes (Gremeaux et al., 2011; Nogueira et al., 2006; Gayda et al., 2004; Verrill et al., 2003). The 6MWT is a self-paced test of walking capacity, in which patients are asked to walk on a measured track or walkway at a comfortable pace for a maximum of six minutes. The 6MWT is recorded as part of the NACR (NACR, 2015). The distance in metres is recorded as the primary outcome, and the time to complete the walk is also recorded if the patient walks for fewer than six minutes.

3.6.10. Hospital Anxiety and Depression Scale

The Hospital Anxiety and Depression Scale (HADS) was devised more than 30 years ago by Zigmond and Snaith to measure anxiety and depression in a general medical population of patients (Appendix 5) (Zigmond and Snaith, 1983). The HADS questionnaire is simple, quick and easy to use. It is one of the tools NICE recommends for diagnosis of depression and anxiety (NICE, 2011a) and has been validated for initial diagnosis and to track progression of psychological symptoms (Snaith, 2003; Bjelland et al., 2002).

The HADS questionnaire comprises seven questions for anxiety and seven questions for depression and takes 2–5 minutes to complete. Although the anxiety and depression questions are interspersed within the questionnaire, it is vital that these are scored separately. Cut-off scores are available for quantification – for example, a score ≥8 has specificity of 0.78 and sensitivity of 0.9 for anxiety and specificity of 0.79 and sensitivity of 0.83 for depression (Table 3.1) (Bjelland et al., 2002).

Table 3.1 Hospital Anxiety and Depression Scale (HADS) score

Score	Description
0–7	Normal
8–10	Borderline abnormal
11–21	Abnormal

3.7. Statistical analysis

The analyses in this research were conducted using IBM Statistical Package for Social Sciences (SPSS) software statistics version 24 (IBM Corp, Armonk, New York, USA) using all available data from CR patients and programme centres across the UK to minimise selection bias. A value of p≤0.05 was considered to be statistically significant. Normal quantile–quantile plots were used to check for variables normality, (Bland, 2000). Some statisticians advocate not using formal tests to check for equal variances, as these are not robust against non-normality, but rather to use a rule of thumb suggested by simulation studies that if the ratio of the maximum (Max) standard deviation (SD) estimates to the minimum (Min) SD does not exceed 2 for the assumption to hold (Dean and Voss, 1999). Effect sizes are reported. Phi and Cramér's V are a measure of the effect size or strength of association of a nominal by nominal relationship (Cohen, 1988).

Phi and Cramér's V ranges in value from 0 to +1 with a value of 0 indicating no association and a value of 1 indicating complete association (Cohen, 1988). Partial eta squared (η^2) also have been reported as an effect size. Cohen's d test was used as a measure of the effect size to indicate the mean difference between two groups in standard deviation units (Cohen, 1988). It shares the same range as standard deviation (–3.0 to 3.0). Variables were considered in the regression equation according to their association (Field, 2018).

Cardiac rehabilitation programmes were aggregated to identify those that met the standard criteria (see Chapter 4). A chi-squared (χ^2) test was conducted to determine the association between a CR programme meeting each standard and the programme's quality category (low, medium or high quality) overall and between the three countries in the NACR (England, Wales, or Northern Ireland) (Cohen, 1988). Data were also analysed using the one-way analysis of variance (ANOVA) test to determine whether the standard criteria and demographic characteristics of CR programmes were different among quality categories (low, medium or high quality) and between the three countries, and results from the Games-Howell post-hoc test were used for multiple comparisons. Two multinomial logistic regression models were also used to test for independent predictors of high-quality delivery of CR.

Frequency tables were generated to categorise CR patients as smokers and quitters according to their recorded pre- and post-CR smoking status. Differences in baseline characteristics were then compared using independent-samples t-test for continuous variables or chi-square test (χ^2) for categorical variables. In addition, a χ^2 test for association was conducted between baseline sociodemographic and clinical characteristics and smokers and quitters participating in CR (Cohen, 1988). Binary logistic regression was used to predict the probability of quitting smoking among CR attenders. Variables were considered in the equation for the binary logistic analysis based on the extent of association between smokers and quitters (Field, 2018). Such a

comparison gives a sense of the importance of distinguishing between patients who continue to smoke and patients who quitted smoking and how this might vary between them in term of outcomes. This comparison is presented, separately for continued smokers and quitters, in Chapter 5. A multiple linear regression model was constructed to understand the effect of continuing smoking or quitting smoking on CR outcomes, with adjustments for the outcome CR score by the baseline CR score for each characteristic. The potential clustering is incorporated within centre into the predictors of quitting smoking and CR outcomes between smokers and quitters analyses which presented within Chapter 5. These analyses were conducted using Stata version 15.0 (StataCorp LLC, College Station, Texas, USA).

For all variables, the extent of missingness and the number of available observations for each variable within the dataset are given in Chapters 4 and 5. The mean and standard deviation are presented for continuous variables, while the numbers in each response category and proportion are presented for categorical variables. Only significant results are fully reported in the chapters' result sections. Bold text in the tables indicates $p \leq 0.05$.

3.7.1. Handling missing data

The NACR includes many variables and many data are missing due to how the NACR collects data, although the NACR team has made massive efforts to improve the quality of the data collected, which can be simply noted when comparing recent data quality to those five years ago. However, we cannot delete incomplete records because this amounts to a substantial loss of costly collected data. Missing data are a substantial problem in epidemiological and clinical research (Sterne et al., 2009). With any cohort study, missing data in several variables often lead to a potential bias and a substantial loss of power and precision due to exclusion of a substantial proportion of the original sample (Kang, 2013). Researchers usually address missing data by including only

complete cases in the analysis – that is, those patients who have no missing data in any of the variables required for that analysis.

Both prospective and retrospective cohort studies have problems with patients lost to follow up and missing data among those who are followed, but the effects of missing data are likely to be different for the two types of study. With the relatively small sample sizes in cohorts, loss of precision and power due to missing data can become an important issue, while the bigger issue for the large sample sizes in NACR cohorts is potential information bias. The risk of bias due to missing data depends on the reasons why data are missing (Kang, 2013).

Rubin first identified the importance of the mechanism leading to missing data when determining appropriate approaches to dealing with such missingness (Sterne et al., 2009; Rubin, 1976). He defined the following three kinds of missing data:

1. Missing completely at random – missing values are not systematically different from the observed values and the reason for missingness is unrelated to the factor being measured, which means that the missingness is not related to the subject of the missing data. For example:
    - a smoking record is not recorded for a patient because the CR programme staff missed work because of a transport strike
    - a questionnaire might be lost in the post
    - BP measurements may be missing for technical reasons
2. Missing at random – missing values are systematically different from the observed values, which can be explained by differences in observed data, and the missingness is to do with the patient but can be predicted from other information about the patient as it is not specifically related to the missing information. For example:

- a CR patient does not attend a pre-CR assessment because the patient is (genuinely) ill; this might be predictable from other data about the patient's health, but it would not be related to what would have been measured had the patient not been ill
- young men are more likely to have a missing smoking record than young women because they do not attend for contraceptive advice and therefore have a smoking history taken prior to prescription of the birth control pill
- missing BP measurements may be lower than measured BP, but only because younger people may be more likely to have missing BP measurements.

3. Missing not at random – missing values are systematically different from the observed values and the reason for missingness is directly related to the factor being observed, which means the missingness is specifically related to what is missing. For example:
    - a CR patient does not attend a physical fitness test because their foot has been amputated
    - patients may be less likely to have their alcohol consumption recorded because some patients avoid attending CR programmes in case they are challenged about their alcohol consumption
    - patients with high BP may be more likely to miss assessments because they have headaches.

There are situations in which analyses of complete cases will not lead to bias. When missing data only happen in an outcome variable that is measured once in each patient, such analyses will not be biased as long as all variables associated with the outcome being missing can be included as covariates (under a missing at random assumption) (Sterne et al., 2009; Steyerberg and van Veen, 2007; Allison, 2000). Missing data in predictor variables do not lead to bias in analyses of complete cases if the causes for

the missing data are irrelevant to the outcome (Sterne et al., 2009; Steyerberg and van Veen, 2007; Allison, 2000). Unfortunately, it is not possible to distinguish between missing at random and missing not at random using observational data. Hence, there are several approaches to dealing with missingness: using complete-case analysis, obtaining missing data, or replacing missing data with imputed values. Each approach has specific drawbacks, some of which are outlined in Sterne et al., and may or may not be appropriate depending on the reason for missingness (Sterne et al., 2009).

When it is conceivable that data are missing at random but not completely at random, analyses based on complete cases may be biased. Such biases can be overcome using methods such as multiple imputation or expectation maximisation methods that allow patients with incomplete data to be included in analyses (Schafer, 1997; RUBIN, 1987). In practice, multiple imputation and expectation maximisation are sometimes implemented differently in ways that can affect the results of data analysis (Collins, Schafer and Kam, 2001).

3.7.1.1. Multiple imputation

Multiple imputation is a missing data approach that provides valid statistical inferences under the missing at random condition. Specifically, multiple imputation was proposed to impute missing data while acknowledging uncertainty by generating a set of plausible values for each unobserved datapoint instead of substituting a single value for each case of missing data, thus resulting in complete datasets, each with one unique estimate of the missing values (Dong and Peng, 2013; Little and Rubin, 2002).

This approach begins with prediction of the missing data using existing data from other variables (Sinharay, Stern and Russell, 2001). The missing values are then replaced with the predicted values, and a full dataset – the imputed dataset – is created. This process iterates repeatability and makes multiple imputed datasets (hence the term ‘multiple imputation’). Each multiple imputation dataset produced is then analysed using the

standard statistical analysis procedures for complete data and gives multiple analysis results. Combining these analysis results produces a single overall analysis result.

The benefit of multiple imputation is that it incorporates the uncertainty due to the missing data in addition to restoring the natural variability of the missing values (Kang, 2013). Incorporating uncertainty is made by producing different versions of the missing data and observing the variability between the imputed datasets. In sum, multiple imputation handles missing data in three steps:

1. imputes missing data number of times to produce complete datasets
2. analyses each dataset using a standard statistical procedure
3. combines the results into one using formulae from Rubin (1987) or Schafer (1997) (Schafer, 1997; RUBIN, 1987).

Multiple imputation analyses have pitfalls. An article in the *British Medical Journal* reported the development of the QRISK tool for predicting cardiovascular risk based on a large general practice research database (Hippisley-Cox et al., 2007). The researchers correctly identified a difficulty with missing data in their database and used multiple imputation to handle the missing data. However, in their published prediction model, cardiovascular risk was found to be unrelated to cholesterol (coded as the ratio of total to high-density lipoprotein cholesterol), which was surprising (Peto, 2007). The authors have subsequently clarified that there was a clear association between cholesterol and cardiovascular risk when they restricted their analysis to individuals with complete information (no missing data). This demonstrates that is important to be aware of practical implications that can occur in multiple imputation analyses.

The findings of a study that examined patterns and extent of missing data in The Health Improvement Network (THIN) – a UK primary care database – and explored the use of multiple imputation suggest that some data, such as height, weight and BP, are missing at random, while others, particularly reported smoking and alcohol, are missing not at

random, which renders multiple imputation inappropriate for at least these latter variables (Marston et al., 2010).

Some data are inherently missing not at random and, in such cases, multiple imputation may give misleading results, as bias in analyses based on multiple imputation may be as big as or bigger than the bias in analyses of complete cases (Sterne et al., 2009).

Multiple imputation is computationally intensive and involves approximations. Some algorithms need to be run repeatedly to yield adequate results, and the required run length increases when more data are missing.

Although these information biases are also problematic for complete-case analyses, it was considered better not to compound the missing data problem with multiple imputation wrongly applied in this research.

3.7.1.2. Expectation maximisation

Expectation maximisation is an approach to missing data that can be used to create a new dataset in which all missing values are imputed with values estimated by maximum likelihood methods (Dempster, Laird and Rubin, 1977). This approach does not 'fill in' missing data but rather estimates the parameters directly by maximising the complete data log likelihood function (Dempster, Laird and Rubin, 1977). For the expectation maximisation method, a predicted value based on the variables that are available for each case is substituted for the missing data. The expectation maximisation approach has many attractive properties. First, an expectation maximisation estimator is unbiased and efficient when the missing mechanism is ignorable (Graham, J.W., 2003). Second, the expectation maximisation algorithm is simple and easy to implement (Dempster, Laird and Rubin, 1977) and stable (Couvreur, 1997). Third, it is straightforward to compare different models using the likelihood ratio test. An important characteristic of the expectation maximisation imputation is that when the new dataset with no missing

values is generated, a random disturbance term for each imputed value is incorporated to reflect the uncertainty associated with the imputation (Kang, 2013).

However, expectation maximisation imputation has some disadvantages. This approach can take a long time to converge, especially when a large proportion of data are missing, and it is too complex to be acceptable by some statisticians.

3.7.1.3. Comparing missing imputation and expectation maximisation methods

Missing imputation and expectation maximisation make similar assumptions and have similar statistical properties. A study discussed and demonstrated the results and performance of these two missing data methods and contrasted them with the complete dataset in terms of bias and standard error (SE) by applying them to a real-world dataset (Dong and Peng, 2013). Results showed that the two methods yielded similar estimates at 20% and 60% missing rates. In terms of SEs, expectation maximisation outperformed multiple imputation by providing slightly smaller SEs. This finding is to be expected because expectation maximisation does not involve the randomness of multiple imputation. The authors therefore suggested that a data analyst needs to make sure that the imputation model is general enough to capture meaningful relationships in the dataset. However, if a researcher is clear about the parameters to be estimated, expectation maximisation is a better choice, because it does not introduce randomness due to imputation into the data and is more efficient than multiple imputation.

Among the two methods, SEs obtained from expectation maximisation were closer to those based on the complete data than multiple imputation (Dong and Peng, 2013). This finding is to be expected, because multiple imputation incorporates the uncertainty associated with plausible missing data estimates into the SE. Other research has also documented the superior power of expectation maximisation compared with multiple

imputation (Graham, Olchowski and Gilreath, 2007; Schafer and Graham, 2002; Collins, Schafer and Kam, 2001).

Multiple imputation is rapidly becoming a popular method for handling missing data, but expectation maximisation has optimal statistical properties and several advantages over multiple imputation. The most important advantage is that there is no potential conflict between an imputation model and an analysis model. Using the expectation maximisation approach, everything is done under a single model and it produces a deterministic result. By contrast, multiple imputation gives a different result every time it is run, because random draws are a crucial part of the process. This variability is reduced by imputing more datasets, but it is not always easy to know how many datasets are enough. Expectation maximisation is also asymptotically efficient, which means that the SEs of expectation maximisation estimates in large samples are as small as possible. On the other hand, the only way to get asymptotic efficiency with multiple imputation is to do an infinite number of imputations – something that is clearly not possible. For large samples, expectation maximisation therefore seems to have a clear advantage.

To avoid the pitfalls of multiple imputation, the analysis results of patients participating in CR were compared from complete-case data and an analysis of all data with missing values was handled through expectation maximisation (Schafer, 1997). There is no established cut off from the literature regarding an acceptable percentage of missing data in a dataset for valid statistical inferences (Dong and Peng, 2013). Patient variables with more than 60% missing values were eliminated from the dataset and only variables with 10–60% of missing values were imputed (Dong and Peng, 2013). Expectation maximisation analyses are presented in the results section of Chapter 5, alongside the original data results. Results of both imputed and complete cases analyses are fully reported. The number of missing values is reported for each variable in addition to the number of cases with complete data.

3.7.2. Absolute deviation around the median

Variables often contain outliers that have unusually large or small values when compared with others in a dataset. Outliers can be caused by incorrect measurements, including data entry errors, or by coming from a different population than the rest of the data. If the measurement is correct, it represents a rare event. The main reason to find outliers is the influencing assumptions of a statistical test – for example, outliers violating the normal distribution assumption. Outliers can be detected by determining an interval spanning the median – the most robust dispersion/scale measure when a dataset has outliers – is easier to implement than the mean and standard deviation, which are particularly sensitive to outliers (Leys et al., 2013). The median plus or minus three times the absolute deviation around the median (Leys et al., 2013) was used to detect outliers in the outcomes study (see Chapter 5). Pre-and post-CR values with more than 3 ± mean absolute deviation (MAD) percentage change for each characteristic were eliminated from the analysis.

3.8. e-Survey

Smoking cessation is a key part of secondary prevention and rehabilitation and is included in the BACPR's core components of lifestyle risk factor management (BACPR, 2017), but there are no published reports on CR services delivered to support CR patients to stop smoking. As part of the NACR, an exploratory, cross-sectional, 11-item audit-based e-survey was therefore sent to smoking cessation services identified as part of CR programmes in the UK (see

Appendix 6). All but one of the survey items were designed in a binary manner calling for a yes/no response.

The sampling frame encompassed the ‘coordinators’ of the 224 CR programmes that enter their data electronically into the NACR, which includes programmes from Wales, England, and Northern Ireland. Scottish programmes do not participate in the NACR and not all CR programmes impute data (224/303 CR programmes participate in NACR) (NACR, 2017). All 224 coordinators that do impute data electronically were contacted via email with a link to the 11-item survey, and the most appropriate member of the CR team was asked to complete the questionnaire.

The CR services were contacted via email and asked to complete the online survey. Several reminders were sent out via email over a period of two months. Data collection took place in the summer of 2016 (May–July 2016). The response rate was 78% (172/224 CR programmes registered in the NACR).

Commonly used descriptive statistical parameters, including number of programmes, percentages, means or medians and standard deviations, were used in this research to explore the data and the questions.

3.9. Conclusions

This chapter has have described in detail the NACR dataset, which is the data source used in this research, including how the data are collected. It defines the variables used in this research and then explained the statistical methods used to describe the cohort. The decisions to use complete-case analysis in addition to handling missingness through the expectation maximisation method and using the absolute median deviation to detect outliers in outcomes study are justified. Finally, this chapter describes an e-survey about quitting smoking support offered to patients participating in CR.

Chapter 4 Quality of delivery of cardiac rehabilitation in the UK

4.1 Abstract

Background: Recent reviews highlight that cardiac rehabilitation (CR) is highly effective but warn that not all routine clinical practice is working to the recommended standards. Huge variability in quality of service delivery of CR in the UK and patient outcomes has consistently been reported.

Objectives: This study assessed the extent to which programmes meet national standards for the delivery of CR as part of the National Certification Programme for Cardiovascular Rehabilitation (NCP_CR), as well as ascertaining whether the variation in quality of CR delivery is associated with participants' characteristics.

Methods: This observational study compared data extracted and validated from the UK's National Audit of Cardiac Rehabilitation (NACR) for the period from 1 April 2013 to 31 March 2014 with six NCP_CR measures criteria. Programmes were given a score of 1 for each measure for which they met the criteria, with a total score ranging from 1 to 6. The quality of CR delivery was categorised into three groups: high (score of 5–6), middle (score of 3–4) and low (score of 1–2). A programme that did not meet any of the six criteria was considered to have failed. The study included a range of patient variables collected by the NACR: patient demographics, cardiovascular risk factors, comorbidities, physical and psychosocial health measures, and index of multiple deprivation.

Results: Data from 170 CR programmes revealed statistically significant differences among UK CR programmes. Based on the NCP_CR criteria, 30.6% of programmes were assessed as high quality, 45.9% as middle quality, and 18.2% as low quality; 5.3% failed

to meet any of the criteria. Programmes with high-quality ratings for delivery of CR had recruited more patients with comorbidities, including diabetes, stroke and asthma, and higher body mass index (BMI) than low- and middle-quality programmes. Patients who participated in high-quality CR programmes tended to be at high risk (e.g. increased waist size and high blood pressure); had high Hospital Anxiety and Depression Scale (HADS) scores; and were more likely to be smokers, have more comorbidities, and be in more socially deprived groups than patients in low-quality programmes. High-quality CR programmes had also recruited more patients with lower fitness levels than low-quality programmes. The chance that a CR patient with more comorbidities attended a high-quality programme was 2.13 and 1.85 times higher than the chance that the same patient attended a low- or middle-quality programme, respectively. The chance that a CR patient with higher BMI or with diabetes comorbidity attended a high-quality programme was 1.49 and 1.10 times higher than the chance that the same patient attended a low-quality programme, respectively. The chance that a CR patient with asthma comorbidity attended a high-quality programme was 1.19 times higher than the chance that the same patient attended a middle-quality programme.

Conclusions: This research shows that high levels of quality delivery are achievable in the era of modern cardiology and that many CR programmes are close to meeting standards. However, substantial variation exists throughout the UK, with some programmes performing below the recommended standards. National certification should be seen as a positive step to ensure that patients, irrespective of where they live, are accessing quality services. Mean total comorbidities, proportion of patients with diabetes or asthma and patients with higher BMI scores had they been recruited by CR programmes categorised as high quality.

4.2 Introduction

Previous chapters have described the evidence for modern cardiac rehabilitation (CR) and the general methods used for this research. This chapter ascertains the extent to which programmes meet national standards for the delivery of CR and assesses whether the variation in quality of CR delivery across the UK is associated with participants' characteristics.

Cardiovascular disease (CVD) is a major contributor to health inequity in the UK (Public Health England Epidemiology and Surveillance team, 2016). Mounting evidence from robust trials and registries has reinforced that CR is clinically beneficial and cost effective – with multifaceted secondary prevention services resulting in reduced cardiovascular morbidity and mortality in patients with CVD – and that CR should be offered to all eligible patients in a timely and appropriate manner (Shields et al., 2018; Sumner, Harrison and Doherty, 2017; Anderson et al., 2016; Rauch et al., 2016; Sagar et al., 2015; Dalal, Doherty and Taylor, 2015). Numerous clinical trials and systematic reviews over the past 20 years have shown the effectiveness of CR (Sumner, Harrison and Doherty, 2017; Anderson et al., 2016; Rauch et al., 2016; Dalal, Doherty and Taylor, 2015). International guidelines from the National Institute for Health and Care Excellence (NICE clinical guideline (CG) 172 and CG108) and leading American, British, and European cardiovascular professional associations, which are underpinned by Class I evidence, also recommend CR as an effective intervention for patients diagnosed with CVD (BACPR, 2017; SIGN, 2017; Piepoli et al., 2016; NICE, 2013c; Smith et al., 2011; NICE, 2010c). The British Association for Cardiovascular Prevention and Rehabilitation (BACPR), NICE, and National Certification Programme for CR (NCP_CR) all seek to ensure that routine provision of CR programmes closely resembles that delivered in effective clinical trials (BACPR, 2017; Furze, Doherty and Grant-Pearce, 2016; NICE, 2013c). The National Audit of Cardiac Rehabilitation (NACR), which is funded by the

British Heart Foundation (BHF), is a clinical audit that monitors service delivery and patient outcomes in CR services in the UK; according to the 2017 NACR report, 303 programmes delivered CR in the UK in 2015–16 (NACR, 2017). In 2015, the BACPR and NACR developed the NCP_CR, which set out to improve delivery of CR, showcase good services, and seek to ensure the effectiveness of routine provision of CR programmes through achievement of a quality level of service delivery across the UK (England, Wales, and Northern Ireland) (BACPR, 2017; NACR, 2017; Furze, Doherty and Grant-Pearce, 2016).

However, the largest UK-based randomised controlled trial of comprehensive CR in the modern era of medical management – 'Rehabilitation after myocardial infarction trial (RAMIT)' – found that CR does not reduce mortality or morbidity and has no beneficial effect on psychosocial wellbeing or lifestyle (West, Jones and Henderson, 2012). The negative findings of RAMIT have led to questions about the quality of delivery of UK-based CR programmes (West and Jones, 2013; Wood, 2012), and a recent clinical review of CR published in the *British Medical Journal* noted that CR is highly effective but warns that not all programmes are working to the standards (Dalal, Doherty and Taylor, 2015). Other authors have also noted that some forms of CR in routine practice are arguably suboptimal in terms of delivery, are less effective, and might not achieve outcomes expected in the modern era of CR (Dalal, Doherty and Taylor, 2015; Doherty and Lewin, 2012; West, Jones and Henderson, 2012; Wood, 2012).

Despite the strong evidence-based standards for delivery of CR services, it has become apparent from recent NACR reports that CR is not delivered equitably across the UK, and there is also huge variability in what constitutes CR in routine practice (NACR, 2017). The NACR showed that CR is being delivered later than recommended, is not underpinned by pre- and post-assessment, and is of shorter duration than the evidence suggests is effective (NACR, 2017; Anderson et al., 2016; NACR, 2016; Piepoli et al., 2016; NACR, 2015; Vanhees et al., 2012). The NACR is committed to promoting and

supporting quality service provision based on measurable indicators of successful delivery (NACR, 2017). The role played by patient characteristics in associating whether delivery of CR services is high, medium, or low quality remains unclear (Doherty et al., 2017). It therefore is important to assess whether the patients who attend CR programmes are the same across the three categories of delivery quality.

The principal aims of the analyses reported in this chapter are to:

1. assess the extent to which programmes meet national standards for the delivery of CR by evaluating quality of CR delivery against national averages in service delivery in the UK according to the NCP_CR
2. assess whether the quality of CR delivery and any variability are associated with the participating patients' characteristics.

4.3 Methods

The data sources, population, and variables are described in detail in Chapter 3 but are briefly summarised here for ease of reference. Any details of methods specific to the analyses in this chapter are also noted here.

4.3.1. Data source

The data source is described fully in Chapter 3. In brief, the analyses were conducted using individual patient data extracted from the UK's NACR database, which has approval to electronically collect anonymised patient data for a range of clinical variables under Section 251 of the NHS Act 2006, which is reviewed annually by NHS Digital (NACR, 2017; NHS, 2012). The audit is voluntary, supports direct entry of data within a secure online system, and collects local programme-level data on the delivery of CR alongside patient-level data on patients who are referred to and undergo CR in the UK.

Data collected include details of the initiating event, treatment type, risk factors, medications, patient demographics, and post-CR clinical outcomes.

The observational study reported in this chapter used validated NACR data that were collected from 1 April 2013 to 31 March 2014; this represents the first year of the NCP_CR standards criteria (see Appendix 3), which are based on the national averages reported by the NACR (Furze, Doherty and Grant-Pearce, 2016; NACR, 2015). Patients were included in the analyses if they started CR, were assessed at baseline, and had follow-up data at an assessment after CR. The observational study reported in this chapter followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines (von Elm et al., 2008).

4.3.2. Service delivery measures

The NCP_CR aims to achieve quality CR programmes across the UK by providing clear guidance on service delivery (available by emailing education@bacpr.com) based on patient-level and programme-level data extracted from the NACR as the NCP_CR report (Furze, Doherty and Grant-Pearce, 2016). The NCP_CR service delivery criteria are based on NICE clinical guidance and national CR statistics for the UK from the 2015 NACR report, which represents the first year of the NCP_CR criteria (NACR, 2015; NICE, 2013c, 2010c).

The NCP_CR report includes six measures deemed to be important to define the delivery of high-quality CR programmes:

1. Offered to all priority groups (PGs):
    - Myocardial infarction (MI)
    - Percutaneous coronary intervention (PCI)
    - Coronary artery bypass surgery (CABG)
    - Heart failure (HF)
2. ≥69% of core CR patients with recorded assessment before starting CR programme (Ax1)
3. ≥49% of core CR patients with recorded assessment after completing CR programme (Ax2)
4. Median waiting time from referral to start (TRS) of CR after MI/PCI (TRS_CR/MIPCI) within 40 days
5. Median waiting time from referral to start of CR after CABG (TRS_CR/CABG) within 54 days
6. Median duration of CR programmes of 54 days for conventional delivery.

The study reported in this chapter used 95% confidence intervals from the NCP_CR report to assess whether CR programmes met the service delivery standards as part of the NCP_CR certification criteria for England, Wales, and Northern Ireland.

4.3.3. NCP_CR scoring

A CR programme was given a score of 1 for each standard that it achieved, with a total score that ranged from 1 to 6. The quality of delivery of CR programmes was categorised into three groups: scores of 5–6 represented high quality, scores of 3–4 represented middle quality, and scores of 1–2 represented low quality. If a programme did not meet any of the six criteria, it was considered to have failed.

Due to the low number of programmes achieving 6 scores (27 of 170 CR programmes) and the difficulty of presenting the score variable statistics to the practice and public, the score variable divided into three categories: low, middle and high. This categorisation has shown a profound impact on the type of presentation and visualization that can be used to make a distinction between theses categorises, make the analysis simpler and more helpful and make sense in terms of understanding what meeting of the standards criteria show.

4.3.4. Baseline characteristics

The research reported in this chapter used a variety of different patient variables collected by the NACR, including demographic characteristics, cardiovascular risk factors, comorbidities, and physical and psychosocial health measures (Table 4.1). To evaluate the role of social deprivation, the study included the LSOA deciles, which are linked to the NACR (Department for Communities and Local Government, 2015). Further detail on characteristics is given in Chapter 3. Proportions (%) and means for a characteristic were calculated for patients with complete data for that characteristic.

Table 4.1 Baseline data used in the research

Type of characteristic	**Characteristic**
Demographics	• Mean age at initiating event (years) • Proportion of female patients (%) • Proportion of unemployed patients (%) • Mean English IMD
Cardiovascular risk factors	• Proportion of high-risk patients (%) • Mean BMI (kg/m^2) • Mean waist circumference (cm) • Proportion of patients with BMI >30 kg/m^2 (%) • Proportion of patients with BP >140/80 mmHg (%) • Proportion of smokers (%)

Comorbidities	• Total comorbidities (mean number of comorbidities)
	• Proportion of patients with each of the following comorbidities (%):
	  ○ Angina
	  ○ Arthritis
	  ○ Cancer
	  ○ Diabetes
	  ○ Rheumatism
	  ○ Stroke
	  ○ Osteoporosis
	  ○ Hypertension
	  ○ COPD
	  ○ Emphysema
	  ○ Asthma
	  ○ Claudication
	  ○ Chronic back problems

	○ Anxiety ○ Depression ○ Family history of CVD ○ Hypercholesterolaemia or dyslipidaemia
Physical health measures	• Mean 6MWT distance (metres) • Mean ISWT distance (metres) • Proportion of patients with self-reported moderate physical activity (150 minutes / week) (%) • Proportion of patients with self-reported vigorous physical activity (75 minutes / week) (%)
Psychosocial health measures	• Proportion of patients rated as borderline anxious or clinically anxious on HADS anxiety scale (%) • Proportion of patients rated as borderline depressed or clinically depressed on HADS depression scale (%)

BMI, body mass index; BP, blood pressure; COPD, Chronic bronchitis pulmonary disease; CVD, cardiovascular disease; HADS, Hospital Anxiety and Depression Scale; IMD, Index of Multiple Deprivation; ISWT, Incremental Shuttle Walk Test; 6MWT, Six-Minute Walk Test.

4.3.5. Statistical analysis

The primary aims of the study reported in this chapter were to investigate whether CR programmes met the NCP_CR's national standards for the delivery of CR and whether the quality of CR delivery was associated with the participating patients' characteristics. Mean and frequency tables were generated to score the programmes according to the certification categories, with the quality categories for CR programmes and the percentages of programmes meeting criteria reported for the whole cohort and for individual countries (England, Wales and Northern Ireland) for initial presentations.

Results for continuous variables are reported as means with standard deviations (SD), while categorical variables are reported as frequencies (percentages). Analyses were conducted using all available data from CR programme centres across the UK to minimise selection bias. The CR programmes were aggregated to identify those that met the NCP_CR criteria. Normal quantile–quantile plots were used to check for normality (Bland, 2000). To check for equal variances, Dean and Voss (1999) advocate not using formal tests, which are not robust against non-normality, but instead to use the rule of thumb suggested by simulation studies that an assumption will hold true if the ratio of the maximum SD estimate to the minimum SD estimate does not exceed 2 (Dean and Voss, 1999).

A chi-squared (χ^2) test was conducted to determine the association between a CR programme meeting each standard and its quality category (low, medium or high quality) overall and between the three countries that contribute to the NACR (England, Wales, or Northern Ireland) (Cohen, 1988). Phi and Cramér's V are both χ^2-based measures of the effect size or strength of association of a nominal-by-nominal relationship (Cohen, 1988). Both range in value from 0 to 1, with a value of 0 indicating no association and a value of 1 indicating complete association (Cohen, 1988). Guidelines for interpreting Phi and Cramér's V are shown in .

Table 4.2.

Table 4.2 Guidelines for interpreting Phi or Cramér's V

Magnitude of effect size	**Value of Phi or Cramér's V**
Small	0.1
Moderate	0.3
Large	0.5

Data were also analysed using the one-way analysis of variance (ANOVA) test to determine whether the standard criteria and demographic characteristics of CR programmes were different among quality categories (low, medium or high quality) and between the three countries. One-way ANOVA is considered robust to non-normality (Wilcox, 2012; Shadish, Cook and Campbell, 2002; Lix, Keselman and Keselman, 1996), and even fairly skewed distributions are not always problematic if sample sizes are not small and the groups are similarly skewed (Maxwell and Delaney, 2004; Sawilowsky and Blair, 1992). However, ANOVA procedures are not very sensitive to unequal variances. The Welch ANOVA – a modified version of the standard one-way ANOVA – conducted and its results interpreted if the assumption of homogeneity of variances violated and results from the Games-Howell post-hoc test used for multiple comparisons which used with unequal variances and also considers unequal group sizes (Field, 2018; Toothaker, 1993). Baseline comparisons between the three categories of CR quality were also analysed using ANOVA for continuous variables. In line with guidelines, the Games-Howell post-hoc test was conducted while performing ANOVA for multiple comparisons because of doubt that group variances and sample sizes were equal (Field, 2018; Toothaker, 1993). Partial eta-squared (η^2) is reported as an effect size; guidelines for interpreting partial η^2 are shown in Table 4.3 (Cohen, 1988).

Table 4.3 Guidelines for interpreting partial eta-squared

Magnitude of effect size	**Value of partial eta-squared**
Small	0.01
Medium	0.06
Large	0.14

An analysis was conducted to investigate the social deprivation among CR programmes in England (Department for Communities and Local Government, 2015). Two multinomial logistic regression models were also used to test for independent predictors of high-quality delivery of CR, using the high-quality category as the reference. Variables were included in the models according to their association with the three CR delivery quality categories, so cardiovascular risk factors, such as body mass index (BMI), and comorbidity variables, such as mean number of comorbidities and proportion of patients with diabetes, stroke and asthma, were included to identify criteria associated with high-quality delivery of CR. Linearity of the continuous variables with respect to the logit of the dependent variable was assessed via the Box-Tidwell procedure (Box and Tidwell, 1962).

A value of $p \leq 0.05$ was considered statistically significant. The analyses were conducted using IBM Statistical Package for Social Sciences (SPSS) software statistics Version 24 (New York, USA).

4.4 Results

4.4.1. Programme quality categories

The data included 89557 patients – 60,864 (68%) men, 25,987 (29%) women, and 2,706 (3%) not specified – who registered in the NACR database during the research period. The mean age was 65.53 (SD 12.40) years for men and 70.16 (SD 13.09) years for women.

The main analysis in this study included a cohort of 40,572 patients – 28,604 (70.5%) men, 10,501 (25.9%) women, and 1,467 (3.6%) not specified – who started CR between 1 April 2013 and 31 March 2014. The mean age was 63.86 (SD 11.66) years for men and 66.75 (SD 12.3) years for women; women were, on average, three years older than men.

The analysis included data for 170 of the 303 CR programmes in the UK; 52 (30.6%) of the included programmes scored 5 or 6, meaning they were high-quality programmes. Middle-quality programmes were the largest group, accounting for 78 (45.9%) of the included programmes, and 31 (18.2%) programmes were considered low quality. Only 27 (15.9%) CR programmes met the standard for all six criteria, while 143 (84.1%) CR programmes were below the scores required to meet any minimum criterion. Programmes that failed (poor) were excluded from the analyses. Table 4.4 presents the programme quality categories.

Table 4.4 Programme quality categories

Programme quality rating	Frequency (n, %)
Poor	9 (5.3)
Low	31 (18.2)
Middle	78 (45.9)
High	52 (30.6)

Scores: 0=poor quality, 1–2=low quality, 3–4=middle quality, 5–6=high quality.

In comparison of the quality criteria with the actual recommendations of BACPR and NICE service guidance that a CR programme should be offered to the priority group, offered early (CR should start within 28 days of referral for patients following MI and PCI or 42 days for CABG), underpinned by assessment before and after CR, and offered no

less than 8 weeks (BACPR, 2017; NICE, 2013c, 2010c); no one programme have achieved or met all of these recommended standards. From the 170 CR programmes, 101 of them offered to the priority groups, 5 programmes underpinned by assessment before CR for their patients, 1 programme underpinned by assessment after CR, 30 programmes offered early CR within 28 days of referral for MI/PCI patients, 44 programmes offered early CR within 44 days of referral for CABG patients, and 107 offered CR with no less than 8 weeks.

4.4.2. Programme quality categories between countries

Table 4.5 presents the proportion of programme quality categories among countries in the UK (England, Wales, and Northern Ireland). England had the highest proportion of high-quality programmes (45/129, 34.9%) while Northern Ireland had the lowest (2/14, 14.3%). Most programmes in the three countries were categorised as middle quality: 48.1%, 58.8%, and 42.9% for England, Wales, and Northern Ireland, respectively. England had the highest proportion of poor-quality programmes (8/9, 88.9%) and Northern Ireland had only one poor quality programme (1/9, 11.1%) while Wales did not have any programme categorised as poor quality.

Table 4.5 Programme quality categories between countries

Programme quality rating	**Country (n, %)**		
	England (n=129)	**Wales (n=17)**	**Northern Ireland (n=14)**
Low	22 (17.1)	2 (11.8)	6 (42.9)
Middle	62 (48.1)	10 (58.8)	6 (42.9)
High	45 (34.9)	5 (29.4)	2 (14.3)

Scores: 1–2=low quality, 3–4=middle quality, 5–6=high quality.

4.4.3. Percentage of CR programmes meeting criteria

The percentage of CR programmes that met each of the six specific criteria of the NCP_CR is presented in

Figure 4.1. Criterion Ax1 (≥69% of core CR patients with recorded assessment before starting CR programme) was achieved by the largest percentage of CR programmes (72.4%), while TRS_CR/MIPCI (waiting time from referral to start of CR after MI/PCI) was achieved by the smallest proportion of programmes (49.4%).

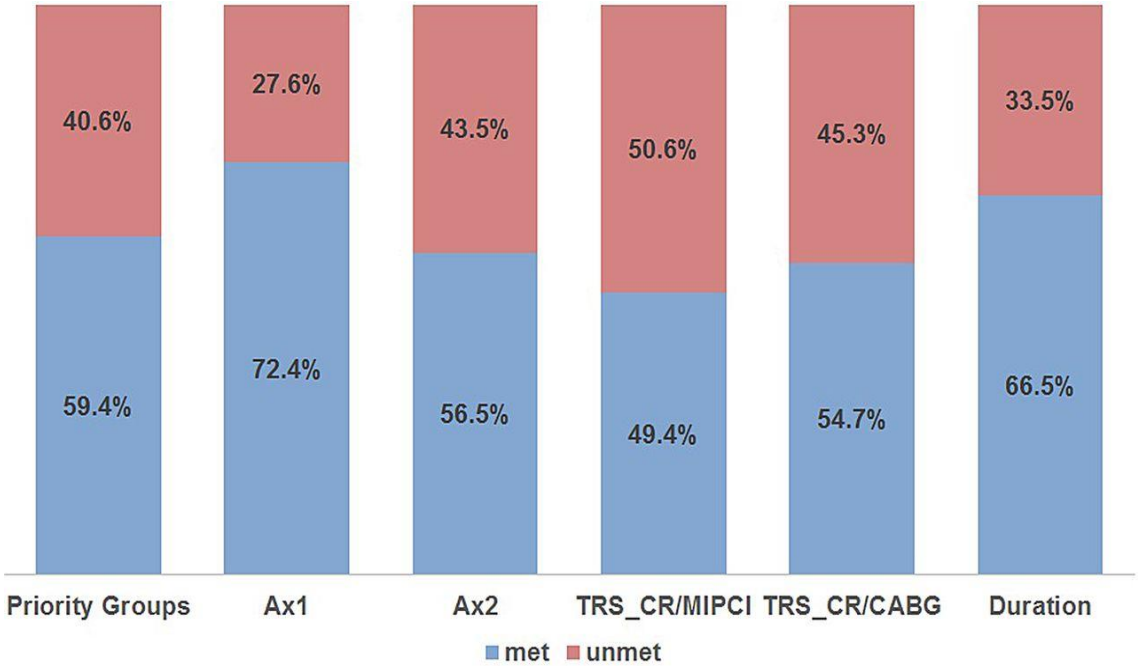


Figure 4.1 Percentage of CR programmes meeting and not meeting each of the six criteria for standards. Ax1, assessment 1; Ax2, assessment 2; CABG, coronary artery bypass surgery; CR, cardiac rehabilitation; MI, myocardial infarction; PCI, percutaneous coronary intervention; TRS_CR/CABG, median waiting time from referral to start CR after CABG; TRS_CR/MIPCI, median waiting time from referral to start of CR after MI/PCI.

The extent to which CR programmes met each standard among quality categories varied significantly (Table 4.6). Criterion Ax1 was the standard met by the most programmes among the low (51.6%), middle (71.8%) and high (98.1%) quality programmes. On the other hand, the criteria met by the lowest proportions of programmes were types of priority groups included (9.7%), TRS_CR/MIPCI (43.6%) and Ax2 (84.6%) among low-

quality, middle quality and high-quality programmes, respectively. Overall, 66.5% of CR programmes met or exceeded the median duration of 54 days; however, 33.5% of CR programmes were delivered at a duration less than 54 days (seven weeks).

Table 4.6 Frequency and percentage of each standard between quality categories

Criterion	Programme delivery quality (n, %)			Cramér's V
	Low (n=31)	Middle (n=78)	High (n=52)	
PG	3 (9.7)	48 (61.5)	50 (96.2)	**0.62***
Ax1	16 (51.6)	56 (71.8)	51 (98.1)	**0.39***
Ax2	7 (22.6)	45 (57.7)	44 (84.6)	**0.44***
TRS_CR/MIPCI	4 (12.9)	34 (43.6)	46 (88.5)	**0.55***
TRS_CR/CABG	7 (22.6)	38 (48.7)	48 (92.3)	**0.52***
Duration	14 (45.2)	51 (65.4)	48 (92.3)	**0.37***

Scores: 0=poor quality, 1–2=low quality, 3–4=middle quality, 5–6=high quality.
Ax1, assessment 1; Ax2, assessment 2; CABG, coronary artery bypass graft; CR, cardiac rehabilitation; MI, myocardial infarction; PCI, percutaneous coronary intervention; PG, priority group; TRS_CR/CABG, median waiting time from referral to start of CR after CABG; TRS_CR/MIPCI, median waiting time from referral to start of CR after MI/PCI.
*p<0.001 (bold text).

A χ^2 test was conducted to determine the association between a programme meeting each of the six specific criteria and the three quality categories. All expected cell frequencies were greater than five.

The association between meeting each standard and the quality categories was statistically significant ($p<0.001$ for all):

- between quality category and meeting PG standard ($\chi^2(2)=62.22$, $p<0.001$)
- between quality category and meeting Ax1 standard ($\chi^2(2)=25.03$, $p<0.001$)
- between quality category and meeting Ax2 standard ($\chi^2(2)=31.28$, $p<0.001$)
- between quality category and meeting TRS_CR/MIPCI standard ($\chi^2(2)=48.90$, $p<0.001$)
- between quality category and meeting TRS_CR/CABG standard ($\chi^2(2)=43.78$, $p<0.001$)
- between quality category and meeting duration standard ($\chi^2(2)=22.30$, $p<0.001$).

There was a moderate to strong association between a programme meeting each standard and the different quality categories (Table 4.6). The PG standard had the largest association with quality categories (Cramér's V 0.62), while the duration of CR programme standard had the lowest association among all categories (Cramér's V 0.37). The association was large between the quality category and meeting standards for PG, TRS_CR/MIPCI and TRS_CR/CABG (Cramér's V 0.62, 0.55, and 0.52, respectively). The association was moderate between the quality category and meeting standards for Ax1, Ax2 and duration (Cramér's V 0.39, 0.44 and 0.37, respectively).

4.4.4. Percentage of CR programmes meeting criteria between countries

A χ^2 test was conducted to determine the association between programmes meeting each specific criterion and the three countries. The extent to which CR programmes met each standard among England, Wales, and Northern Ireland is presented in Table 4.7. All expected cell frequencies were greater than five. A higher percentage of programmes in England met each standard than in Northern Ireland. More programmes in England

and Wales met both the PG and TRS_CR/MIPCI standards compared with Northern Ireland. There was a statistically significant association among countries between meeting the PG standard and the TRS_CR/MIPCI standard ($p<0.05$ for all). There was a statistically significant association between country group and meeting PG standard ($\chi^2(2)=13.61$, $p=0.001$) and TRS_CR/MIPCI standard ($\chi^2(2)=6.93$, $p=0.03$). The association was small between country group and PG standard (Cramér's V=0.28) and between country group and TRS_CR/MIPCI standard (Cramér's V=0.20).

Table 4.7 Percentage of total CR programmes meeting each of the six criteria by countries

Criterion	**Programmes meeting criteria (n, %)**		
	England (n=129)	**Wales (n=17)**	**Northern Ireland (n=14)**
PG*	**84 (61.3)**	**14 (82.4)**	**3 (20)**
Ax1	101 (73.7)	10 (58.8)	11 (73.3)
Ax2	81 (59.1)	6 (35.30)	8 (53.3)
TRS_CR/MIPCI*	**70 (51.1)**	**11 (64.7)**	**3 (20)**
TRS_CR/CABG	76 (55.5)	12 (70.6)	5 (33.3)
Duration	90 (65.7)	15 (88.2)	8 (53.3)

Ax1, assessment 1; Ax2, assessment 2; CABG, coronary artery bypass graft; CR, cardiac rehabilitation; MI, myocardial infarction; PCI, percutaneous coronary intervention; PG, priority group; TRS_CR/MIPCI, median waiting time from referral to start of CR after MI/PCI; TRS_CR/CABG, median waiting time from referral to start of CR after CABG.
*p<0.05 (bold text).

4.4.5. Standards between quality categories

As the assumption of homogeneity of variance was met for the criteria Ax2, TRS_CR/CABG and duration, a one-way ANOVA was conducted to determine whether the mean value of these three criteria was different among quality categories (Table 4.8). The assumption of homogeneity of variance was violated for Ax1 and TRS_CR/MIPCI, so one-way Welch ANOVA was conducted to determine whether the mean value of each of these two criteria was different among quality categories (Table 4.8). Significant results are fully reported in

Appendix 7. The effect sizes were largest for TRS_CR/MIPCI and TRS_CR/CABG (partial η^2 0.19 and 0.12, respectively), intermediate for Ax1 and Ax2 (partial η^2 0.09 for each) and smallest for programme duration (partial η^2 0.04).

Table 4.8 ANOVA with post-hoc results between quality categories

Criterion	Quality category (%)			Effect size
	Low	Middle	High	
Ax1	**68.45***	**76.42†**	**89.44*,†**	0.09
Ax2	**41.05***	**52.25†**	**63.98*,†**	0.09
TRS_CR/MIPCI	**54.39‡**	**42.94‡**	**31.32‡**	0.19
TRS_CR/CABG	**61.85***	**55.61†**	**41.99*,†**	0.12
Duration	**57.59***	64.56	**70.33***	0.04

Ax1, assessment 1; Ax2, assessment 2; CABG, coronary artery bypass graft; CR, cardiac rehabilitation; MI, myocardial infarction; PCI, percutaneous coronary intervention; PG, priority group; TRS_CR/MIPCI, median waiting time from referral to start of CR after MI/PCI; TRS_CR/CABG, median waiting time from referral to start of CR after CABG.
*Post-hoc significance between low-quality and high-quality categories: p≤0.05 (bold text).

† Post-hoc significance between middle-quality and high-quality categories: p≤0.05 (bold text).
‡Post-hoc significance among low-quality, middle-quality and high-quality categories: p≤0.05 (bold text).

Table 4.8 shows that the average of the standards for the low-quality programmes was statistically and significantly different to that for the middle- and high-quality programmes. When the average standards for each category were compared, every standard in the low-quality programmes was outside the minimum criteria. This differed compared with the middle-quality programmes, for which minimum criteria for some standards – such as assessments – were met, but both referral times were outside of the boundaries. The high-quality programme averages all sat within the boundaries.

4.4.6. Standards between countries

A one-way ANOVA was conducted to determine whether the mean value of each of the five criteria (Ax1, Ax2, TRS_CR/MIPCI, TRS_CR/CABG, and duration) were different among quality categories, as the assumption of homogeneity of variances was met (Table 4.9). Significant results are fully reported in Appendix 8. The effect size among countries was medium for CR programme duration and small for the other criteria (partial η^2 0.01, 0.05, 0.02, and 0.03 for Ax1, Ax2, TRS_CR/MIPCI, and TRS_CR/CABG, respectively). Table 4.9 also shows that CR programmes in Northern Ireland rated higher for recording assessments before and after CR than England or Wales, while CR programmes in Wales rated lower for TRS_CR/MIPCI and TRS_CR/CABG compared with England or Northern Ireland. The CR programmes in Wales offered CR of longer average duration than England and Northern Ireland (11 weeks versus nine weeks and eight weeks, respectively).

Table 4.9 ANOVA with post hoc results between countries

Criterion	Programmes meeting criteria (%)			Effect size
	England	Wales	Northern Ireland	
Ax1	77.68	68.37	79.70	0.01
Ax2	**54.53***	**36.78*†**	**59.28†**	0.05
TRS_CR/MIPCI	42.64	37.79	51.97	0.02
TRS_CR/CABG	53.55	44.72	62.32	0.03
Duration	63.45	**79.32†**	**57.46†**	0.06

Ax1, assessment 1; Ax2, assessment 2; CABG, coronary artery bypass graft; CR, cardiac rehabilitation; MI, myocardial infarction; PCI, percutaneous coronary intervention; PG, priority group; TRS_CR/MIPCI, median waiting time from referral to start of CR after MI/PCI; TRS_CR/CABG, median waiting time from referral to start of CR after CABG.
*Post-hoc significance between England and Wales, p≤0.05 (bold text).
†Post-hoc significance between Northern Ireland and Wales, p≤0.05 (bold text).

4.4.7. Demographic characteristics between quality categories

A one-way ANOVA was conducted to determine whether the mean number of patients who started CR, total staff hours, and number of qualified staff in the multidisciplinary team (MDT) were different among quality categories as the assumption of homogeneity of variances was met (Table 4.10). Significant results are fully reported in Appendix 9. The effect size among quality groups was medium for the number of patients who started CR, total staff hours and number of MDT (partial η2 0.10, 0.10, 0.06, respectively). Table 4.10 shows that the average number of patients who started CR, total staff hours, number of qualified staff in the MDT in the low-quality programmes were statistically and

significantly different to those in high-quality programmes. When comparing the demographic characteristics in each category, each one in the low-quality or middle-quality programmes was lower than in the high-quality programmes. Overall, 63% of low-quality programmes include at least three different professions in the CR MDT, while 73.7% and 85.4% of middle- and high-quality programmes are delivered by MDTs with at least three different professions, respectively.

Table 4.10 Demographic characteristics between quality categories

Characteristic	Quality category (N)			Effect size
	Low	Middle	High	
Number of patients who started CR	**126.16*‡**	**261.15‡**	**289.67***	0.10
Total staff hours	**60.78***	**91.91†**	**137.06*†**	0.10
Number of qualified staff in MDT	**3.03***	3.71	**4.56***	0.06
MDT (3+)	17	55	41	0.08

CR, cardiac rehabilitation; MDT, multidisciplinary team; MDT (3+), at least three qualified members of multidisciplinary team.
*Post-hoc significance between low-quality and high-quality categories, p≤0.05 (bold text).
†Post-hoc significance between middle-quality and high-quality categories, p≤0.05 (bold text).
‡Post-hoc significance between low-quality and middle-quality categories, p≤0.05 (bold text).

4.4.8. Demographic characteristics between countries

As the assumption of homogeneity of variance was met for number of qualified staff in the MDT, one-way ANOVA was conducted to determine whether the mean value of number of qualified staff in the MDT was different among countries (Table 4.11). The assumption of homogeneity of variance was violated for the number of patients who started CR and total staff hours, so one-way Welch ANOVA was conducted to determine whether the mean value of both of these was different among countries (Table 4.11).

Significant results are fully reported in Appendix 10. Table 4.11 shows that the average of number of patients who started CR and total staff hours in England were statistically and significantly different to those in Northern Ireland. When comparing the demographic characteristics in each category, each one in Northern Ireland were lower than England or Wales programmes. In Northern Ireland, 53.3% of CR programmes included at least three different professions in the CR team while 74.2% and 82.4% of programmes in England and Wales were delivered by an MDT with at least three different professions, respectively.

Table 4.11 Demographic characteristics between countries

Criterion	Countries (N)			Effect size
	England	Wales	Northern Ireland	
Number of patients who started CR	**252.58***	**238.71*†**	**122.47*†**	0.04
Total staff hours	**102.02***	**120.01*†**	**38.32*†**	0.05
Number of MDT	3.77	4.41	2.80	0.03
MDT (3+)	92/124	14/17	8/15	0.16

CR, cardiac rehabilitation; MDT, multidisciplinary team; MDT (3+), at least three qualified members of multidisciplinary team.
*Post-hoc significance between England and Northern Ireland, p≤0.05 (bold text).
†Post-hoc significance between Wales and Northern Ireland, p≤0.05 (bold text).

4.4.9. Missing data

The number and percentage of missing data for demographic and health state variables between quality categories are shown in Table 4.12

Table 4.12 Variables with missing values among quality categories

Variable	Missing (n) (%)		
	Low (31)	**Middle (78)**	**High (52)**
Age (years)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Female (%)	1 (3.2%)	1 (1.3%)	0 (0.0%)
Unemployment (%)	11 (35.5%)	13 (16.7%)	4 (7.7%)
IMD (deciles)	7 (22.6%)	12 (15.4%)	6 (11.5%)
High risk (%)	19 (61.3%)	25 (32.1%)	7 (13.5%)
BMI (kg/m2) (mean)	1 (3.2%)	1 (1.3%)	1 (1.9%)
Waist (cm) (mean)	6 (19.4%)	15 (19.2%)	8 (15.4%)
BP ≥140/90 mmHg (%)	6 (19.4%)	8 (10.3%)	0 (0.0%)
Smoker (%)	13 (41.9%)	18 (23.1%)	4 (7.7%)
6MWT (metres) (mean)	18 (58.1%)	51 (65.4%)	27 (51.9%)
ISWT (metres)	24 (77.4%)	48 (61.5%)	27 (51.9%)
150 minutes moderate/week (%)	0 (0.00%)	2 (2.6%)	0 (0.0%)
75 minutes vigorous/week (%)	1 (3.2%)	2 (2.6%)	0 (0.0%)
HADS anxiety (%)	13 (41.9%)	10 (12.8%)	2 (3.8%)
HADS depression (%)	14 (45.2%)	12 (15.4%)	2 (3.8%)

%, proportion of patients; BP, blood pressure; BMI, body mass index; HADS, Hospital Anxiety and Depression Scale; IMD, Index of Multiple Deprivation, ISWT, Incremental Shuttle Walk Test; 6MWT, Six-Minute Walk Test.

4.4.10. Demographics of patients

Proportions/means were calculated for patients with complete data for each characteristic (more detail on characteristic variables is given in Chapter 3). One-way ANOVA was conducted to determine whether the mean values of patients' characteristics were different among CR quality categories (Table 4.13). The effect size was small for age, percentage of female, percentage of unemployed and IMD (partial η^2 0.01 for each). Table 4.13 shows no significant differences in age, gender or employment status between the three quality categories. The mean values of characteristics in low-quality programmes were lower than in middle- or high-quality programmes. In the high-quality programmes, patients at baseline tended to be from the most deprived 10% of LSOAs nationally compared with those in the low- and middle-quality programmes.

Table 4.13 Demographics of patients in cardiac rehabilitation (CR) programmes classified as having low-, middle- and high-quality service delivery

Patient demographics	Quality category			p value	Effect size
	Low	Middle	High		
Age (years)	63.94	64.25	64.64	0.33	0.01
Female (%)	25.64	26.01	26.89	0.59	0.01
Unemployment (%)	15.96	19.27	17.78	0.56	0.01
IMD (deciles)	6.23	5.90	5.86	0.57	0.01

%, proportion of patients; IMD, Index of Multiple Deprivation.

4.4.11. Baseline health states

One-way ANOVA was conducted to determine whether there were differences in mean value of baseline health states of CR patients among the three categories of quality delivery (Table 4.14). The non-significant results were fully reported in Appendix 11.

Table 4.14 Baseline health states of patients in cardiac rehabilitation (CR) programmes classified as having low-, middle- and high-quality service delivery

Patient baseline health state	Quality category			p value	Effect size
	Low	Middle	High		
High risk (%)	16.28	21.84	23.39	0.32	0.02
BMI (kg/m^2) (mean)	**27.49**	**28.02**	**28.39**	**0.04***	0.04
Waist (cm) (mean)	97.47	98.07	101.00	0.44	0.01
BP ≥140/90 mmHg (%)	28.69	32.64	33.47	0.24	0.02
Smoker (%)	8.32	12.68	11.39	0.09	0.04
6MWT (metres) (mean)	342.74	276.66	280.61	0.15	0.06
ISWT (metres) (mean)	374.58	326.18	352.33	0.62	0.02
150 minutes moderate/week (%)	36.49	28.04	29.53	0.12	0.03
75 minutes vigorous/week (%)	8.38	6.20	6.56	0.31	0.02
HADS anxiety (%)	28.05	32.58	31.54	0.16	0.03
HADS depression (%)	18.24	21.89	21.69	0.22	0.02

%, proportion of patients; BP, blood pressure; BMI, body mass index; HADS, Hospital Anxiety and Depression Scale; ISWT, Incremental Shuttle Walk Test; 6MWT, Six-Minute Walk Test.

*p≤0.05 (bold text).

The average of BMI increased from the low-quality category (n=30, mean 27.49 (SD=2.09)), to the middle-quality (n=77, 28.02 (SD=1.63)), to high-quality category (n=51, 28.39 (SD=0.86)). There was heterogeneity of variances, as assessed by the max SD:min SD ratio (2.09 / 0.86=5.22). The differences among these groups was statistically significant (Welch's $F(2, 67.77)=3.42$, $p=0.04$, $\eta^2=0.04$).

4.4.12. Comorbidity profile

The proportions were calculated for patients with complete data for comorbidity profile (More detail on comorbidity profiles are given in Chapter 3). One-way ANOVA was conducted to determine whether mean total of comorbidities and proportion of each comorbidity were different among quality categories (Table 4.15). The non-significant results were fully reported in Appendix 12.

Table 4.15 Baseline comorbidity profiles of patients in cardiac rehabilitation (CR) programmes classified as having low-, middle- and high-quality service delivery

Patient baseline health state	Quality category (%)			p value	Effect size
	Low	Middle	High		
Total comorbidities (mean)	**1.36**	**1.44**	**1.72**	**0.05**	0.04
Angina	11.57	9.52	9.30	0.25	0.02
Arthritis	2.99	4.32	4.73	0.10	0.03
Cancer	2.76	3.40	3.07	0.40	0.01
Diabetes	**9.99**	**13.93**	**15.90**	**0.01***	0.06
Rheumatism	1.77	1.61	2.09	0.43	0.01
Stroke	**2.07**	**3.28**	**3.79**	**0.01**	0.06
Osteoporosis	1.08	1.27	1.86	0.05	0.04
Hypertension	31.89	31.87	35.58	0.47	0.01
Chronic bronchitis (e.g. COPD)	1.22	3.04	2.62	0.54	0.01
Emphysema	0.53	1.50	1.80	0.13	0.03
Asthma	**4.59**	**4.65**	**6.55**	**0.01***	0.06
Claudication	3.07	1.47	2.41	0.19	0.02
Chronic back problems	5.02	6.58	8.33	0.12	0.03
Anxiety	4.78	1.96	2.82	0.29	0.02
Depression	4.92	2.73	3.20	0.48	0.01
Family history of CVD	9.58	11.28	11.69	0.74	0.00
Hypercholesterolaemia or dyslipidaemia	17.21	15.58	18.74	0.56	0.01

COPD, chronic obstructive pulmonary disease; CVD, cardiovascular disease. *p≤0.05.

The average of total of comorbidities increased from the low-quality category (n=31, mean (SD) 1.36 (0.82)) to the middle-quality category (n=78, 1.44 (0.66)) to the high-quality category (n=52, 1.72 (0.78)). There was homogeneity of variances, as assessed by the max SD:min SD ratio (0.82:0.66=1.24). The difference among these groups was statistically significant ($F(2, 158)=3.06$, $p=0.05$, $\eta^2=0.040$).

The average proportion of patients started CR with diabetes comorbidity increased from the low- (n=31, mean 9.99 (SD=9.03)), to middle- (n=78, 13.93 (SD=8.43)), to high-quality category (n=52, M=15.90 (SD=6.98)). There was homogeneity of variances, as assessed by the max SD:min SD ratio (9.03 / 6.98=1.29). The differences among these quality categories was statistically significant ($F(2, 158)=5.18$, $p=0.01$, $\eta2=0.06$). Games-Howell post-hoc analysis found that the mean increases from low- to high-quality category (5.91 (95% CI 1.36 to 10.47, p=0.01) was statistically significant.

The average proportion of patients started CR with stroke comorbidity increased from the low- (n=31, mean 2.07 (SD=2.81)), to middle- (n=78, 3.28 (SD=2.31)), to high-quality category (n=52, 3.79 (SD=2.32)). There was homogeneity of variances, as assessed by the max SD:min SD ratio (2.81 / 2.31=1.21). The differences among these quality categories was statistically significant ($F(2, 158)=4.98$, $p=0.01$, $\eta2=0.06$). Games-Howell post-hoc analysis found that the mean increases from low- to high-quality categories (1.72 (95% CI 0.27 to 3.16, p=0.02) was statistically significant.

The average proportion of patients started CR with asthma comorbidity increased from the low (n=31, mean 4.59 (SD=4.48)), to middle- (n=78, 4.65 (SD=3.23)), to high-quality category (n=52, 6.55 (SD=3.30)). There was homogeneity of variances, as assessed by the max SD:min SD ratio (4.48 / 3.23=1.39). The differences among these quality categories was statistically significant ($F(2, 158)=5.22$, $p=0.01$, $\eta2=0.06$). Games-Howell post-hoc analysis found that the mean increases from middle- to high-quality category (1.90 (95% CI 0.51 to 3.29, $p<0.001$) was statistically significant.

The effect size was small for all comorbidity profiles except proportion of diabetes, stroke, and asthma which was medium effect size (partial η2=0.06 for each). Mean total of comorbidities and proportion of patients with diabetes, stroke, and asthma differed significantly among the three service delivery quality categories (Table 4.15).

4.4.13. Multinomial regression

Table 4.16 and Table 4.17 outline the results of the two multinomial logistic regression models, which include all baseline parameters that were statistically significant according to ANOVA. The first regression was performed to ascertain the effects of BMI and mean total of comorbidities at baseline on the likelihood that patients would be enrolled in high-quality programmes. While the second regression was performed to ascertain the effects of proportion of patients with comorbidities: diabetes, stroke and asthma at baseline on the likelihood that patients would be enrolled in high-quality programmes.

The multinomial logistic regression was performed to ascertain the effects of number of comorbidities and BMI on the likelihood that programmes categorised as high quality. The reference category for the outcome variable was 'high quality category'; each of the other two categories was compared to this reference group. There was no evidence of multicollinearity, as assessed by tolerance values greater than 0.1. Linearity of the number of comorbidities and BMI variables with respect to the logit of the quality category variable was assessed via the Box-Tidwell procedure (Box and Tidwell, 1962). A Bonferroni correction was applied using all five terms in each model resulting in statistical significance being accepted when $p<0.01$ (Tabachnick and Fidell, 2014). Based on this assessment, all continuous independent variables were found to be linearly related to the logit of the dependent variable. The model was based on 158 CR programmes (Low=30, middle=77, High=51) with complete data. The deviance goodness-of-fit test indicated that the model was a good fit to the observed data, $\chi2(310)=311.67$, $p=0.46$. The multinomial logistic regression model was statistically significant,

χ2(4)=14.05, p=0.01. The model explained 9.7% (Nagelkerke R2) of the variance in the three quality categories and correctly classified 51.9% of programmes. Of the two predictor variables, both were statistically significant: number of comorbidities and BMI. An increase in mean number of total comorbidities was associated with a decrease in the odds of being in the low-quality service delivery category compared to high category, with an odds ratio of 0.47, 95% CI [0.24, 0.90], p=0.02. An increase in mean BMI was associated with a decrease in the odds of being in the low-quality service delivery category compared to high category, with an odds ratio of 0.67, 95% CI [0.49, 0.93], p=0.02. In addition, an increase in mean number of total comorbidities was associated with a decrease in the odds of being in the middle-quality service delivery category compared to high category, with an odds ratio of 0.54, 95% CI [0.32, 0.90], p=0.02. Regression coefficients and standard errors can be found in Table 4.16 (below).

Table 4.16 Multinomial regression models for independent predictors of category of quality for CR deliver

Measured variables	**b (SE)**	**Lower CI**	**OR**	**Upper CI**
Low- vs high-quality categories				
Intercept	**11.86 (4.69)***			
Mean total comorbidities	**–0.76 (0.34)***	**0.24**	**0.47**	**0.90**
BMI	**–0.40 (0.17)***	**0.49**	**0.67**	**0.93**
Middle- vs high-quality categories				
Intercept	7.71 (4.15)			
Mean total comorbidities	**–0.62 (0.26)***	**0.32**	**0.54**	**0.90**
BMI	–0.22 (0.15)	0.60	0.80	1.06

b= regression coefficient; BMI, body mass index; CI=Confidence Interval for odds ratio; OR, odds ratio; SE; standard error of the coefficient.
*p≤0.05 (bold text).

The multinomial logistic regression was performed to ascertain the effects of the proportion of patients with comorbidities: diabetes, stroke and asthma on the likelihood that programmes categorised as high quality. The reference category for the outcome variable was 'high quality category'; each of the other two categories was compared to this reference group. There was no evidence of multicollinearity, as assessed by tolerance values greater than 0.1. Linearity of the proportion of patients with comorbidities: diabetes, stroke and asthma variables with respect to the logit of the quality category variable was assessed via the Box-Tidwell procedure (Box and Tidwell, 1962). A Bonferroni correction was applied using all seven terms in each model resulting in statistical significance being accepted when $p<0.01$ (Tabachnick and Fidell, 2014). Based on this assessment, all continuous independent variables were found to be linearly related to the logit of the dependent variable. The model was based on the 161 CR quality programmes (Low=31, middle=78, High=52) with complete data. The deviance goodness-of-fit test indicated that the model was a good fit to the observed data, $\chi2(298)=290.03$, $p=0.62$. The multinomial logistic regression model was statistically significant, $\chi2(6)=24.79$, $p<0.001$. The model explained 16.3% (Nagelkerke R2) of the variance in the three quality categories and correctly classified 54.7% of programmes. Of the three predictor variables, two were statistically significant: proportion of diabetes comorbidity and proportion of asthma comorbidity.

An increase in mean proportion of patients with diabetes comorbidity was associated with a decrease in the odds of being in the low-quality compared to high category, with an odds ratio of 0.91, 95% CI [0.83, 0.99], $p=0.04$. An increase in mean proportion of patients with asthma comorbidity was associated with a decrease in the odds of being in the middle-quality compared to high category, with an odds ratio of 0.84, 95% CI [0.74, 0.96], $p=0.01$. Regression coefficients and standard errors can be found in Table 4.17 (below).

Table 4.17 Multinomial regression models for independent predictors of category of quality for CR delivery

Measured variables	b (SE)	Lower CI	OR	Upper CI
Low- vs high-performing categories				
Intercept	**1.19 (0.52) ***			
Diabetes (%)	**-0.09 (0.05) ***	**0.83**	**0.91**	**0.99**
Stroke (%)	-0.24 (0.13)	0.62	0.79	1.01
Asthma (%)	0.03 (0.09)	0.87	1.03	1.23
Middle- vs high-performing categories				
Intercept	**1.27 (0.44) ***			
Diabetes (%)	-0.01 (0.03)	0.95	1.00	1.05
Stroke (%)	0.05 (0.09)	0.88	1.05	1.25
Asthma (%)	**–0.17 (0.07) ***	**0.74**	**0.84**	**0.96**

%, proportion of patients; b, regression coefficient; BMI, body mass index; CI=Confidence Interval for odds ratio; OR, odds ratio; SE, standard error.
*p≤0.05 (bold text).

4.5 Discussion

Every section below discusses the findings for an aim of the study. The conclusions, strengths and limitations of this set of analyses are then described. The implications for clinical practice and research of the findings from these analyses are summarised in Chapter 6.

4.5.1. Quality of cardiac rehabilitation programmes (Aim 1)

Overall, 170 CR programmes pooled from the patient-level data were collected in the NACR to identify those who met the agreed national standards of the NCP_CR and thus to assess the overall quality of CR delivery. Statistically significant differences were found among CR programmes in the UK with regard to meeting the standards in terms of quality delivery of CR classified into three distinct categories – low (30.6%), middle (45.9%) and high (18.2%) quality. The NACR is the only national audit that collects data on the quality of care and clinical outcomes for patients taking part in CR (NACR, 2015). The principal finding was that, based on NACR data from 2013 to 2014, only 15.9% (27 programmes out of 170 UK CR programmes) met all six standards included in the NCP_CR report (NACR, 2015). This finding supports the warning in the clinical review of CR published in the *British Medical Journal* that not all CR programmes are working to the standards (Dalal, Doherty and Taylor, 2015). This finding also depends on the use of the more lenient interpretation of the report, in which the 95% CI of the annual averages of the standards was used, as using the 95% CI increases the data range for meeting a particular standard. Previously, CR programmes were required to meet a particular data cut-point for most standards within the NCP_CR report, and if this latter method had still been in place, fewer programmes would have been classed as high quality. Only 52 from 170 CR programmes (30.6%) in the UK are considered as high-quality programmes. More than 80% of CR programmes in England and Wales (83% and 88%, respectively) are considered as middle or high quality compared to 57% of programmes in Northern Ireland. This findings agree with other studies that showed that CR offered varies considerably between and within countries with respect to content, duration, intensity and volume (Zwisler et al., 2012; Bjarnason-Wehrens et al., 2010).

The results of the research reported here demonstrate the huge variation in CR programmes meeting the standards. The analysis also showed that, within low-quality categories, CR is being delivered later than recommended, is not being offered for the

PGs, is not underpinned by pre- and post-assessment and is shorter in duration than the recommended standards suggested by the BACPR (BACPR, 2017). It therefore would be surprising if there was no variation in outcomes. The central question raised by the results of RAMIT is the quality of participating CR programmes (Wood, 2012), as RAMIT showed that CR as typically delivered in the UK did not provide any added value over usual care CR and may not be effective as provided in 'real life' (West, Jones and Henderson, 2012) . Such differences in outcomes from the latest three recent meta-analyses highlight the ongoing need for well-designed studies with specified standards in CR delivery and study reporting (Sumner, Harrison and Doherty, 2017; Anderson et al., 2016; Rauch et al., 2016).

The analysis showed that a large proportion of the variance in the quality categories (38.44% and 19%, respectively) was associated with the standards for offering CR to PGs and with the time from referral to the start of CR among MI/PCI patients: 40.6% of programmes in the UK did not offer CR to PGs (patients after MI, PCI, CABG, and HF). Although 65.5% of CR patients had a post-CR assessment, this finding is weakened by the knowledge that 43.5% of patients attending CR did not received a post-CR assessment. Not having a post-CR assessment not only fails to align with BACPR standards but also means that patients do not obtain a long-term management goal or plan (NACR, 2015). Waiting time to start a CR programme after referral was longer than six weeks after MI in 50% of CR programmes in the UK and was even longer (eight weeks after CABG) in 45% of CR programmes in the UK, so early opportunities to help patients understand their disease and its treatment, address anxiety and depression, and reduce their overall cardiovascular risk following diagnosis are being missed (Wood, 2012). Furthermore, 33.5% of CR programmes were delivered with a duration shorter than 54 days (seven weeks), which is too short compared with the BACPR recommended standards (minimum duration of eight weeks) (BACPR, 2017; NACR, 2017).

The results of this research demonstrated that, when comparing the average standards in each quality category, every standard for the low-quality programmes was outside the criteria. This differed for the middle-quality programmes, which met some standards such as assessments but with both referral times outside of the criteria. The high-quality programme averages all sat within the criteria. In addition, low-quality programmes were less multidisciplinary and comprehensive than middle- and high-quality programmes.

The research results highlight that the quality of programmes in the UK varies significantly in terms of meeting the standards, as well as considerable differences in quality between countries in terms of meeting the delivery standards for CR (BACPR, 2017). Differences in duration of CR programmes and inconsistencies in pre- and post-assessment practices are cited as likely contributing factors. The ability of NACR to quality assure data at the local level is helping commissioners and providers of CR recognise barriers to uptake and develop interventions to improve service quality and outcomes of CR services (NACR, 2017). Variation in the duration of CR by country is not unanticipated, as the health delivery infrastructure is commissioned, funded and incentivised differently (NACR, 2017). The ability to report service-level quality and inequalities in CR delivery is dependent on the infrastructure, resources and financial models that support CR services (NACR, 2017).

This study is the only UK-specific study that identifies the proportion of programmes meeting national standards for the delivery of CR. This study accounted for six standard measures that form part of the NCP_CR report. This study shows that high quality is achievable in the modern cardiology era and that many programmes deemed to be mid-level quality are close to meeting high-quality standards. However, substantial unacceptable variation, below the accepted standards, exists. This study has shown that NCP_CR criteria can be used to differentiate the quality of CR delivery and the findings thus support national certification as a positive step to ensuring that patients, irrespective of where they live, are able to access good quality services.

4.5.2. Cardiac rehabilitation patient population characteristics (Aim 2)

There were significant differences in the patient population among the quality categories for delivery of CR services. This research investigated whether the three quality categories differed with regard to the populations being treated within them. A CR programme was more likely to be categorised as high quality if it included patients with a higher mean total of comorbidities, including diabetes, stroke and asthma, in addition to high BMI.

According to the research findings, high-quality programmes recruit more patients with multiple comorbidities, who are more representative of the broader CVD population than those with few comorbidities. The presence of multiple comorbidities including stroke, diabetes and chronic obstructive pulmonary disease is an important factor associated with a lower likelihood of a patient being referred to and participating in CR (Listerman et al., 2011; Brown et al., 2009; Suaya et al., 2007; Witt et al., 2004), and the authors of a systematic review warned that CR programmes need to pay greater attention to recruitment of patients with multiple morbidities (Anderson et al., 2016). However, patients with multiple morbidities represent populations at significantly increased cardiovascular risk who may benefit from the services provided in CR (Listerman et al., 2011; Brown et al., 2009; Suaya et al., 2007; Witt et al., 2004).

For one additional comorbidity, the odds of a CR programme being of high quality rather than low quality increased by a factor of 2.13 and being of high quality rather than middle quality increased by a factor of 2.13, which indicates that high-quality programmes take on more complicated cases and potentially higher risk patients than low- or middle-quality programmes. The higher quality programmes seem able to recruit patients with multiple morbidities, who might not adhere with middle- or low-quality programmes. The presence of multiple comorbidities is an important factor associated with lower odds of

referral to, participation in and uptake of CR (Listerman et al., 2011; Brown et al., 2009; Suaya et al., 2007; Witt et al., 2004). High-quality CR programmes included more patients with the most dominant morbidities associated with CVD (except angina) according to the NACR (NACR, 2017) – hypertension, hypercholesterolaemia or dyslipidaemia; diabetes; combination of respiratory conditions (chronic bronchitis, emphysema, and asthma); arthritis; chronic back problems; cancer; and stroke – at entry to CR than the low-quality programmes.

For each unit increase in the BMI, the odds of a programme being of high quality rather than low quality increased by a factor of 1.49. Cardiac rehabilitation programmes do not generally include weight-loss components (Ades, Savage and Harvey-Berino, 2010) but CR programmes with high-quality delivery recruit more patients with CVD and higher BMI than those with low-quality delivery. Obesity is an independent risk factor for the development of CVD (Mandviwala, Khalid and Deswal, 2016). At entry into CR, more than 80% of patients were overweight and 30% had BMI >30 kg/m^2 (NACR, 2017; Ades, Savage and Harvey-Berino, 2010). A population-based study across 10 large US prospective cohorts, with 3.2 million person-years of follow-up from 1964 to 2015 concluded that higher BMI was associated with shorter longevity and significantly increased risk of cardiovascular morbidity and mortality compared with normal BMI (Khan et al., 2018). Although differences in BMI scores were statistically significantly different between quality categories, the mean differences were of little clinical importance, as a statistically significant result is not necessarily clinically important (small to medium effect size).

For each percent increase in the proportion of patients with diabetes as a comorbidity, the odds of a programme being of high quality rather than low quality increased by a factor of 1.10. Despite the fact that CVD is the most prevalent cause of mortality and morbidity in diabetic populations (Matheus et al., 2013) and in addition to the fact that patients with diabetes had more CVD risk factors and lower physical capacity than

patients without diabetes at the beginning of CR (Matheus et al., 2013; Mourot et al., 2010), the findings show that high-quality programmes recruit more patients with CVD and diabetes than low-quality programmes. Previous studies have examined the benefit of CR in diabetes (Banzer et al., 2004; Vergès et al., 2004; Milani and Lavie, 1996). The relative risk for CVD morbidity and mortality in adults with diabetes compared with those without diabetes ranged from 1 to 3 in men and from 2 to 5 in women (Rivellese, Riccardi and Vaccaro, 2010; Huxley, Barzi and Woodward, 2006). A study based on 952 patients with diabetes attending CR emphasised the need to target diabetic patients in CR programmes with an aggressive programme of risk factor management (Banzer et al., 2004). The prevalence of patients with diabetes in CR programmes seems to be increasing and is likely to continue to rise as the current trends indicating increase of prevalence of diabetes (Wild Sarah et al., 2004). Patients with diabetes are more depressed following a diagnosis of CVD and have lower scores for functional status, wellbeing, and total quality of life than non-diabetic patients (Milani and Lavie, 1996). Cardiac rehabilitation in diabetic patients results in marked reduction in depression to a prevalence identical to that in non-diabetic patients, in addition to improvements in exercise capacity and total quality of life following CR (Milani and Lavie, 1996).

For each percent increase in the proportion of patients with asthma comorbidity, the odds of a CR programme being of high quality rather than middle quality increased by a factor of 1.19. The findings show that high-quality programmes recruit more patients with CVD and asthma than low- and middle-quality programmes. Asthma is one of the most common global morbidities and the most common chronic respiratory disease worldwide, and was prospectively associated with increased risk of major CVD (WHO, 2017a; Iribarren et al., 2012). A recent meta-analysis indicated that asthma was associated with an increased risk of CVD and all-cause mortality in cohort studies (Xu, Xu and Yang, 2017). Large cohort studies provide more evidence that patients with asthma have a higher CVD event rate and an increased risk of death compared with non-asthmatics

(Tattersall et al., 2015; Chung et al., 2014). A retrospective systematic review of consecutive health records that included 1,328 cardiac patients discharged following MI, PCI and CABG suggests that asthma was associated with a decreased likelihood of CR attendance (King, Humen and Teo, 1999).

The analysis of social deprivation showed no statistically significant difference in social deprivation among quality categories; high-quality programmes tended to recruit more socially deprived patients than low- and middle-quality programmes. Previous studies suggested that socioeconomic deprivation is associated with lower participation in CR, as non-participants tend to be more socially deprived (Sage, 2013; Martin et al., 2012; Mosleh, Campbell and Kiger, 2009). A systematic review showed that patients with greater deprivation are less likely to attend CR programmes but may have the most to gain from CR because of a linear relation between socioeconomic status and cardiac outcomes (Cooper et al., 2002). Strong evidence from many studies of specific NHS services shows that patients from lower socioeconomic groups use specialist services less in relation to need than those from higher socioeconomic groups (Dixon et al., 2007).

Patients who participated in high-quality CR programmes tended to be those with high-risk status, high BMI score, high waist circumference, high blood pressure, high HADS anxiety and depression score, and more comorbidities; smokers; and in more socially deprived groups than patients in the low-quality programmes. In addition, high-quality CR programmes also take on patients with lower fitness levels than low-quality programmes. Such patients often have more severe functional impairment and are most in need of CR, as well as being most likely to benefit (Beswick et al., 2004).

Ensuring equity of access to CR and improving the consistency of delivery should increase long-term behaviour changes and contribute to a reduction in CVD-related health inequality (Furze et al., 2016).

The research reported in this thesis is the only UK-specific study to ascertain whether variation in quality of CR delivery is determined by patient characteristics, while also addressing whether these differences are associated with better quality delivery. This study accounted for the range of patients within programmes in terms of demographic characteristics, cardiovascular risk factors, comorbidities, and physical and psychosocial health measures collected by the NACR. Evaluation and dissemination of information about the populations served by CR programmes may help low-quality programmes to be more inclusive.

4.6 Conclusions

This research aimed to identify the proportion of programmes meeting national standards for the delivery of CR and ascertain whether variation in quality of CR delivery is determined by patients' characteristics. Only 30% of the CR programmes in the UK that contributed to the NACR met the criteria for high-quality CR, with a further 18% seen as low quality and 5% failing to meet any of the criteria. This research is the first to evaluate CR against standards and report the extent of deficit in CR services in the UK. Mean total comorbidities, higher BMI scores, and the proportions of patients with diabetes or asthma were associated with CR programmes categorised as high quality. This finding shows that the quality of delivery of a CR programme is associated with the morbidity profile of its patient population. Further research is needed to investigate the extent of patient outcomes between high-quality, middle quality and low-quality CR programmes.

4.7 Strengths

The strength of these analyses, like much of the research reported in this thesis, lies in the use of an observational approach based on routinely collected patient data to investigate what is happening in the real world.

4.8 Limitations

Retrospective observational studies have known limitations in terms of data capture and quality of the 303 CR programmes in the UK, according to the 2017 NACR report, only 224 (74%) programmes entered data electronically to the NACR. Although it can be argued that there are enough data to be representative and carry out a reliable analysis, future work should aim to achieve greater capture of available data across the UK. Although CR programmes are encouraged to provide complete patient records, a proportion of patient data were expected to be missing due to non-completion of patient records. On the basis of the NACR data, 43.5% of all patients who started CR did not have a post-CR assessment recorded, which might have affected the representativeness of research sample. The sample did differ in 2 factors, age and gender, in the study from overall population.

4.9 Summary of findings

- Evidence of huge variation in meeting the standards among CR programmes
- CR offered varies considerably between and within countries
- Only 30% of CR programmes the UK met the criteria for high-quality CR
- High-quality CR service delivery is achievable in the modern cardiology era
- The NCP_CR criteria can be used to differentiate the quality of CR delivery
- The quality of delivery of a CR programme is associated with the morbidity profile of its patient population
- A CR programme was more likely to be categorised as high quality if it included patients with a higher mean total of comorbidities, including diabetes, stroke and asthma, in addition to high BMI.

Chapter 5 Outcomes of Cardiac Rehabilitation

5.1. Abstract

Background: Quitting smoking and participation in cardiac rehabilitation (CR) are effective in reducing morbidity and mortality. However, little is known about predictors of quitting smoking in those who attend CR, and the literature is also uncertain about the extent to which those who attend CR gain weight while trying to quit smoking.

Objectives: This study aimed to determine sociodemographic and clinical factors associated with the likelihood of CR attenders quitting smoking and to ascertain whether CR, as delivered in routine practice, is associated with helping patients quit smoking and avoid weight gain.

Methods: Baseline and outcome data, including patient demographics, cardiovascular risk factors, comorbidities, physical and psychosocial health measures, and patient-reported smoking status (continued smoker or quitter) before and after CR, were extracted from the UK's National Audit of Cardiac Rehabilitation (NACR) database for patients entered into the database between April 2013 and March 2016. Binary logistic regression was performed to identify predictors of quitting smoking among CR attenders. A multiple linear regression model was constructed to understand the effect of continuing smoking or quitting smoking on CR outcomes, with the CR outcome score adjusted by the baseline CR score for each characteristic. An e-survey collected information about the smoking cessation support offered to patients attending CR.

Results: Overall, 92.6% of CR programmes in the UK offer smoking cessation support for CR attenders. Of the 130,961 patients who started CR and were entered into the NACR database, 2,052 were continued smokers (mean age 58.59±10.49 years, 73.6% men) and 1,238 were quitters (mean age 57.63±10.36 years, 75.8% men). The median

duration of CR was 9 weeks. Patients who quit smoking tended to have lower cardiovascular risk, fewer comorbidities, and lower depression scores when starting CR and were more likely to be in a relationship. Quitting smoking during CR was associated with a mean increase in body weight of 0.4 kg, which is much less than seen in systematic reviews. Quitters who attended CR also had better improvements in physical activity status and psychosocial health measures than smokers.

Conclusions: Patients with high cardiovascular risk, multiple comorbidities and higher severity of depression and those in employment and with single status were unlikely to quit smoking during CR. This research highlights routine factors that determine smoking cessation outcomes, which could inform the delivery of CR to better help patients quit smoking. As delivered in routine practice, CR is associated with helping patients quit smoking and avoid weight gain. This study also showed that CR programmes in the UK adhere to the guideline recommendations for smoking cessation interventions.

5.2. Introduction

The previous chapter described the first substantive set of analyses for this thesis, which ascertained the quality of CR in the UK compared with national standards for the delivery of CR and evaluated whether variation in quality of CR delivery is associated with patients' characteristics.

Research is required to explore the extent to which patients meet outcomes targets among high-, middle- and low-quality CR programmes. However, it is increasingly difficult to evaluate outcomes among the quality categories due to the complexity of reporting the extent of change. The scale of the challenge in terms of clinical presentation and potential for change, at the point patients start CR, is very different from programme to programme.

Additional outcomes such as quitting smoking need to be taken into account before conclusions can be drawn about the quality of CR programmes. Smoking and obesity are themselves interrelated. Smoking cessation is associated with substantial health benefits, but weight gain is cited as a primary reason for not trying to quit smoking. Numerous studies did not measure changes in physical activity to examine whether that influenced weight gain after quitting smoking. Moreover, a level of positive association evidence exists between obesity and anxiety and depression.

This chapter investigates the sociodemographic and clinical factors associated with likelihood of quitting smoking among CR attenders, ascertains whether weight gain is associated with smoking cessation in patients who attend CR, evaluates CR as an intervention to manage weight gain associated with smoking cessation in patients attending CR, and evaluates the smoking cessation support offered to CR attenders using an e-survey.

5.2.1. Cardiac rehabilitation contribution to smoking cessation

The average proportion of patients who entered CR as non-smokers among the 24 health regions in the UK was 93.6% (range 85.9% to 98.8%) (NACR, 2017). Supporting patients to quit smoking remains a top priority, and some CR programmes perform rather well, with an average reduction in the number of patients smoking after CR of 12.5%, while other CR programmes result in no change or even a worsening, with some having an increase in the number of patients identified as smokers after CR (NACR, 2017). Overall, the contribution of CR to smoking cessation at a national level remains positive, with an average reduction of 1.4% (NACR, 2017). However, the burden in terms of the percentage of smokers and the ability to support patients to quit smoking varies across the 24 health regions (NACR, 2017), and the situation is more complex at the local level, with 19 CR programmes showing a negative change (NACR, 2017).

The profile of smoking status at the point patients start CR is very different from programme to programme. For instance, in 25 CR programmes, 100% of patients were not smoking before CR, whereas about 25% of patients in one other programme were smoking before CR (NACR, 2017). These differences make any comparison of change at a programme level difficult to judge, as the potential for change is non-existent in some programmes with initially lower levels of spoken and much greater in those programmes with initially high levels of smoking.

5.2.2. Cardiac rehabilitation contribution to physical activity status

Physical activity status is a measure of how much physical activity (e.g. walking and light housework) an individual does in an average week. The chief medical officers for all nations of the UK recommend at least 150 minutes per week of moderate intensity physical activity (30 minutes for 5 days/week) or 75 minutes per week of vigorous physical activity, or a combination, as part of a public health initiative for adults (Bull et al., 2010). This requirement has been adopted as a basic minimum requirement for the World Health Organization, European, BACPR and SIGN recommendations (BACPR, 2017; SIGN, 2017; Piepoli et al., 2016; WHO, 2010).

Among the 24 health regions of the UK, 41.6% of patients met the recommendation of 150 minutes (range 20.3% to 52.3%) when they started CR, which increased to 70% following CR (NACR, 2017). As with smoking status, the profile of physical activity status at the point patients start CR is very different from programme to programme. In one programme, only 8% of patients met the 150-minute recommendation at baseline compared with 90% in another programme (NACR, 2017). Again, this makes any comparison of change at a programme level percentage difficult to judge, as the potential for change is non-existent in programmes with higher baseline levels of activity and much greater in those programmes with initially low levels of meeting the baseline physical activity recommendation levels.

5.2.3. Cardiac rehabilitation contribution to weight management

A key aim of CR and a goal for most patients is to bring BMI below <30 kg/m^2 (BACPR, 2017). On average, 30% of patients among the 24 health regions in the UK started CR with a body mass index (BMI) >30 kg/m^2 (NACR, 2017). Some CR programmes do rather well at achieving BMI <30 kg/m^2, while others do not achieve any change and, even worse, some report increases in the number of patients with BMI >30 kg/m^2 after CR (NACR, 2017). The contribution of CR to reducing BMI at a national level is low, with an average change of 0.8% in patients with BMI <30 kg/m^2 after CR (NACR, 2017). This highlights the difficulty in addressing this risk factor. However, the burden in terms of the percentage of patients starting CR with BMI >30 kg/m^2 and the ability to support patients with weight management varies across the 24 health regions, and the situation at a local level is very different from programme to programme, with 37 CR programmes showing a negative change (NACR, 2017). The range of change across programmes was –1.2 to 7.6 percentage points, which suggests that some CR programmes may be doing slightly better than others (NACR, 2017). Once again, any comparison of change at a programme level is difficult to judge, with no potential for change in some programmes with lower BMI at the start of CR and much greater potential for change in programmes with initially high proportions of patients with BMI >30.

5.2.4. Weight gain and smoking cessation

Additional factors need to be taken into account before drawing conclusions about how well CR programmes support weight management. The prevalence of smokers per programme is important, as the ability for a programme to make substantial change in patients' BMI may be hindered by their own success in smoking cessation. Although smoking cessation results in considerable improvements in health, it is often accompanied by weight gain, with patients trying to quit smoking more likely to put on 3–5 kg of weight in the first three months to a year (Aubin et al., 2012). This substantial effect may inhibit reporting of some successful weight loss programmes. The link between smoking and body weight is closely related and poses significant challenges for researchers investigating intervention effect in smokers.

A meta-analysis by Aubin et al. of 62 clinical trials that described weight gain in smokers who quit smoking for up to 12 months suggest that body weight increased on average by 1.12 kg, 2.26 kg, 2.85 kg, 4.23 kg and 4.67 kg at one, two, three, six and 12 months, respectively, after quitting (Aubin et al., 2012). Most of the weight gain occurs within three months of quitting, and estimates of weight gain were similar among smokers using different pharmacotherapies to support smoking cessation (Aubin et al., 2012). The variation in weight change is large, with about 16% of quitters losing weight and 13% gaining more than 10 kg (Aubin et al., 2012).

A large systematic review and meta-analysis of the association between smoking cessation and weight gain that included 35 prospective cohort studies with 63,403 quitters and 388,432 continuing smokers found that quitting smoking was associated with mean weight gain of 4.10 kg and mean BMI gain of 1.14 kg/m^2 over an average of 5 years (Tian et al., 2015). The participants in this meta-analysis were more similar to the general population than participants in the meta-analysis by Aubin et al. (Aubin et al., 2012), so the findings can be generalised. In addition, the cohort studies in the study by

Tian et al. (Tian et al., 2015) had longer follow-up than those in the meta-analyses by Aubin et al. (Aubin et al., 2012), which allows assessment of the effects of quitting smoking on weight change beyond 12 months.

In addition, a comprehensive review evaluated 70 cross-sectional and longitudinal studies show that, on average, smokers weigh less than non-smokers and former smokers weigh more than both smokers and non-smokers (Klesges et al., 1989). Numerous cohort studies also show that people who stop smoking gain weight (Lycett et al., 2011; Pistelli, Aquilini and Carrozzi, 2009; Eisenberg and Quinn, 2006; Filozof, Fernández Pinilla and Fernández-Cruz, 2004; Froom, Melamed and Benbassat, 1998; Perkins, 1993; Klesges et al., 1989). For example, in a prospective cohort with 8-year follow-up of people trying to stop smoking that examined the association between weight change and baseline BMI between continuing and quitting smokers, those who continued smoking for 8 years gained 2.24 kg, those who abstained from smoking for 8 years gained 8.79 kg, those who smoked for the first year but were abstinent at 8 years gained 8.33 kg, and those who stopped smoking for a whole year but were smoking again by 8 years gained 3.28 kg, with weight gain similar to and not significantly different from that in continuous smokers (Lycett et al., 2011). Obese smokers gain most weight when quitting smoking, while obese continuing smokers are likely to lose weight or their weight remains stable. Lycett et al. concluded that smokers who quit smoking gain 6–7 kg more than if they had continued smoking. This study did not measure changes in physical activity to examine whether that influenced weight gain after stopping smoking.

A literature review indicated that the risk of weight gain is highest during the 2 years immediately after smoking cessation and declines thereafter; on average, sustained quitters gain about 5–6 kg in weight (Froom, Melamed and Benbassat, 1998). Another literature review suggested that most smokers who quit experience weight gain, particularly within one year of quitting and this may persist for up to 8 years after smoking cessation (Pistelli, Aquilini and Carrozzi, 2009).

Eisenberg and Quinn tested a method that produces an unbiased estimate of the average effect of smoking cessation on weight gain by reanalysis of data from the LungHealth Study (Eisenberg and Quinn, 2006; O'Hara et al., 1998). The LungHealth Study, which was a randomised controlled trial conducted in the United States between 1986 and 1994, was a randomised smoking cessation trial with 5,887 smokers aged 35–60 (O'Hara et al., 1998). The reanalysis estimated weight gain of 9.7 kg over 5 years due to smoking cessation compared with the conventional estimate of 5.3 kg (Eisenberg and Quinn, 2006).

Filozof, Fernández Pinilla and Fernández-Cruz suggested that therapeutic approaches that can prevent weight gain after smoking cessation might result in more patients willing to quit smoking and higher rates of success (Filozof, Fernández Pinilla and Fernández-Cruz, 2004). Another literature review indicated that exercise attenuates the amount of weight gained after smoking cessation (Froom, Melamed and Benbassat, 1998).

5.2.5. Weight gain and anxiety and depression

Although weight gain does not offset the health benefits of smoking cessation which far exceed any health risks that may result from smoking cessation-induced weight gain, it is frequently a source of concern for smokers planning to quit (Pistelli, Aquilini and Carrozzi, 2009).

Gaining weight while stopping smoking can lead to anxiety and depression. A systematic review and meta-analysis of 16 epidemiological studies (two prospective and 14 cross-sectional) found a moderate level of evidence for a positive association between obesity and anxiety in the general population (Gariepy, Nitka and Schmitz, 2010). A systematic review found strong evidence and a significant and bidirectional association between obesity and depression (Rajan and Menon, 2017). A family-based observational study that examined the relationship between obesity and depression found that obesity was associated with an increased risk of depression, with the odds ratio for depression

increasing with BMI (Dong, Sanchez and Price, 2004). A systematic review and meta-analysis of 15 studies found that overweight, obesity and depression interacted reciprocally and that overweight and obesity increased the risk for depression (Luppino et al., 2010). In this review, obese people at baseline had a 55% increased risk for depression over time compared with a 27% increased risk of depression for overweight people. Finally, a systematic review of nine observational studies found that overweight or obesity was consistently associated with depression and that people with obesity were 32% more likely to have depression than those with normal weight (Pereira-Miranda et al., 2017).

5.2.6. Smoking

Smoking is a major risk factor for cardiovascular disease (CVD) and one of the biggest threats the world has ever faced, being the cause of death of more than 7 million people per year (WHO, 2017b). Smoking is a major preventable risk factor for the development of non-communicable diseases, including cardiovascular, cancers and respiratory diseases (U.S. Department of Health and Human Services, 2014). According to statistics from the Centers for Disease Control and Prevention, smoking remains the single largest preventable cause of death and disease in the United States (U.S. Department of Health and Human Services, 2014).

The recent large and highly comprehensive meta-analysis of the link between smoking and CVD used data from 25 prospective cohorts in the Consortium on Health and Ageing: Network of Cohorts in Europe and the United States (CHANCES) found that smoking is a strong independent risk factor for CVD and mortality in people aged ≥60 years (Mons et al., 2015). This analysis found that smokers had a two-fold higher risk of cardiovascular mortality compared with non-smokers, smoking advanced the risk of death from CVD by more than five years, smoking cessation in older adults is still beneficial, and the increased excess risk among quitters declined with time after smoking

cessation (Mons et al., 2015). Even at older ages, quitting smoking is beneficial in reducing the excess cardiovascular risk caused by smoking. Given the increasing numbers of older people and the higher incidence of CVD and mortality at older age, there is tremendous potential for smoking and CVD prevention (Mons et al., 2015).

A meta-analysis of 12 cohort studies estimated that mortality in patients who continue to smoke after myocardial infarction (MI) is 20% and suggested that smoking cessation is associated with a significant decrease in mortality (Wilson et al., 2000). A retrospective analysis of data from an American study showed that people who continued to smoke after percutaneous coronary revascularisation had a 76% increased risk of death after an average of 4.5 years of follow-up compared with non-smokers and a 44% higher risk of death compared to those who quit smoking (Hasdai et al., 1997).

Even stronger evidence comes from a 15-year follow-up of Dutch patients who underwent coronary bypass surgery (Voors et al., 1996). Patients who were smoking 1 year after surgery had a risk of subsequent myocardial infraction and reoperation more than two times higher than those of patients who had quit smoking since surgery (Voors et al., 1996). Patients who were still smoking at 5 years after surgery had even higher risks of MI and reoperation and a significantly increased risk of angina pectoris compared with patients who stopped smoking after surgery and patients who never smoked. Moreover, risks of MI were similar among non-smokers and those who were successful in quitting after surgery (Voors et al., 1996).

Quitting smoking is the most cost-effective strategy for CVD prevention (Piepoli et al., 2016). A systematic review of 20 prospective cohort studies showed that quitting smoking is associated with a 36% reduction in the risk of all-cause mortality for patients with coronary heart disease who quit compared with those who continued smoking (Critchley and Capewell, 2003).

International guidelines recommended that CVD prevention should be delivered in patients at moderate to high risk of CVD and patients with established CVD by tackling smoking as a risk factor and considered quitting smoking as an important target in both primary and secondary prevention of CVD (BACPR, 2017; Gerhard-Herman et al., 2017; Piepoli et al., 2016; Smith et al., 2011) Adopting healthy behaviours such as quitting smoking is the cornerstone of prevention and control of CVD, as prevention is effective and elimination of health risk behaviours could prevent at least 80% of cases of CVD and 40% of cancers (BACPR, 2017; Gerhard-Herman et al., 2017; Liu et al., 2012; Smith et al., 2011; NICE, 2010b).

Across the UK, CR is delivered in accordance with the British Association for Cardiovascular Prevention and Rehabilitation (BACPR) standards, which aim to reduce cardiovascular risk and promote quality of life through coordinated core components of CVD prevention and rehabilitation (BACPR, 2017). Through the lifestyle risk factor management of its core component, the BACPR recommend supporting people who have recently quit smoking with weight management in addition to smoking cessation and relapse prevention (BACPR, 2017).

5.2.7. Smoking cessation and cardiac rehabilitation

One challenge around reporting patient outcomes is that some measures are inter-related – for example, most patients who try to quit smoking will have increases in body weight (Tian et al., 2015; Aubin et al., 2012). As weight gain may be a barrier to quitting smoking or a reason to restart smoking, CR has not been evaluated to control weight gain after smoking cessation. With such an interaction, it would be wrong to judge the success of weight management and smoking cessation associated with CR programmes at a named local level without taking this relationship into account.

Smoking cessation is associated with substantial health benefits. Weight gain is cited as a primary reason for not trying to quit smoking (Klesges et al., 1988). Both overweight/obesity and smoking are risk factors for CVD. Furthermore, smoking and obesity are themselves interrelated. Better designed observational studies are needed to determine which factors are associated with successfully quitting smoking in CR attenders. To date, research on the determinants of likelihood of quitting smoking among CR participants has been limited. A more thorough investigation is required to identify the predictors of quitting smoking in CR- specific influencing factors that could inform tailored interventions to increase quitting smoking.

As weight gain may be a barrier against quitting smoking, it is interesting to investigate smoking cessation support services provided in CR to help patients quit smoking. Little is known about how routinely CR programmes support smoking cessation. An exploration could encourage knowledge exchange and discussion. This chapter depicts an e-survey of CR programmes in the UK that explored the support to quit smoking offered for CR patients. The overall aim was to explore whether CR programme offer support for patients with quitting smoking and specifically whether patients attending CR received smoking cessation support at the CR programme, were referred to external support, or both. Furthermore, reasons why CR programmes do not provide support for quitting smoking were explored.

The principal aims of the analyses reported in this chapter were to:

1. investigate and determine sociodemographic and clinical factors associated with likelihood of quitting smoking among CR attenders
2. ascertain whether weight gain associated with smoking cessation in patients attending CR and whether CR, as delivered in routine practice, is associated with helping patients stop smoking and avoid weight gain.
3. evaluate the extent of smoking cessation support offered to CR patients using an e-survey.

5.3. Methods

The data sources, population, and variable are described in detail in Chapter 3 but are briefly summarised here for ease of reference. Any details of methods specific to the analyses in this chapter are also noted here.

5.3.1. Data source

The data source is described fully in Chapter 3. In brief, the analyses were conducted using individual patient data collected electronically in the National Audit of Cardiac Rehabilitation (NACR). The NACR is a web-based registry of CR in the UK funded by the British Heart Foundation. Practitioners involved in CR delivery electronically enter data on patients eligible and referred for CR into the individual patient dataset according to a data dictionary (www.cardiacrehabilitation.org.uk/nacr/downloads.htm), and the data quality is checked by a member of the NACR team. The audit is voluntary, supports direct entry of data within a secure online system, and collects local programme-level data for those who are referred to and undergo CR. It includes details of a patient's initiating event, treatment type, risk factors, drugs, patient demographics, and post-CR clinical outcomes. The NACR has approval to collect anonymised patient data for a range of clinical variables without explicit consent from individual patients for the purposes of audit

and research under Section 251 of the NHS Act 2006 (NACR, 2017). Approval is reviewed annually by NHS Digital. Separate ethical approval was not required as part of this research in addition to the e-survey project, which is also a NACR audit process. In both cases the rationale for data collection was to improve the quality of CR service delivery for public benefit. This observational study was reported following the guidelines of the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines (von Elm et al., 2008).

5.3.2. Participants

The research cohort included data from patients added to the NACR database between 1 April 2013 and 31 March 2016, which have been validated and extracted retrospectively. The analysis included data on sociodemographic and clinical characteristics for patients who started CR and had a smoking status assessment at baseline (pre-CR) and follow-up (post-CR). There were no exclusion criteria.

5.3.3. Smoking outcome measures

Smoking status in the NACR database is recorded with information obtained by patient self-report questionnaires (NACR, 2017), and the NACR assessment questionnaire on which variables were collected and used is given in Appendix 2. Patients are categorised according to smoking status pre- and post-CR to one of the following statuses:

- Never smoked
- Ex-smoker
- Stopped smoking since event
- Currently smoking.

From the smoking status record pre- and post-CR for each CR patient, patients were defined, for the purposes of this research, as:

- continued smokers, if they were current smokers in the pre- and post-CR assessments
- quitters, if they were current smokers at the pre-CR assessment but had no smoking status at the post-CR assessment.

See Figure 3.3 in Chapter 3 for a graphic representation of this measure definition.

5.3.4. Baseline characteristics

Numerous past studies have used a variety of baseline characteristics to assess the difference between continued smokers and quitters (Jampaklay et al., 2015; Kim and Cho, 2014; Li et al., 2010; Lee and Kahende, 2007; Tucker et al., 2005; Hyland et al., 2004; McMahon and Jason, 2000; Osler and Prescott, 1998; Hymowitz et al., 1997; Rose et al., 1996; Centers for Disease Control and Prevention, 1993; Hatziandreu et al., 1990; McWhorter, Boyd and Mattson, 1990). The research used a variety of different patient variables collected by the NACR primary dataset, including demographics, comorbidities, cardiovascular risk factors, and physical and psychosocial health measures (Table 5.1). Further detail on characteristics are given in Chapter 3.

Table 5.1 Data used in the research.

Sociodemographic characteristics	Cardiovascular risk factors	Comorbidities	Physical health measures	Psychosocial health measures
• Age at initiating event • Gender (male/female) • Marital status (partnered/single) • Work status (employed/unemployed/retired) • Ethnocultural background (White British, Other) • English IMD	• Cardiovascular risk (low/middle/high) • Weight • BMI • BP >140/80 mmHg • Alcohol consumption	• Number of comorbidities	• Self-reported moderate physical activity (150 minutes/week; yes/no) • Self-reported vigorous physical activity (75 minutes/week; yes/no)	• HADS anxiety score • HADS depression score

BMI, body mass index; BP, blood pressure; HADS, Hospital Anxiety and Depression Scale; IMD, Index of Multiple Deprivation.

5.3.5. e-Survey

With the knowledge that smoking cessation is a key part of secondary prevention and rehabilitation and is included in the BACPR core components of lifestyle risk factor management (BACPR, 2017), a cross-sectional 11 item e-survey was sent to CR services to explore smoking cessation services provided by CR programmes in the UK. The sampling frame encompassed the 'coordinators' of the 224 CR programmes in the UK that enter their data electronically to the NACR. Several reminders were sent out via email over a period of two months. Data collection took place in the summer of 2016 (May 2016–July 2016). The response rate was 78% (175/224 CR programmes registered in the NACR). Further detail on e-survey method are given in Chapter 3. The survey of the 11 items is given in Appendix 6.

5.3.6. Statistical analysis

All analyses were performed in the IBM Statistical Package for Social Sciences (SPSS) software statistics Version 24 (New York, USA). $p \leq 0.05$ was considered statistically significant.

The primary focus in this chapter was to investigate sociodemographic and clinical factors associated with likelihood of quitting smoking among CR attenders, evaluate whether CR as delivered in routine practice helps patients quit smoking and avoid weight gain, and evaluate the smoking cessation support offering for patients attending CR programmes in the UK. Pre- and post-CR smoking status record for the whole cohort described, then study flow and sample size. Smoking status was valued as 1 for quitters and 0 for smokers. Frequency tables were generated to categorise CR patients as smokers and quitters according to their recorded pre- and post-CR smoking status. Analyses were conducted using all available data from CR attendees to minimise selection bias. Continuous variables are shown as mean (standard deviation (SD)) and categorical variables as frequencies (percentage). Descriptive statistics were used to

describe and compare a variety of sociodemographic and baseline characteristics between smokers and quitters among CR attendees in the UK. Both continuous and categorical variables were used depending on the method of data collection in the NACR. Differences in baseline characteristics were then compared using independent-samples t-test for continuous variables or chi-square test (χ^2) for categorical variables. To check for normality, normal quantile–quantile plots was used (Bland, 2000). To check for homogeneity of variances, Levene's test for equality of variances was used. A modified t-test referred to as the unequal variance t-test or the Welch t-test was used when the assumption of homogeneity of variances was violated (Welch, 1947). The independent-samples t-test results for group comparison provide: sample size (n), mean (M) and standard deviation (SD) for both groups, the statistical value (t or F), degrees freedom (df), significance (p), and 95% confidence interval (95% CI).

Cohen's d test was used as a measure of the effect size to indicate the mean difference between two groups in standard deviation units (Cohen, 1988). It shares the same range as standard deviation (–3.0 to 3.0). The standard guidelines for interpreting Cohen's d test are shown in Table 5.2 (Cohen, 1988).

Table 5.2 Guidelines for interpreting Cohen's d test.

Effect size strength	**Cohen's d test**
Small	0.2
Moderate	0.5
Large	0.8

In addition, a χ^2 test for association was conducted between baseline sociodemographic and clinical characteristics and smokers and quitters participating in CR (Cohen, 1988). Phi and Cramér's V tests are a measure of the effect size or strength of association of a nominal by nominal relationship (Cohen, 1988). They range in value from 0 to 1, with a value of 0 indicating no association and a value of 1 indicating complete association (Cohen, 1988). Only significant results were fully reported. Guidelines for interpreting Phi and Cramér's V are shown in Table 5.3.

Table 5.3 Guidelines for interpreting Phi or Cramér's V.

Magnitude of effect size	**Value of Phi or Cramér's V**
Small	0.1
Moderate	0.3
Large	0.5

The number of missing values reported for each variable of interest in addition to the number of cases with complete data for each important component of the analysis. Patient variables with more than 60% missing values were eliminated from the dataset and only variables with 10–60% of missing values were imputed (Dong and Peng, 2013). I compared and described differences between analysis results of CR patients from the original with those from an analysis of all data after replacement of missing values, which were handled through the expectation maximisation method (Schafer, 1997). Expectation maximisation data analyses are presented in the results section alongside the original data results. Only significant results of original data were fully reported. The relevant parameters (regression coefficients, standard errors, etc) were combined according to the rules presented by Rubin (RUBIN, 1987). Further detail on handling missing values and the expectation maximisation method are given in Chapter 3.

Binary logistic regression was used to predict the probability of quitting smoking among CR attenders. Variables were considered in the equation for the binary logistic analysis based on the extent of association between smokers and quitters (Field, 2018). Checks were performed to ensure that the models were a good fit through assumptions associated with the regressions. The final model's goodness-of-fit was evaluated using a Hosmer and Lemeshow test (Field, 2018).

Percentage or relative change was used to measure the difference in outcome (post-CR) from baseline (pre-CR) (Zhang and Han, 2009; Törnqvist, Vartia and Vartia, 1985). It is calculated by:

(percentage change=pre-CR value – post-CR value/pre-CR value) * 100

Outliers were detected by the median plus or minus 3 times the median absolute deviation (3±MAD) method (Leys et al., 2013). Pre-and post-CR values with more than 3±MAD percentage change for each characteristic were eliminated from the analysis.

A multiple linear regression model was constructed to understand the effect of continuing smoking or quitting smoking on CR outcomes, with adjustments for the outcome CR score by the baseline CR score for each characteristic. Post-CR outcomes (with respect to baseline) were introduced into multiple linear regression models (as continuous dependent variables) and tested against smoking status (a score of 0 was categorised as smoker, whereas score 1 was categorised as quitter). To take account of the nested nature of the primary dataset, patients are clustered within CR centres. The binary logistic regression and multiple linear regression models were constructed using cluster analysis.

The short electronic survey utilised as a uniformed and easy method to collect information about smoking cessation support offering for CR patients. Commonly used

descriptive statistical parameters, including number of programmes, percentages, means or medians, and standard deviations, were used to explore the data.

5.4. Results

5.4.1. Cohort characteristics

The NACR cohort included 130,961 patients (mean age 64.97±11.90 years, 73.1% male) who started CR during the research period (Table 5.4). Overall, 91.4% of the patients who started CR and had a smoking status recorded were classified as no smoking status (31,832 had never smoked; 35,417 were ex-smokers; 7,808 had stopped smoking since event).

Figure 5.1 shows the study flow. Of the 49,725 patients who had smoking status recorded pre- and post-CR, 46,435 (93.4%) were classified as non-smokers (mean age 65.72±11.08 years, 74.7% male), 2,052 (4.1%) as continued smokers (mean age 58.59±10.49 years, 73.6% male) and 1,238 (2.5%) as quitters (mean age 57.63±10.36 years, 75.8% male). The median duration of CR was 9 weeks. For the purposes of this research, patients were categorised as continued smokers or quitters (Table 5.5).

Table 5.4 Smoking status measurement record pre and post-CR.

Smoking status record	**Pre-CR (n) (%)**	**Post-CR (n) (%)**
Never smoked	31,832 (24.3%)	23,348 (17.8%)
Ex-smoker	35,417 (27.0%)	25,152 (19.2%)
Stopped smoking since event	7,808 (6.0%)	4,842 (3.7%)
Currently smoking	7,084 (5.4%)	2,847 (2.2%)
Missing	48,820 (37.3%)	56,189 (57.1%)
Total	130,961 (100.0%)	130,961 (100.0%)

n=Number of patients; %= percentage of patients.

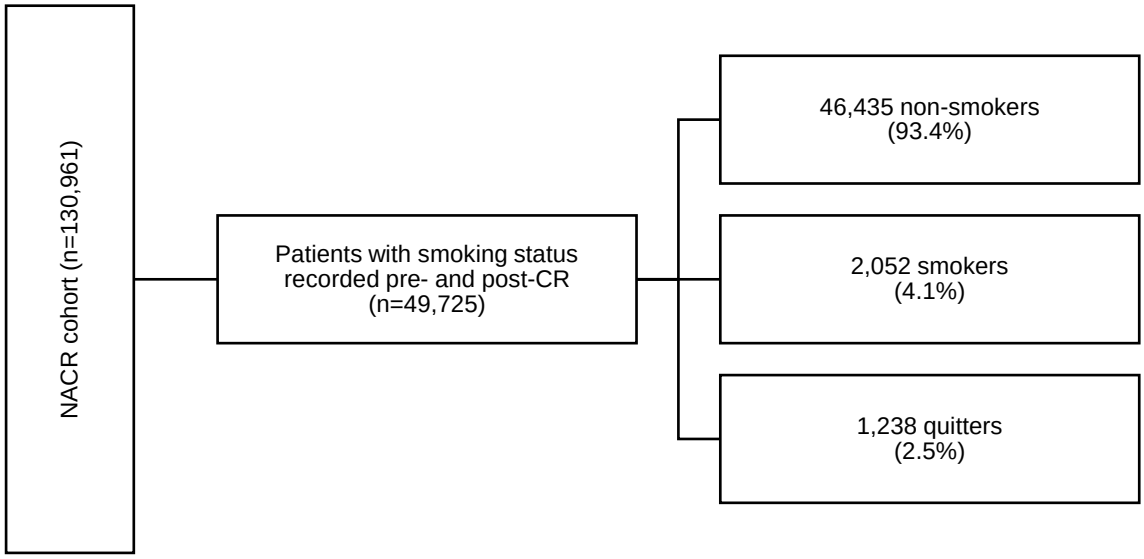


Figure 5.1 Study flow and sample size. NACR: National Audit of Cardiac Rehabilitation.

Table 5.5 Smoking categorisation groups.

Group	Frequency (n)	Percent (%)
Smokers	2052	62.4
Quitters	1238	37.6
Total	3290	100

n=Number of patients; %, percentage of patients.

5.4.2. Missing values

The number and percentage of missing values for variables with 10–60% of missing values are shown in Table 5.6.

Table 5.6 Variables with missing values.

Variable	Missing (n)	Percent (%)
Waist (Ax1)	1,964	59.7
Waist (Ax2)	1,925	58.5
Risk Assessment Score	1,767	53.7
Alcohol (Ax2)	1,531	46.5
Alcohol (Ax1)	1,409	42.8
Self-reported vigorous physical activity (75 minutes/week) (Ax2)	1,381	42.0
Self-reported vigorous physical activity (75 minutes/week) (Ax1)	1,373	41.7
HADS depression score (Ax2)	1,101	33.5
HADS anxiety score (Ax2)	1,101	33.5
Self-reported moderate physical activity (150 minutes/week) (Ax1)	1,099	33.4
HADS depression score (Ax1)	1,069	32.5
HADS anxiety score (Ax1)	1,069	32.5
Self-reported moderate physical activity (150 minutes/week) (Ax2)	1,029	31.3
Marital status	895	27.2
Employment status	716	21.8
IMD decile	707	21.5
BMI (Ax2)	672	20.4
Weight (Ax2)	578	17.6
BP (Ax2)	511	15.5
BMI (Ax1)	492	15.0
Weight (Ax1)	429	13.0
BP (Ax1)	380	11.6
Gender	52	1.6

Ax1, record at Assessment 1; Ax2, record at Assessment 2; BMI, body mass index; BP, blood pressure; HADS, Hospital Anxiety and Depression Scale; IMD, Index of Multiple Deprivation; n=Number of patients.

5.4.3. Smokers versus quitters (baseline characteristics)

The mean baseline characteristics of smokers and quitters using original data and expectation maximisation data are summarised in Table 5.7 and Table 5.8.

Baseline characteristics for each level of smoking were normally distributed, as assessed by normal quantile–quantile plots. An independent-samples t-test was run to determine whether sociodemographic and clinical characteristics differed between smokers and quitters (Table 5.7). Expectation maximisation results are presented in Table 5.7 alongside the original data results. Use of expectation maximisation to handle missing data seemed to give similar results to the original analysis. Only significant results from the original data were fully reported.

Table 5.7 Baseline characteristics of smokers and quitters participating in cardiac rehabilitation (continuous measures).

Characteristics	Group	Original data mean (SD)/n	Effect size	EM data mean (SD)/n	Effect size
Age	Smokers	**58.59 (10.49)/2,052***	0.09	**58.59 (10.49)/(2,052)***	0.09
	Quitters	**57.63 (10.36)/1,238***		**57.63 (10.36)/(1,238)***	
Comorbidities	Smokers	**1.85 (1.80)/2,052***	0.18	**1.85 (1.80)/(2,052)***	0.18
	Quitters	**1.54 (1.58)/1,238***		**1.54 (1.58)/(1,238)***	
Weight	Smokers	**81.63 (18.45)/1,793***	0.09	**81.68 (17.40)/(2,052)***	0.08
	Quitters	**83.27 (18.43)/1,068***		**83.04 (17.21)/(1,238)***	
BMI	Smokers	28.03 (0.14)/1,763	0.00	28.03 (5.42)/(2,052)	0.01
	Quitters	28.03 (0.16)/1,035		28.06 (4.79)/(1,238)	
Waist	Smokers	98.72 (14.38)/918	0.01	98.66 (13.11)/(2,052)	0.01
	Quitters	98.63 (15.33)/408		98.79 (12.64)/(1,238)	
Alcohol	Smokers	9.09 (15.29)/1,240	0.02	9.07 (11.95)/(2,052)	0.00
	Quitters	8.78 (14.19)/641		9.01 (10.30)/(1,238)	
HADS anxiety score	Smokers	**7.31 (4.64)/1,478***	0.10	**7.29 (4.01)/(2,052)***	0.09
	Quitters	**6.84 (4.52)/743***		**6.93 (3.60)/(1,238)***	
HADS depression score	Smokers	**5.96 (4.28)/1,477***	0.21	**5.92 (3.68)/(2,052)***	0.18
	Quitters	**5.08 (4.01)/744***		**5.30 (3.19)/(1,238)***	
IMD decile	Smokers	4.86 (2.90)/1,585	0.01	4.84 (2.57)/(2,052)	0.02
	Quitters	4.89 (2.90)/998		4.88 (2.61)/(1,238)	

BMI, body mass index; EM, expectation maximisation; HADS, hospital anxiety and depression scale; IMD, Index of multiple deprivation; SD, standard deviation; n=Number of patients.

*p≤0.05 (bold text).

An independent-samples t-test was run to determine whether there were differences in age between smokers and quitters. There was homogeneity of variances, as assessed by Levene's test for equality of variances (p=0.85). Smokers' age (n=2,052, M=58.59, SD=10.49) was higher than quitters (n=1,238, M=57.63, SD=10.36), a statistically significant difference, M=0.96, 95% CI 0.22 to 1.70, *t*(3288)=2.56, p=0.01, Cohen's d effect size value (d=0.09). These results were the same with expectation maximisation data, as the age variable did not have missing values.

A Welch t-test was run to determine whether there were differences in the number of comorbidities between smokers and quitters due to the assumption of homogeneity of variances being violated, as assessed by Levene's test for equality of variances (p<0.001). The number of comorbidities in smokers (n=2,052, M=1.85, SD=1.80) was statistically lower than for quitters (n=1,238, M=1.54, SD=1.58): M=0.31 (95% CI 0.19 to 0.43), t(2,872.93)=5.14, p<0.001. These results were the same with expectation maximisation data, as the number of comorbidities variable did not have missing values.

An independent-samples t-test was run to determine whether there were differences in pre-CR weight between smokers and quitters. There was homogeneity of variances, as assessed by Levene's test for equality of variances (p=0.66). Smokers weight (n=1,793, M=81.63, SD=18.45) was statistically higher than for quitters (n=1,068, M=83.27, SD=18.43): M=–1.64 (95% CI –3.03 to –0.24), *t*(2,859)=–2.30, p=0.02. Cohen's d effect size value (d=0.09) suggested a large practical significance.

An independent-samples t-test was run to determine whether there were differences in pre-CR HADS anxiety score between smokers and quitters. There was homogeneity of variances, as assessed by Levene's test for equality of variances (p=0.51). Smokers HADS anxiety score (n=1,478, M=7.31, SD=4.64) was statistically higher than for quitters (n=743, M=6.84, SD=4.52): M=0.46 (95% CI 0.06 to 0.87), *t*(2219)=2.24, p=0.03.

An independent samples t-test was run to determine whether there were differences in pre-CR HADS depression score between smokers and quitters. There was homogeneity of variance, as assessed by Levene's test for equality of variances (p=0.06). Smokers' HADS depression score (n=1,477, M=5.96, SD=4.28) was statistically higher than for quitters (n=744, M=5.08, SD=4.01): M=0.89 (95% CI 0.52 to 1.25), *t*(2219)=4.70, p<0.001. Cohen's d effect size value (d=0.21) suggested a small practical significance.

A χ^2 test for association was conducted between baseline sociodemographic and clinical characteristics and the two smoking categories: smokers and quitters participating in CR. All expected cell frequencies were greater than five (Table 5.8).

Table 5.8 Crosstabulation of baseline characteristics of smokers and quitters who participated in cardiac rehabilitation.

Characteristics		**Original data (%)**		**Effect size**
		Smokers	**Quitters**	
Gender	Male	73.6	75.8	–0.02
	Female	26.4	24.2	
Ethnic group	White	77.3	77.1	0.00
	other	22.7	22.9	
Marital status	Partnered	**62.1***	**73.7***	0.12
	Single	**37.9***	**26.3***	
Work status	Employed	**33.6***	**44.8***	0.11
	Unemployed	**33.6***	**27.1***	
	Retired	**32.8***	**28.1***	
Cardiovascular risk	Low	**39.5***	**49.3***	0.10
	Moderate	**38.9***	**34.6***	
	High	**21.6***	**16.2***	
BP >140/80 mmHg	Yes	27.1	27.6	0.01
	No	72.9	72.4	
Exercise: 150 minutes/week of moderate activity	Yes	30	29.8	0.00
	No	70	70.2	
Exercise: 75 minutes/week of vigorous activity	Yes	7.5	6.4	0.00
	No	92.5	93.6	

BP, blood pressure.

*p≤0.05 (bold text).

A χ^2 test for association was conducted between the smokers and quitters and marital status: partnered (n=1,594) and single (n=801). There was a statistically significant association between smoking group and marital status, $\chi^2(1)=34.55$, $p<0.001$; small association phi=0.12).

A χ^2 test for association was conducted between the smokers and quitters and work status: employed (n=973), unemployed (n=802) and retired (n=799). There was a statistically significant association between smoking and work status: $\chi^2(2)=32.31$, $p<0.001$; small association Cramér's V=0.11.

A test χ^2 test for association was conducted between the smokers and quitters and cardiovascular risk assessment: low (n=655), middle (n=569), and high (n=299). There was a statistically significant association between smoking group and cardiovascular risk assessment, $\chi^2(2)=14.63$, $p<0.01$; small association Cramér's V=0.10).

5.4.4. Binomial logistic regression

The following characteristics were considered in the final model to identify CR attenders who quitted smoking:

- Age
- Marital status
- Employment status
- Cardiovascular risk
- Comorbidities
- Weight
- Hospital anxiety and depression scale (HADS)
    - Anxiety score
    - Depression score

A binomial logistic regression was performed to ascertain the effects of the baseline characteristics on the likelihood that CR attenders quit smoking (original data results presented in Table 5.9; expectation maximisation data results presented in Table 5.10). Only original data regression results from original data were fully reported, as expectation maximisation gave similar results. Linearity of the continuous variables with respect to the logit of the dependent variable was assessed via the Box Tidwell procedure (Box and Tidwell, 1962). A Bonferroni correction was applied using all 14 terms in the model, resulting in statistical significance when $p<0.00357$ (Tabachnick and Fidell, 2014). Based on this assessment, all continuous independent variables were found to be linearly related to the logit of the dependent variable. No studentised residual was found using case diagnostics.

Table 5.9 Binomial logistic regression predicting likelihood of quitting smoking among patients who attended cardiac rehabilitation (original data).

	B	SE	Wald	df	p	OR	95% CI for OR	
							Lower	Upper
Age	–0.01	0.01	1.50	1.00	0.22	0.99	0.97	1.01
Marital status (single)	–0.52	0.16	10.03	1.00	**0.00***	0.60	0.43	0.82
Employment status (Retired as reference)	0.10		2.48	2.00	0.29	1.10		
Employment status (employed)	0.10	0.22	0.21	1.00	0.65	1.11	0.72	1.71
Employment status (unemployed)	–0.20	0.24	0.69	1.00	0.41	0.82	0.52	1.30
Cardiovascular risk (high as reference)	–0.68		8.62	2.00	**0.01***	0.51		
Cardiovascular risk (low)	0.54	0.22	6.10	1.00	**0.01***	1.71	1.12	2.62
Cardiovascular risk (moderate)	0.14	0.22	0.41	1.00	0.52	1.15	0.75	1.78
Comorbidities	–0.13	0.05	7.48	1.00	**0.01***	0.88	0.80	0.96
Weight	0.01	0.00	2.11	1.00	0.15	1.01	1.00	1.01
HADS anxiety score	0.03	0.02	1.57	1.00	0.21	1.03	0.98	1.08
HADS depression score	–0.06	0.03	4.16	1.00	**0.04***	0.95	0.90	1.00
Constant	–0.11	0.86	0.02	1.00	0.90	0.90		

B=unstandardised regression coefficient; CI=Confidence Interval for odds ratio; df, degrees of freedom; HADS, hospital anxiety and depression scale; OR, odds ratio. S.E.; standard error of the coefficient. *p≤0.05 (bold text).

Table 5.10 Binomial logistic regression predicting likelihood of quitting smoking among patients who attended cardiac rehabilitation (expectation maximisation data).

	B	SE	Wald	df	p	OR	95% CI for OR	
							Lower	Upper
Age	–0.01	0.01	0.92	1.00	0.34	0.99	0.97	1.01
Marital status (single)	–0.52	0.15	12.53	1.00	**0.00***	0.59	0.45	0.79
Employment status (retired as reference)	–0.04		1.59	2.00	0.45	0.96		
Employment status (employed)	0.13	0.20	0.37	1.00	0.54	1.13	0.76	1.69
Employment status (unemployed)	–0.09	0.22	0.16	1.00	0.69	0.92	0.60	1.40
Cardiovascular risk (high as reference)	–0.88		10.80	2.00	**0.00***	0.41		
Cardiovascular risk (low)	0.61	0.20	9.39	1.00	**0.00***	1.83	1.24	2.70
Cardiovascular risk (moderate)	0.27	0.20	1.81	1.00	0.18	1.31	0.89	1.93
Comorbidities	–0.16	0.04	12.83	1.00	**0.00***	0.86	0.79	0.93
Weight	0.01	0.00	3.36	1.00	0.07	1.01	1.00	1.02
HADS anxiety score	0.02	0.02	1.01	1.00	0.31	1.02	0.98	1.07
HADS depression score	–0.05	0.03	3.92	1.00	**0.05***	0.95	0.90	1.00
Constant	–0.38	0.79	0.23	1.00	0.63	0.69		

B=unstandardised regression coefficient; CI=Confidence Interval for odds ratio; df, degrees of freedom; HADS, hospital anxiety and depression scale; OR, odds ratio. S.E.; standard error of the coefficient. *p≤0.05 (bold text).

The original data logistic regression model was statistically significant ($\chi^2(10)=59.32$, $p<0.0001$), explained 9.3% (Nagelkerke R^2) of variance in smoking status, and correctly classified 64.7% of cases. Sensitivity was 25.5%, specificity 87.6%, positive predictive value 54.5%, and negative predictive value 66.9%. To assess the model for influential cases, Cook's distance test and leverage values were computed but neither test produced unusually high values ($p<1.00$ for all). The Hosmer–Lemeshow test in the final model was not statistically significant ($p=1.00$), indicating that the model is not a poor fit.

Only four predictor variables were statistically significant: marital status, cardiovascular risk, comorbidities and HADS depression score (Table 5.9). The probability of quitting smoking was 40% lower (odds ratio (OR) 0.60 (95% CI 0.43 to 0.82)) for single than partnered patients and 71% higher (OR 1.71 (95% CI 1.12 to 2.62)) for low- than high-risk patients. The probability of quitting smoking decreased by 12% (OR 0.88 (95% CI 0.80 to 0.96)) per additional comorbidity and by 5% (OR 0.95, 95% CI 0.90 to 0.99) per 1-point increase in HADS depression score. Patients with partners had 0.60 times lower odds (95% CI 0.43 to 0.82) of quitting smoking than single patients, and low-risk patients had 1.71 times higher odds (95% CI 1.12 to 2.62) of quitting smoking than high-risk patients. Increasing number of comorbidities and HADS depression score were associated with decreasing likelihood of quitting.

A binomial logistic regression linear regression was performed to ascertain the effects of the baseline characteristics on the likelihood that CR attenders quit smoking, using the cluster analysis to account for the nested nature of the of the primary dataset. The results seemed to give similar results to the original analysis. Please see Appendix 18 and Appendix 19 for the original data and expectation maximisation data results.

5.4.5. Smokers versus quitters (outcomes)

The CR outcome results between smokers and quitters using original data and expectation maximisation data are summarised in Table 5.11. Use of expectation maximisation to handle missing data seemed to give similar results to the original analysis.

Table 5.11 Baseline and outcome values for CR patients included in the analysis

	Original data						Expectation maximisation data					
	Smokers			Quitters			Smokers			Quitters		
	Pre-CR	Post-CR	n	Pre-CR	Post-CR	n	Pre-CR	Post-CR	n	Pre-CR	Post-CR	n
Weight	81.64	81.68	1,499	83.83	84.28	881	81.66	81.75	2,052	83.35	83.75	1,238
BMI	27.99	28.28	1,442	28.01	28.47	833	27.97	28.01	2,052	28.17	28.33	1,238
Waist	98.47	98.09	657	97.39	97.11	272	98.47	98.03	2,052	98.93	98.58	1,238
Alcohol consumption	17.78	13.80	486	15.66	11.28	298	17.12	12.85	2,052	16.73	12.26	1,238
HADS anxiety score	7.89	7.39	1,046	6.92	5.79	546	7.77	6.73	2,052	7.44	6.11	1,238
HADS depression score	6.53	5.68	1,032	5.44	4.24	530	6.33	5.22	2,052	5.84	4.56	1,238

BMI, body mass index; CR, cardiac rehabilitation; HADS, hospital anxiety and depression scale; n=number of patients.

After controlling for baseline, predictions were made to determine outcome change for those patients who quit smoking while attending CR. Only CR patients with both pre- and post-CR values were included in the analysis after excluding pre- and post-values with percentage change more than 3 ± MAD.

Outcomes for each level of smoking were normally distributed, as assessed by normal quantile-quantile plots.

A multiple regression model was constructed to understand the effect of quitting smoking on CR outcomes with adjustments for the outcome CR score by the baseline CR score for each characteristic. Moreover, post-CR outcomes (with respect to baseline) were introduced into multiple linear regression models (as continuous dependent variables) and tested against smoking status (score 0 for smokers; score 1 for quitters).

For all multiple regression models conducted:

- There was linearity as assessed by partial regression plots and a plot of standardised residuals against the predicted values.
- There was homoscedasticity, as assessed by visual inspection of a plot of standardised residuals versus standardised predicted values.
- There was no evidence of multicollinearity, as assessed by tolerance values >0.1.
- There were no leverage values >0.2 or values for Cook's distance above 1.
- The assumption of normality was met, as assessed by a Q–Q plot.
- Table 5.12 and Table 5.13 give regression coefficients and standard errors.

Only original data regression results from original data were fully reported as expectation maximisation give similar results to the original data results.

Table 5.12 Summary of multiple regression analysis (original data)

Variable (N)		Unstandardised coefficients		Standardised coefficients		95% CI		Effect size
		B	S.E.	Beta	Sig.	Lower	Upper	
Weight (n=2,380)	Constant	0.75	0.24		0.00	0.28	1.23	0.01
	Baseline weight	0.99	0.00	0.99	0.00	0.99	1.00	
	Smoking	0.43	0.11	0.01	**0.00***	0.22	0.63	
BMI (n=2,275)	Constant	0.41	0.10		0.00	0.22	0.61	0.01
	Baseline BMI	0.99	0.00	0.99	0.00	0.98	0.99	
	Smoking	0.18	0.04	0.02	**0.00***	0.10	0.25	
Waist (n=929)	Constant	4.52	0.75		0.00	3.05	5.99	0.00
	Baseline waist	0.95	0.01	0.97	0.00	0.94	0.97	
	Smoking	0.05	0.23	0.00	0.83	-0.40	0.49	
Alcohol consumption (784)	Constant	3.86	0.54		0.00	2.80	4.91	0.01
	Baseline alcohol consumption	0.56	0.02	0.73	0.00	0.52	0.60	
	Smoking	-1.34	0.68	-0.05	**0.05***	-2.68	0.00	
HADS anxiety score (1592)	Constant	0.86	0.16		0.00	0.56	1.17	0.02
	Baseline HADS anxiety score	0.77	0.02	0.76	0.00	0.74	0.80	
	smoking	-0.75	0.15	-0.08	**0.00***	-1.04	-0.45	
HADS depression score (1562)	Constant	0.64	0.14		0.00	0.37	0.91	0.01
	Baseline HADS depression score	0.74	0.02	0.74	0.00	0.70	0.77	
	smoking	-0.58	0.14	-0.07	**0.00***	-0.86	-0.30	

B=unstandardised regression coefficient; Beta=standardized coefficient; BMI, body mass index; CI=Confidence Interval for unstandardised regression coefficient; CR, cardiac rehabilitation; HADS, hospital anxiety and depression scale; n=Number of patients; S.E.=standard error of the coefficient. *p≤0.05 (bold text).

Table 5.13 Summary of multiple regression analysis (expectation maximisation data)

Variable		Unstandardised coefficients		Standardised coefficients		95% CI		Effect size
		B	SE	Beta	Sig.	Lower	Upper	
Weight (n=3,290)	Constant	0.81	0.20		0.00	0.41	1.21	0.01
	Baseline weight	0.99	0.00	0.99	0.00	0.99	1.00	
	Smoking	0.31	0.08	0.01	**0.00***	0.16	0.46	
BMI (n=3,290)	Constant	0.45	0.08		0.00	0.28	0.61	0.01
	Baseline BMI	0.99	0.00	0.99	0.00	0.98	0.99	
	Smoking	0.13	0.03	0.01	**0.00***	0.07	0.18	
Waist (n=3,290)	Constant	2.85	0.29		0.00	2.28	3.42	0.00
	Baseline waist	0.97	0.00	0.99	0.00	0.96	0.97	
	Smoking	0.11	0.07	0.00	0.11	-0.03	0.24	
Alcohol consumption (n=3,290)	Constant	3.18	0.20		0.00	2.79	3.56	0.00
	Baseline alcohol consumption	0.57	0.01	0.72	0.00	0.55	0.58	
	Smoking	–0.38	0.17	–0.03	**0.03***	–0.72	–0.03	
HADS anxiety score (n=3,290)	Constant	0.60	0.10		0.00	0.41	0.79	0.01
	Baseline HADS anxiety score	0.79	0.01	0.78	0.00	0.77	0.81	
	Smoking	–0.36	0.07	–0.05	**0.00***	–0.50	–0.21	
HADS depression score (n=3,290)	Constant	0.40	0.08		0.00	0.23	0.56	0.01
	Baseline HADS depression score	0.76	0.01	0.76	0.00	0.74	0.78	
	Smoking	–0.29	0.07	–0.05	**0.00***	–0.42	–0.16	

B=unstandardizsd regression coefficient; Beta=standardized coefficient; BMI, body mass index; CI=Confidence Interval for unstandardised regression coefficient; CR, cardiac rehabilitation; HADS, hospital anxiety and depression scale; n=Number of patients; S.E.=standard error of the coefficient. *p≤0.05 (bold text).

5.4.5.1. Weight

A multiple regression analysis was run to predict outcome weight from baseline weight and smoking status. There was independence of residuals, as assessed by a Durbin–Watson statistic of 1.88. R^2 for the overall model was 98.1%, with adjusted R^2 of 98.1%, which is a large size effect (Cohen, 1988). The multiple regression model statistically significantly predicted post-CR weight: $F(2, 2377)=60,443.13$, $p<0.001$, partial $\eta^2=0.01$.

Smoking status is a significant predictor of post-CR weight ($p<0.001$). Adjusting for pre-CR weight, quitters on average gained 0.43 kg more than those who continued to smoke. The coefficient for smoking status was 0.43 (95% CI 0.22 to 0.63), which represents the difference in the post-CR weight of quitters compared to smokers.

5.4.5.2. BMI

A multiple regression analysis was run to predict outcome BMI from baseline BMI and smoking status. There was independence of residuals, as assessed by a Durbin–Watson statistic of 1.94. R^2 for the overall model was 97.2%, with an adjusted R^2 of 97.2% – again, a large size effect (Cohen, 1988). The multiple regression model statistically significantly predicted post-CR BMI: $F(2, 2272)=40,101.17$, $p<0.001$, partial $\eta^2=0.01$.

Smoking status is a significant predictor of post-CR BMI ($p<0.001$). Adjusting for pre-CR BMI, BMI of quitters was, on average, 0.18 kg/m^2 higher than for those who continued to smoke. The coefficient for smoking status was 0.18 (95% CI 0.22 to 0.63), which represents the difference in the post-CR BMI of quitters compared to smokers.

5.4.5.3. Waist

A multiple regression analysis was run to predict outcome waist from baseline waist and smoking status. There was independence of residuals, as assessed by a Durbin–Watson statistic of 1.91. R^2 for the overall model was 94.5%, with an adjusted R^2 of 94.5% – once

again, a large size effect (Cohen, 1988). The multiple regression model statistically significantly predicted post-CR waist: F (2, 926)=7,984.78, p<0.001, partial η^2=0.00.

Smoking status is not a significant predictor of post-CR waist (p=0.83). Adjusting for pre-CR waist, quitters were, on average, 0.05 cm wider in the waist than those who continued to smoke. The coefficient for smoking status was 0.05 (95% CI –0.40 to 0.49) represents the difference in the post-CR waist of quitters compared to smokers.

5.4.5.4. Alcohol consumption

A multiple regression analysis was run to predict outcome alcohol consumption from baseline alcohol consumption and smoking status. There was independence of residuals, as assessed by a Durbin–Watson statistic of 1.89. R^2 for the overall model was 53.2%, with an adjusted R^2 of 53.1% – a large size effect (Cohen, 1988). The multiple regression model statistically significantly predicted post-CR alcohol consumption: F (2, 781)=443.56, p<0.001, partial η^2=0.01.

Smoking status was a significant predictor of post-CR alcohol consumption (p=0.049). Adjusting for pre-CR alcohol consumption, quitters drank, on average, 1.34 fewer units than those who continue to smoke. The coefficient for smoking status is –1.34 (95% CI –2.678 to –0.004) represents the difference in the post-CR alcohol consumption of quitters compared to smokers.

5.4.5.5. Hospital Anxiety and Depression Scale (HADS) anxiety score

A multiple regression analysis was run to predict outcome HADS anxiety score from baseline HADS anxiety score and smoking status. There was independence of residuals, as assessed by a Durbin–Watson statistic of 1.81. R^2 for the overall model was 58.7%, with an adjusted R^2 of 58.7% – a large size effect (Cohen, 1988). The multiple regression

model statistically significantly predicted post-CR HADS anxiety score: F(2, 1589)=1,131.09, p<0.001, partial η^2=0.02.

Smoking status was a significant predictor of post-CR HADS anxiety score (p<0.001). Adjusting for pre-CR HADS anxiety score, quitters had, on average, an anxiety score –0.75 less than those who continue to smoke. The coefficient for smoking status was –0.75 (95% CI –1.04 to –0.46), which represents the difference in the post-CR HADS anxiety score of quitters compared to smokers.

5.4.5.6. HADS depression score

A multiple regression analysis was run to predict outcome HADS depression score from baseline HADS depression score and smoking status. There was independence of residuals, as assessed by a Durbin–Watson statistic of 1.68. R^2 for the overall model was 55.9%, with an adjusted R^2 of 55.8% – a large size effect (Cohen, 1988). The multiple regression model statistically significantly predicted post-CR HADS depression score, F(2, 1559)=987.03, p<0.001, partial η^2=0.01.

Smoking status was a significant predictor of post-CR HADS depression score (p<0.001). Adjusting for pre-CR HADS depression score, quitters had, on average, a score 0.58 lower than those who continue to smoke. The coefficient for smoking status was –0.58 (95% CI –0.86 to –0.30), which represents the difference in the post-CR HADS depression score of quitters compared to smokers.

5.4.5.7. Physical activity

A χ^2 test was conducted for the association between smokers and quitters and self-reported moderate physical activity (150 minutes/week) outcomes: improved (n=679), no change (n=1,126) and worsened (n=93). There was a statistically significant association between smoking group and moderate physical activity outcomes: $\chi^2(2)=23.50$, $p<0.001$; small association Cramér's V=0.11 (Table 5.14).

A χ^2 test was conducted for the association between smokers and quitters and self-reported vigorous physical activity (75 minutes/week) outcomes: improved (n=338), no change (n=1,217) and worsened (n=47). There was a statistically significant association between smoking status and vigorous physical activity outcomes: $\chi^2(2)=17.88$, $p<0.001$; small association Cramér's V=0.11) (Table 5.14).

Table 5.14 Summary of multiple regression analysis (expectation maximisation data)

Physical activity outcomes	**Smokers (%)**			**Quitters (%)**		
	Improve	**No change**	**Worsen**	**Improve**	**No change**	**Worsen**
Δ 150 mins/week (moderate)	31.9	62.8	5.4	43	52.9	4.1
Δ 75 mins/week (vigorous)	18.0	79.3	2.6	26.6	70.0	3.5

Δ, change; %, percentage

The smoking data was more completed in high quality programmes (92.3%) compared to middle (76.9%) and low (58.1) categories, which may introduce biases; we cannot carried out any further analyses between quality categorises in terms of outcomes although I have clustered the outcome by quality categorisation (Appendix 17). Multiple linear regression was performed to understand the effect of continuing smoking or quitting smoking on CR outcomes, using the cluster analysis to account for the nested nature of the of the primary dataset. The results seemed to give similar results to the

original analysis. Please see Appendix 20 for the CR outcomes between smokers and quitters by centre clustration.

5.4.6. e-Survey

The results reported in this section answer aim 3 of this study – to investigate and evaluate the smoking cessation support offered for patients attending CR programmes using an e-survey.

Overall, 175 CR programmes participated – a response rate of 78% (175/224 CR programmes registered in the NACR). The following results present an overview of the survey results (Figure 5.2).

Most CR programmes in the UK offered smoking cessation support for CR attenders: 162 (92.6%) programmes while 13 (7.4%) CR programmes did not provide for patients with support to stop smoking.

About half of CR programmes (87 (49.7%) programmes) offered both internal and external smoking cessation support for CR attenders. Six CR programmes only offered internal support by delivering the smoking cessation support services at the CR programme site, while 69 (39.4%) CR programmes only offered external referral.

Notably, 72/93 (77.4%) CR programmes that delivered smoking cessation support at the CR programme site (internal delivery: 6 only internal + 87 both=93 internal) offer one-to-one sessions. On the other hand, 41 (44.1%) CR programmes offered group education support as internal support.

84 (90.3%) CR programmes that offered smoking cessation support internally delivered it through the CR team. On the other hand, 30 (32.3%) CR programmes delivered smoking cessation support through other qualified member of staff.

60/156 (38.5%) CR programmes that offered external referral smoking cessation support (external delivery: 69 only external + 87 both=156 external), offered referral to doctor or general practitioner. While 133/156 (85.3%) of CR programmes offered referral to community-based cessation programme as an external support.

For 73/162 (45.1%) CR programmes that offered smoking cessation support, patient preference was the factor that most decided whether a patient attended the internal CR programme's smoking cessation service or was referred to external support (Table 5.15). However, eight (4.9%) CR programmes suggested availability as a factor that decided whether a patient would receive internal or external support, one (0.6%) suggested funding constraints, and 36 (22.2%) CR programme suggested specific patient needs (eg. hardened smoker).

Funding was the most common factor for not providing support for smoking cessation for CR attenders, as it was given as the reason by 12/13 (92.3%) CR programmes that did not provide support for patients to stop smoking. The other factor suggested by only one CR programme was lack of appropriate staff.

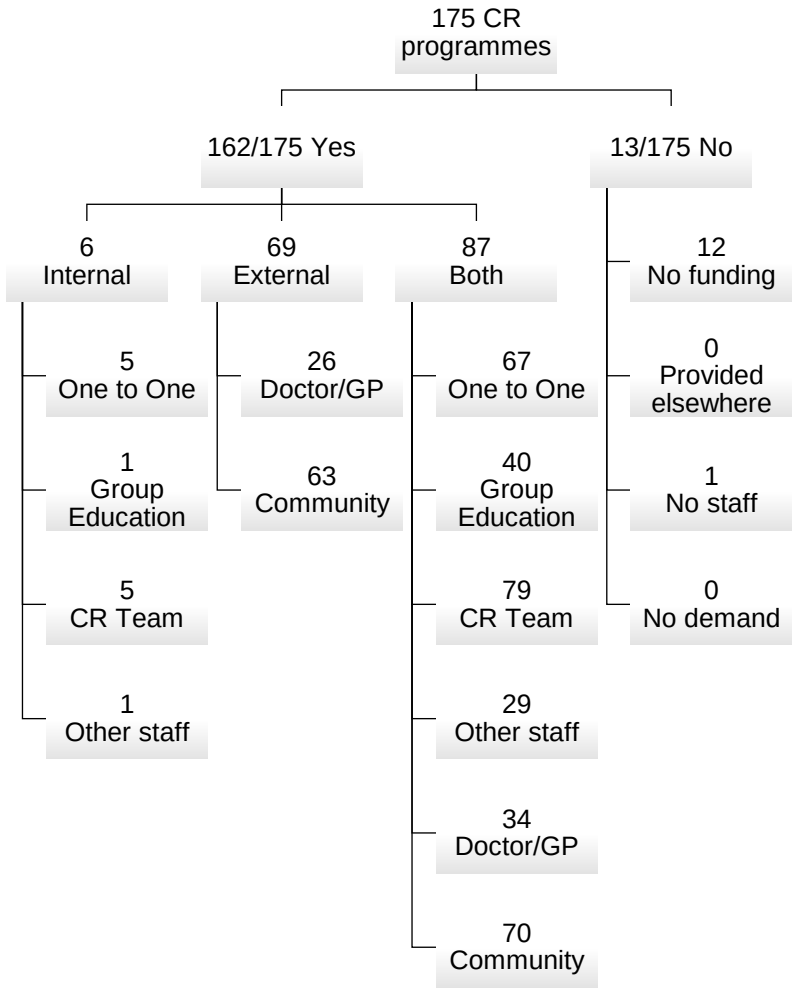


Figure 5.2 Number of cardiac rehabilitation programmes provide stopping smoking support. CR: cardiac rehabilitation; Internal: delivering the smoking cessation support services at the CR programme site; External: external referral.

Table 5.15 What might decide whether a patient would attend the CR Programme or be referred out?

Reason	n=162	Percentage (%)
Availability	8	4.9
Patient preference	73	45.1
Funding constraints	1	0.6
Specific patient needs	36	22.2

n=Number of programmes; %, percentage of programmes.

5.5. Discussion

The sections below discuss the findings for each of the three aims of this chapter. The conclusions, strengths and limitations of this set of analyses are then described. The implications for clinical practice and research of the findings from these analyses are discussed in Chapter 6 – Synthesis.

5.5.1. Predictors of quitting smoking (Aim 1)

This retrospective secondary analysis of data from the NACR found that age, comorbidities, cardiovascular risk, marital status, work status, weight, and HADS anxiety and depression scores differed statistically significantly between continued smokers and quitters. Compared with continued smokers, quitters were younger and weighed more, had fewer comorbidities and lower cardiovascular risk, were less anxious and depressed, and were more likely to have a partner and be employed. No meaningful differences in gender, social deprivation, or physical activity were observed.

Identification of quitting smoking predictors among CR attenders is highly necessary, as this could help provide smokers with interventions that are more likely to help them quit. Programmes designed to encourage smokers to stop may need to account for factors related to partner support as part of an existing prevention programmes to encourage smokers to quit. Tailored intervention thus is needed to help smokers quit, as these research findings highlight that CR programmes need to prioritise patients with multiple comorbidities, high cardiovascular risk, more severe depression, and no partner.

5.5.1.1. Gender and age

There is no gender difference in the likelihood of quitting smoking according to the results of this research. Previous research has found that demographic characteristics are associated with quitting smoking; however, few such differences were identified by this research. For example, quitting smoking had no relationship with gender and being female was not predictive of quitting smoking. This is similar to the findings of numerous studies (Jampaklay et al., 2015; Lee and Kahende, 2007; Hyland et al., 2006; Westmaas and Langsam, 2005; McMahon and Jason, 2000; Rose et al., 1996; Centers for Disease Control and Prevention, 1993), while some studies have reported male gender as a strong predictor of quitting smoking (Li et al., 2010; Osler and Prescott, 1998; Hymowitz et al., 1997), and other studies have also identified female gender as a significant predictor of quitting smoking (Kim, 2014; Tillgren et al., 1996; Waldron, 1991). Interestingly, the number of quitters in this study was higher than those presented in other studies and used data from routine practice, which reflects the real-world situation.

In a large, cohort, population-based study, Hymowitz et al. interviewed smokers aged 25–64 years from 20 American and two Canadian communities in 1988 and again in 1993 as part of the National Cancer Institute's Community Intervention Trial for Smoking Cessation and found that male gender was a statistically significant predictor of smoking

cessation, with lower cessation rates among women (Hymowitz et al., 1997). The research reported in this thesis included 610 (25.3%) men and 284 (34.3%) women aged ≥65 years, which more reflects the real-life population for people with CVD, as Hymowitz et al. did not interview people aged ≥65 years. The results reported by Hymowitz et al. are also consistent with those reported by Li et al. in a longitudinal study that followed Southeast Asian adult smokers for one year (868 patients in Thailand; 1,558 in Malaysia) and by Osler and Prescott in a Copenhagen longitudinal study of Danish adults aged 30–60 years in 1982/1984 (Li et al., 2010; Osler and Prescott, 1998). However, in Li et al.'s longitudinal study, which surveyed and followed up adult smokers for one year in Asia (868 patients in Thailand and 1,558 in Malaysia) to examine prospective predictors of smoking cessation in 2005, only 3.7% of smokers were female (Li et al., 2010) compared wikth 25.1% of the patients in the research reported here.

In addition, the finding that being older was not an important determinant of quitting smoking aligns with the results reported by Hyland et al. (Hyland et al., 2006) but is not consistent with results of previous studies (Jampaklay et al., 2015; Li et al., 2010; Tucker et al., 2005; Osler and Prescott, 1998; Hymowitz et al., 1997). The observational research reported here also shows that quitters were younger than smokers, indicating that older age is not a motivation to quit, but other studies have suggested that older age is another strong predictor of successful cessation (Kim and Cho, 2014; Lee and Kahende, 2007; Hyland et al., 2004; Osler and Prescott, 1998; Hymowitz et al., 1997; Hatziandreu et al., 1990; McWhorter, Boyd and Mattson, 1990).

A prospective cohort study to test for predictors of smoking cessation among smokers in four developed countries (Australia, Canada, UK and US) using a survey of the International Tobacco Control Policy Evaluation Project found that demographic characteristics such as age and gender were not associated with quitting smoking

(Hyland et al., 2006), which aligns with the results reported here. It should be noted that the number of quitters in the research reported here was higher than that presented in some other studies.

On the other hand, a longitudinal study of 2,000 Thai adult smokers from the International Tobacco Control Southeast Asia survey with over four years of follow-up found that age was a strong independent predictor of quitting smoking, as older age was associated with increased success of quitting smoking (Jampaklay et al., 2015). Only 176 (11.8%) of the Thai survey sample (n=1,489) were aged >65 years, whereas 908 (27.60%) of the 3,290 patients included in the analysis reported here were aged ≥65 years old, which is more reflective of the real-life population.

The results reported by Jampaklay et al. are also consistent with those of Li et al. and Osler and Prescott in Asia and Western Europe, respectively (Jampaklay et al., 2015; Li et al., 2010; Osler and Prescott, 1998). Jampaklay et al. suggested that this may be because older people are more likely to experience health problems and thus are more motivated to quit. The percentage of smokers aged ≥55 years in the study reported by Li et al. was 23.9% in Malaysia and 31.1% in Thailand (Li et al., 2010) compared with 63.53% in the study reported here. Osler and Prescott found that quitting smoking was associated with older age (Osler and Prescott, 1998); however, this study did not include individuals aged ≥60 years, while the research reported here included 1,336 (40.61%) patients aged ≥60 years.

Lee and Kahende used a large population-based sample from the 2000 National Health Interview Survey of adults in the US to identify predictors of quitting smoking and found that quitters were more likely to be older (Lee and Kahende, 2007). However, the

percentage of smokers and quitters aged ≥65 years were 5.6% and 11.6%, respectively, while the research reported here included 28.5% and 26.1%, respectively.

5.5.1.2. Marital status

The probability of quitting smoking in the research reported here was 40% lower for single patients compared with patients with partners. Marital status was identified as a major predictor of stopping smoking. This is similar to the findings of the British Household Panel Survey from 1991 to 2000, in which marital status was an important sociodemographic predictor of quitting smoking (Chandola, Head and Bartley, 2004); the findings of Kim, who reported that being married was a significant predictor of successful smoking cessation in patients in the fourth Korea National Health and Nutrition Examination Survey (Kim, 2014); the findings of West et al. who reported that smokers whose partners objected to smoking were more likely to quit (West et al., 2001); and the findings of Gourlay et al., who reported that marital status was the strongest predictor of quitting smoking (Gourlay et al., 1994). Other studies have also identified being married as a significant predictor of quitting smoking (Broms et al., 2004; Chandola, Head and Bartley, 2004; Tillgren et al., 1996; Derby et al., 1994). Moreover, these findings are consistent with the results of the large population-based sample from the 2000 National Health Interview Survey of adults in the US, which showed quitters were more likely to be married or living with a partner (Lee and Kahende, 2007). The US Public Health Service clinical practice guideline also states that social support during smoking cessation increases the likelihood of quitting smoking and recommends that smokers are counselled to ask for social support from their spouse or partner, friends, and co-workers (Fiore et al., 2009). Stopping smoking thus seems to be influenced strongly by the social environment, and CR programmes that promote smoking cessation might benefit from involving partner/spouse to encourage quitting smoking.

5.5.1.3. Comorbidities and cardiovascular risk

The probability of quitting smoking decreases by 12% (OR 0.88 (95% CI 0.80 to 0.96)) per additional comorbidity and is 71% higher (OR 1.71 (95% CI 1.12 to 2.62)) for low-risk patients compared with high-risk patients. Numerous studies have addressed the impact of individual sociodemographic characteristics or clinical measure characteristics on quitting smoking. The limitation of these studies is that they have not taken a holistic approach where smokers' sociodemographic, clinical measures, cardiovascular risk and comorbidity profile are examined together. Although the Danish study found that self-rated health status was not associated with quitting smoking, it suggested that patients with high cardiovascular risk and multiple comorbidities are less likely to quit smoking (Osler and Prescott, 1998), which is similar to the findings of the research reported here.

5.5.1.4. Depression

The probability of quitting smoking decreases by 5% (OR 0.95, 95% CI 0.90 to 0.99) per additional point increase in the HADS depression score. This is in line with the finding of a meta-analysis of 42 trials by Hitsman et al. in which major depression has a modest adverse effect on quitting smoking (Hitsman et al., 2013) and also agrees with a review that concluded that depression greatly decreases the likelihood of quitting smoking (Glassman, 1993) and the results of the National Health and Nutrition Examination Survey (NHANES) and follow-up NHANES Epidemiologic study, which suggested that smokers with higher severity of depression are less likely to quit than smokers with less severe depression (Anda et al., 1990).

5.5.2. Quitting smoking and cardiac rehabilitation (Aim 2)

The research findings based on routine clinical data show that, after CR, quitters, on average, gain 0.43 kg (0.31 kg using expectation maximisation data) more than those who continue to smoke ($p<0.001$) and have a BMI 0.18 kg/m^2 (0.13 kg/m^2 using expectation maximisation data) more than those who continue to smoke ($p<0.001$). Although differences in weight and BMI scores after CR were statistically significantly different for quitters and continued smokers, the mean differences of 0.43 kg and 0.18 kg/m^2 were of little clinical importance, as a statistically significant result is not necessarily clinically important. However, the data are sufficient to make a strong clinical recommendation regarding the impact of CR to prevent weight gain after cessation.

Evidence suggests that quitting smoking is associated with a mean increase in body weight of 3–5 kg, with most weight gain occurring within 3 months of quitting (Tian et al., 2015; Aubin et al., 2012); however, the research findings reported here show that smokers who quit smoking while attending CR do not gain weight, which aligns with the findings of Farley et al. that exercise could reduce post-cessation weight gain (Farley et al., 2012). With regard to smoking and weight interactions, the extent of weight gain associated with smoking cessation in patients attending CR is much less than previous studies suggest. These research findings provide evidence that CR is positively associated with weight management during smoking cessation.

Statistical significance only indicates whether the result is not likely due to sampling error, which, although important in its own right, does not indicate the ‘strength’ of the differences. This is where confidence intervals can help, as they not only provide most of the information about the statistical test but also information on the magnitude of the difference. The confidence interval for mean difference in weight between continued smokers and quitters after CR was 0.22 to 0.63 kg (0.16 to 0.46 kg using expectation

maximisation data) and for mean difference in BMI is 0.1 to 0.25 kg/m^2 (0.07 to 0.18 kg/m^2 using expectation maximisation data). Because of the well-documented health benefits of quitting smoking, clinicians should inform smokers about the likelihood of weight gain and encourage them to attend CR to avoid excess weight gain.

There is no evidence for the clinical effectiveness of smoking cessation interventions within CR, but the research findings suggest CR as delivered in routine practice is associated with helping patients quit smoking and avoid weight gain. The NACR data regarding smoking status suggest that about 37.6% of patients who are smoking when recruited to CR successfully stop after CR. Quitting smoking is considered a tremendous element in both primary and secondary prevention of cardiovascular disease (Mons et al., 2015).

Following CR, quitters on average drink 1.34 units of alcohol consumption fewer than those who continue to smoke. Following CR, 43% and 26.6% of quitters improved to achieve the recommended UK moderate and vigorous physical activity guidelines, respectively, compared with 31.9% and 18% of continued smokers. An even stronger benefit was seen in both HADS anxiety and depression scores, which showed that quitters on average score 0.75 and 0.58 less than those who continue to smoke.

Comprehensive CR programmes seem to have a beneficial role in helping patients after a cardiac event or procedure, with significant improvements in smoking behaviour, weight management, physical activity levels, psychosocial health, and alcohol consumption. When a comprehensive CR includes exercise with smoking cessation and patient education, this research initiate evidence for improvements in cardiac risk factors, particularly increased smoking cessation and improvements in physical and psychosocial health.

5.5.3. e-Survey (Aim 3)

This is the first survey to enquire about the smoking cessation support offered to CR attenders in the UK. This survey explored current smoking cessation support services offered in routine practice to CR attenders to give context to findings around the association between CR and outcomes of quitting smoking and to assess the potential of CR in helping patients quit smoking.

The survey had a high response rate of 78%. Although one study has shown low levels of cessation support following hospital discharge (Boggon et al., 2014), the e-survey showed that 92.6% of CR programmes in the UK offer smoking cessation support for patients attending CR. These results show that CR programmes in the UK adhere to guideline recommendations for smoking cessation interventions (NICE, 2018; BACPR, 2017; SIGN, 2017; NICE, 2013c). In addition, the research results suggest that CR programmes in the UK offer assistance for patients who smoke by delivering smoking cessation support at the CR programme site in the form of individualised one-to-one sessions or group educational sessions, as well as referral for external smoking cessation support. The internal support is provided by the CR team or another qualified member of staff. One-to-one sessions are the dominant service offered at the site of CR programmes, while external provision is predominantly through referral to community-based cessation programmes. Patient preference is the factor that most decides whether a patient would attend the CR programme (internal) or be referred out (external).

Provision of smoking cessation support in CR could have multiple benefits: the presence of such a programme could entice more smokers to attend CR, and the increased support for cessation they receive could encourage them to remain in the CR programme generally. Prior studies suggest that CR attendance improves smoking cessation rates,

and Riley et al. found a strong relationship between smoking cessation and CR attendance (Riley et al., 2017).

Failure of adherence to guideline recommendations to provide support for smoking cessation for CR attenders was predominantly due to funding challenges. Cutting funds to CR services is a false economy, as evidence shows that smoking cessation services provide effective support for smokers who want to quit (Bauld et al., 2009) and lack of this provision leads to higher costs for the NHS to manage and treat diseases caused by smoking in the long term. The National Institute for Health and Care Excellence (NICE) estimates that for every pound invested in smoking cessation, £2.37 in benefits are generated (Pokhrel et al., 2016). Moreover, lack of investment in CR programmes may impact on service provision. In Yorkshire, for example, a qualitative study found staff to be aware of limited service availability (Lindsay, 2008), which may influence which patients are invited. Finally, it should not have to be a choice that some smokers who attending CR are supported to quit and others are not.

5.6. Conclusions

This research aimed to determine sociodemographic and clinical factors associated with the likelihood of quitting smoking among CR attenders; ascertain whether weight gain is associated with smoking cessation in patients attending CR and whether CR, as delivered in routine practice, helps patients stop smoking and avoid weight gain; and evaluate the smoking cessation support offering for CR attenders.

Patients with high cardiovascular risk, multiple comorbidities, no partner, and more severe depression were unlikely to quit smoking during CR. This research highlights routine factors that determine smoking cessation outcomes and that could inform the delivery of CR to better help patients quit smoking.

Cardiac rehabilitation is an effective intervention to manage weight gain when quitting smoking. Quitting smoking during CR is associated with a mean increase of 0.4 kg in body weight, which is much less than seen in recent systematic reviews. Quitters who attend CR improved in physical activity status and psychosocial health measures compared with smokers.

This research is the first to evaluate smoking cessation support in CR services in the UK, with 92.6% of CR programmes in the UK offer smoking cessation support for CR attenders. These results demonstrate adherence of CR in the UK to the guideline recommendations for smoking cessation interventions. Future research linking smoking cessation to quality is needed.

5.7. Strengths

The strength of these analyses, like much of the research reported in this thesis, lies in the use of an observational approach based on routinely collected patient data, a prospective cohort design, and use of large dataset taken from routine clinical practice and representing a CR intervention with a median duration of nine weeks. The study included many of the potentially important factors associated with quitting smoking, and expectation maximisation analyses was used to adjust for missing values.

5.8. Limitations

Retrospective observational studies have known limitations in terms of data capture and the quality of the 303 CR programmes in the UK – according to the 2017 NACR report, only 224 (74%) programmes entered data electronically to the NACR. Although it can be argued that there are enough data to be representative and carry out a reliable analysis, future work should aim to achieve greater capture of available data across the UK.

Although CR programmes are encouraged to provide complete patient records, a proportion of patient data were expected to be missing due to non-completion of patient records. On the basis of the NACR data, 43.5% of all patients who started CR did not have a post-CR assessment recorded, which might have affected the representativeness of the research sample.

A limitation of the study is the use of self-reported data to determine smoking status, which may be subject to recall and social desirability biases. Some relevant factors that influenced quitting smokinghave been missed from the analysis due to high levels of missing data: variables with more than 60% missing values were eliminated from the dataset and some may not have been collected in the NACR. Some characteristics known to influence quitting smoking in the literature were not collected by the NACR, such as motivation to stop smoking, number of cigarettes per day, proportion of smokers in the household, and exposure to warning labels (Shang, Chaloupka and Kostova, 2014; Li et al., 2010; Chandola, Head and Bartley, 2004; Osler and Prescott, 1998). Although expectation maximisation is a validated robust method of handling missingness in the data, it remains a computational approximation process of replacing the missing value with a range of values that the real value could have taken.

5.9. Summary of findings

- Patients with high cardiovascular risk, multiple comorbidities, no partner, and more severe depression were unlikely to quit smoking during CR.
- Patients who quit smoking tended to have lower cardiovascular risk, fewer comorbidities, and lower depression scores when starting CR and were more likely to be in a relationship.
- Quitting smoking during CR is associated with a mean increase of 0.4 kg in body weight, which is much less than seen in recent systematic reviews.
- Quitters who attend CR improved in physical activity status and psychosocial health measures compared with smokers.
- As delivered in routine practice, CR is associated with helping patients quit smoking and avoid weight gain
- 92.6% of CR programmes in the UK offer smoking cessation support for CR attenders.

Chapter 6 Conclusion

6.1. Research aims

Huge variability in the quality of service delivery of cardiac rehabilitation (CR) and patient outcomes in the United Kingdom (UK) has consistently been reported, and the beneficial effects of CR have been challenged in recent years, so there is a need to investigate whether current CR programmes, delivered in the context of modern cardiology, still benefit patients. The research reported in this thesis therefore aimed to overcome the limited scientific evidence around the quality of service delivery for CR in the UK by evaluating CR quality and outcomes to ascertain the extent to which programmes meet recommended standards for the delivery of CR and assess whether variation in quality of CR delivery is determined by the characteristics of CR attenders. In addition, this research aimed to determine predictors of quitting smoking and to ascertain whether CR is associated with helping patients quit smoking and avoid weight gain. The specific aims of this research were to:

1. assess the extent to which programmes meet national standards for the delivery of CR
2. assess whether the quality of CR delivery is associated with the participating patients' characteristics
3. determine sociodemographic and clinical factors associated with the likelihood of quitting smoking among CR attenders
4. ascertain whether CR helps patients quit smoking and avoid weight gain
5. evaluate the smoking cessation support offered to CR patients using an e-survey.

The research aims were achieved with favourable findings, which make several contributions to the current literature. The major finding for each research aim were addressed in Chapters 4 and 5, with a brief discussion of these findings below.

The literature review in Chapter 2 stated that several recent studies, meta-analyses (Sumner, Harrison and Doherty, 2017; Anderson et al., 2016; Rauch et al., 2016; Sagar et al., 2015) and recommendations of international guidelines (BACPR, 2017; Piepoli et al., 2016; Smith et al., 2011) suggest a beneficial effect of CR in patients with cardiovascular disease (CVD), but considerable scientific doubt is still apparent about the quality and type of CR offered, which varies considerably between and within countries (NACR, 2017; Zwisler et al., 2012; Bjarnason-Wehrens et al., 2010). This research is the only UK-specific study that evaluates the quality of CR in routine practice, clarifies the extent to which it reflects the evidence base, and shows that high-quality CR is achievable in the modern cardiology era and that many programmes deemed to provide mid-level quality of CR are close to meeting high-quality standards. However, substantial unacceptable variation, below the accepted standards, exists.

6.2. Quality of delivery of cardiac rehabilitation in the UK

Chapter 4 described the statistically significant differences among CR programmes in terms of meeting the recommended standards for quality delivery of CR in the UK, as well as significant differences in the patient population among the quality categories for delivery of CR services. The main finding of the research reported in Chapter 4 was that 30% of the CR programmes in the UK that contributed to the National Audit of Cardiac Rehabilitation (NACR) met the standards criteria for the delivery of high-quality CR. Despite the fact that there are no accepted standards for judging the quality of CR

delivery worldwide, leaving uncertainty about the effectiveness of CR as delivered in routine clinical practice (Zwisler et al., 2012; Bjarnason-Wehrens et al., 2010), the ability to differentiate the quality of CR delivery based on the National Certification Programme for Cardiovascular Rehabilitation (NCP_CR) criteria, which is based on clinical guidance from the National Institute for Health and Care Excellence (NICE) and national CR statistics for the UK from NACR reports (NACR, 2015; NICE, 2013c, 2010c) is important. The findings reported in this thesis strengthen the importance of the quality assessment by explaining how this impacts through meet service standards for CR delivery (BACPR, 2017; Furze, Doherty and Grant-Pearce, 2016; NACR, 2017).

The British Association for Cardiovascular Prevention and Rehabilitation (BACPR) has developed standards and core components for delivery of CR within the UK (BACPR, 2017). The NACR is committed to promoting and supporting quality service provision based on measurable indicators of successful delivery, and its database makes it possible to compare the quality of CR delivery with recommended standards (NACR, 2017). In this thesis, for the first time, quality of CR at a local programme level is reported, including variation across CR programmes in the UK. The standards defined by BACPR are achievable for CR programmes to aim for while still delivering a good quality standard of CR service and are derived from the national average in the latest published version of the NACR annual report (BACPR, 2017; Furze, Doherty and Grant-Pearce, 2016; NACR, 2015). There is no doubt that the results of this research align with findings from the latest NACR, which reported that CR in routine practice is not delivered equitably across the UK, is being delivered later than recommended, is not underpinned by pre- and post-assessment, and is of shorter duration than recommended standards (NACR, 2017; Anderson et al., 2016; NACR, 2016; Piepoli et al., 2016; NACR, 2015; Vanhees et al., 2012).

In a two year period since NCP_CR started less than 40 programmes submitted for the formal BACPR panel review for certification (BACPR/NACR, 2018b). At this rate it would take 15 years to certify all programmes. In May 2018 the Steering Group of NCP_CR decided to run certification annually as part of the NACR report (BACPR/NACR, 2018a). Information on the extent by which programmes achieve or come close to being certified will be shared with each programme, as part of a quality assurance check, prior to the publication of the report. This new approach to certification, partly informed by my thesis, allows providers and commissioners of CR services to obtain an up to date assessment of the quality of CR delivery.

The findings reported in Chapter 4 add further rigour to the approach of this research, as they assessed the whether the quality of CR delivery is associated with participating patients' characteristics. Mean total comorbidities, higher body mass index (BMI) scores, proportion of patients with diabetes or asthma were associated with CR programmes categorised as high quality. Patients who participated in high-quality CR programmes tended to be those with high-risk status, high BMI score, high waist circumference, high blood pressure, high Hospital Anxiety and Depression Scale (HADS) anxiety and depression score, and more comorbidities; smokers; and in more socially deprived groups than patients in the low-quality programmes. In addition, patients in high-quality CR programmes include patients with lower fitness levels than low-quality programmes. Patients with lower fitness levels often have more severe functional impairment and are most in need of CR, as well as being most likely to benefit (Beswick et al., 2004). Ensuring equity of access to CR and improving the consistency of delivery should increase long-term behaviour changes and contribute to a reduction in CVD-related health inequality (Furze et al., 2016). Evaluation and dissemination of data about the populations attended CR programmes in the UK may help low-quality programmes to be more inclusive.

6.3. Impact of CR on smoking cessation

Chapter 5 reports on the evaluation of whether CR, as delivered in routine practice, is associated with helping patients quit smoking and avoid weight gain. Using the NACR data, which reflects the reality of routine clinical practice, the extent of weight gain associated with smoking cessation in patients attending CR is much less than previous studies suggest (Tian et al., 2015; Aubin et al., 2012). These new findings provide evidence that CR is positively associated with weight management during smoking cessation. One of the challenges for clinicians and researchers is reporting patient outcomes, as some outcome measures are inter-related, and this is especially so for weight gain among patients who quit smoking. With such an interaction, it would be incorrect to consider the success of weight management and smoking cessation associated with CR programmes at a named local level without taking this relationship into account.

The impact of CR on weight gain after smoking cessation had not been evaluated prior to this study. The research findings reported in this thesis suggest that smokers who quit smoking while attending CR do not gain weight. The data are sufficient to make a strong clinical recommendation regarding the impact of CR on weight gain after cessation. Because of the well-documented health benefits of quitting smoking, clinicians should inform smokers about the likelihood of weight gain and encourage them to attend CR to avoid excess weight gain. There is no evidence for the clinical effectiveness of smoking cessation interventions within CR, but the findings of this research suggest that CR, as delivered in routine practice, is associated with helping patients quit smoking and avoiding weight gain. The NACR data regarding smoking status suggest that about 37.6% of patients who are smoking when recruited to CR successfully stop after CR.

Quitting smoking is considered a vital component of both primary and secondary prevention of CVD (Mons et al., 2015).

The conclusion of this research is based on the results from incomplete records of NACR data for patients participating in CR; an analysis of all data with missing values handled through expectation maximisation gave similar results to the original analysis. The multiple linear regression models discussed in Chapter 5 showed that people who quit smoking following CR also reduced alcohol consumption and achieved the UK‘s recommendations for moderate and vigorous physical activity compared with continued smokers. An even stronger benefit was seen in terms of psychosocial health measures (both HADS anxiety and depression scores), as quitters had less severe psychosocial problems than those who continued to smoke.

What became clear from this research was that comprehensive CR programmes seem to have a beneficial role in helping patients after a cardiac event or procedure, with significant improvements in smoking behaviour, weight management, physical activity levels, psychosocial health, and alcohol consumption. This research found evidence for improvements in cardiac risk factors, particularly increased smoking cessation and improvements in physical and psychosocial health.

The findings reported in Chapter 5 also showed that identification of characteristics that predict quitting smoking among CR attenders is highly needed. Existing programmes designed to encourage smokers to quit may need to account for factors related to partner support to encourage them to quit. Tailored intervention is needed to help smokers quit, as these research findings highlight that CR programmes need to prioritise patients with multiple comorbidities, high cardiovascular risk, more severe depression, and no partner.

The results of the e-survey of CR programmes in the UK that explored the support to quit smoking offered for CR patients discussed in Chapter 5 showed that CR programmes in the UK routinely offer smoking cessation services to help patients quit smoking. This short survey will be used to add programme-level details so that future NACR reports can take account of this when evaluating the impact of CR on smoking.

6.4. Implications

The research reported in this thesis is a pioneering study of evaluation of CR quality and outcomes using the NACR database. The NACR reports have highlighted that that CR in routine practice is not delivered equitably across the UK in terms of standards and outcomes. The results found in the evaluation of quality of CR delivery, which were presented at the BACPR conference in Cardiff, Wales, in October 2016 and have been published in *Open Heart* (Appendix 13), show that high-quality CR is achievable in the modern cardiology era and that many other CR programmes deemed as mid-level quality are close to achieving high-quality delivery of CR. The results of the evaluation of the association of the quality of CR delivery with participating patients' characteristics was presented at the Australian Cardiovascular Health and Rehabilitation Association (ACRA) annual scientific meeting in Perth in August 2017, with the associated abstract published in the *European Heart Journal* (Appendix 14). My manuscript "To what extent is the variation in cardiac rehabilitation quality associated with patient characteristics?" has been assessed by BMC Health Services Research reviewers and they have accepted it after minor revisions Appendix 15.The findings reported in Chapter 5 were presented at the BACPR conference in London in October 2017, where I have been awarded the New Investigator Award from the BACPR and also received a prize for my oral presentation Appendix 16, and at the American Heart Association conference in Los Angeles in November 2017.The research reported in this thesis has evaluated CR quality

against standards that are used to help clinicians to categorise as high-quality services. This new approach to assessing the quality of CR programmes, in which the extent to which programmes meet standards is benchmarked against national average, provides a robust and meaningful appraisal of how CR programmes are performing. About 30% of CR services meet the recommended standards for the delivery of high-quality CR. However, 70% failed to meet these high-quality criteria which is an unacceptably large number of services. More work is needed to support CR teams to overcome barriers to delivering high-quality CR. More emphasis should be placed on strategies to improve quality of CR delivery. Such strategies have the potential to benefit many CR programmes as they progress to high quality.

Despite having tariff-based NHS funding and NICE clinical guidelines, which define the service specification for the delivery of CR, the results of this research showed that the quality of programmes in the UK varies significantly in terms of meeting the recommended standards. The results also highlight considerable differences in programmes meeting the delivery standards for CR quality between the countries in the UK that contribute to the NACR (England, Wales and Northern Ireland) (BACPR, 2017). Differences in duration of CR and inconsistencies in pre- and post-assessment practices between programmes are cited as likely contributing factors. The ability of NACR to quality assure data at a local level is helping commissioners and providers of CR understand barriers to uptake and develop interventions to improve service quality and outcomes (NACR, 2017). Variation in the duration of CR by country is not unanticipated, as the commissioning, funding and incentivisation the health delivery infrastructure differs between countries (NACR, 2017). Understanding of service-level quality and inequalities in CR delivery is dependent on healthcare infrastructure and resources that support CR services. With relatively small changes to service delivery standards, many programmes could meet the recommended standards. The extent of the benefit of CR

programmes seen through benchmarked standard measures should focus the attention of all CR programmes, as it is likely that these metrics will be viewed as surrogates for high-quality services in the future.

Because of the well-documented health benefits of quitting smoking, clinicians should inform smokers about the likelihood of weight gain and encourage them to attend CR to avoid excess weight gain. The data used in this research are sufficient to make a strong clinical recommendation regarding the impact of CR on weight gain after smoking cessation. When comprehensive CR combines exercise with a multifactorial programme including smoking cessation and patient education, this research found evidence for improvements in cardiac risk factors, particularly increased smoking cessation and improvements in physical and psychosocial health. The e-survey will be used by the NACR to add programme-level details so that future NACR reports can take this into account when evaluating the impact of CR on smoking. The findings reported in Chapter 5 show that identification of characteristics that predict quitting smoking among CR attenders is highly desirable, as this could help match smokers with strategies that are more likely to help them quit, identify smokers who might need more intensive treatment (who would then require referral to specialist centres), and make the most of healthcare resources. Programmes designed to encourage smokers to quit may need to account for factors related to partner support as part of existing prevention programmes to encourage smokers to quit. We felt there is a need to analyse and share these initial findings to help clinical teams feel reassured that patients who smoke can benefit from CR.

At present, too little evidence is available on the quality of CR to make a recommendation on improving the quality of standards. However, the results reported in Chapters 4 and 5 of this thesis are applicable to the clinical setting by showing the importance of setting

standard measures for delivery of high-quality CR services, including the proportion of populations with higher comorbidities and BMI served by CR programmes; the proportion who successfully quit smoking; and smoking services targeting patients with high cardiovascular risk, multiple comorbidities, no partner, and more severe depression. Setting targets for CR services, including the number of patients with more comorbidities who use the service and the proportion who successfully quit smoking, may improve quality of CR delivery.

6.5. Limitations of the study

As discussed in Section 4.8 and 5.8, only 224 (74%) of the 303 CR programmes in the UK, according to the 2017 NACR report, entered data electronically to the NACR (NACR, 2017). Future work should aim to achieve greater capture of available data across the UK. Our study population had a good sample size and is considered representative of modern routine CR. Only 62% of patients that start CR have a recorded post assessment (NACR, 2017). 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 post assessments and baseline demographics would improve the power given to research such as this.

The NACR 2017 reported that less than a third of patients had recorded pre-CR and post-CR physical fitness measurements either ISWT or 6MWT at baseline (NACR, 2017). This does limit the study results in that there may have been some reporting bias. Another limitation with this study is that the study could not include intensity/dose of CR. The length of CR was included as a covariate as duration; however, the NACR currently has insufficient information regarding the number of sessions to calculate the dose.

The IMD variable for a measure of social deprivation is reduced the population to only England. As it is becoming more evident that the inter-country variations in terms of the CR offer and the structure within centres is diverse, future research is needed when a multi-country (Wales and Northern Ireland) measure of social deprivation is available.

In addition to completeness of data, there are some issues around the use of self-reported data questionnaires to determine patients' smoking status, as honesty of patients recording smoking status may be questioned and could lead to recall and social desirability biases. A breath carbon monoxide measure in smoking cessation is recommended in future studies for validating smoking self-report (Velicer and Prochaska, 2004; Middleton and Morice, 2000). It is also possible that some relevant factors that influenced quitting smoking (potential confounders) have been missed from the analysis due to high levels of missing data, and some may not have been collected in the NACR.

Since the smoking data was more completed in high quality programmes (92.3%) compared to middle (76.9%) and low (58.1) categories, which may introduce biases; we cannot carried out any further analyses between quality categorises in terms of outcomes (Appendix 17). As large as dataset is, there is low prevalence of smoking in population due to its observational nature. We lacked information on the long-term follow up data available in case of smoking relapse that may have influenced the readiness for smoking cessation.

In the research analysis we included an expectation maximisation method, a validated robust method of handling missingness in the data, which helped fill in missing data, and the population used was representative of modern CR patients in the UK. It remains a computational approximation process of replacing the missing value with a range of values that the real value could have taken. The statistical methods used in this paper

were justified, however, repeat analysis of this study using a greater sample size will help to validate these findings. Each year the completeness of data improves with the NACR, perhaps when coverage reaches a higher level in some years a repeat of the analysis may confirm that the missingness was not a selection or reporting bias, although we confident it is not and the expectation maximisation was for increasing statistical power.

6.6. Recommendations for improvement and future study

The thesis reports the first research to evaluate CR services in the UK against recommended standards. Further improvements in evaluations, presently underway by the NACR, aim to utilise country-specific averages and compare CR programmes within countries against their national averages. There is a need to assess the extent by which CR programmes meet the standards for each health region and country to create a clearer picture of the variation in quality of CR delivery in addition to assessing the variation in participating patients' characteristics. This approach to nation-specific analysis of the quality of CR programmes will help national leads and CR programmes in each country to see where their strengths and weaknesses lie and use this to help inform their strategies for improvement (NACR, 2017). This approach reflects the context, infrastructure and resources for each country, which will help set realistic expectations. Evaluation of data about the populations served by CR programmes and characteristics of the programmes may help low-quality programmes to be more inclusive.

The findings from this research indicate regional variation in quality of service delivery but also highlight a need for greater entry of data to the NACR – a core component of the BACPR standards (BACPR, 2017; NACR, 2017). There is a need to greater capture available data across the UK. Overall, 7,128 patients completed CR without having an assessment, and not performing a post-CR assessment not only fails to align with BACPR standards but also means that patients do not obtain a long-term management goal or plan.

Measurement of the quality of CR programmes based on the recommended standards criteria has the potential to ensure equitable service provision and deliver international excellence in CR and is one method in which CR programmes can demonstrate this commitment. Quality scoring of criteria offers an opportunity for CR programmes not only to be recognised for high-quality care but also to undertake an objective, self-driven, reflective appraisal of the programme's strengths and unharnessed potential. Assessment of the quality of CR delivery through these criteria represents a positive step to ensuring that patients, irrespective of where they live, are able to access good-quality services. It provides information for patients on the level of service they can expect from a CR programme and provides commissioners with a badge of quality assurance for their local CR services.

In future trials, it would be useful to pay increased attention to recruitment of patients who are more representative of the broader CHD population, including those at higher risk and with major comorbidities. Clinical and research efforts should be directed towards improving the rate of smoking cessation in patients with cardiovascular disease.

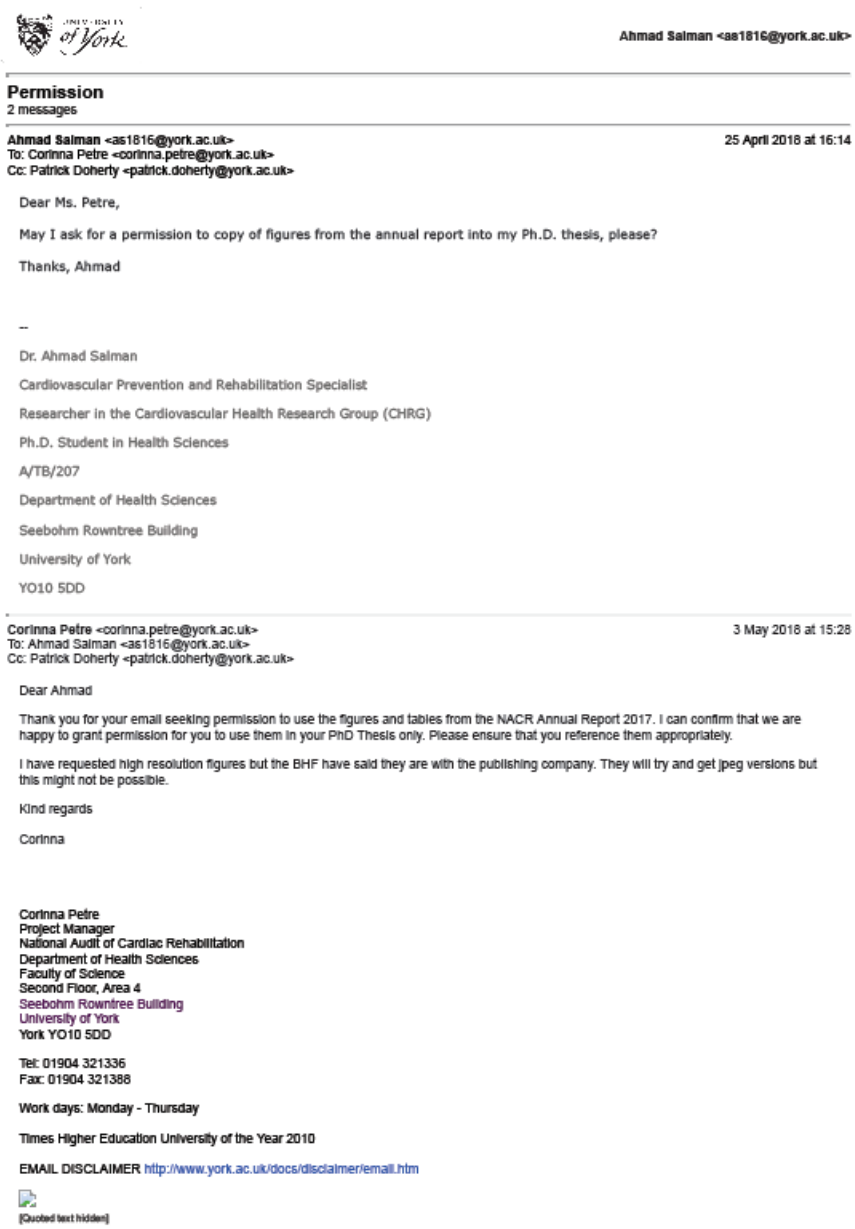
Patients willing to make change more likely to go to CR, perhaps such a low prevalence of smoking in the NACR data is an indicator that smokers do not come. Future research is important to look at this matter. Also, future research linking smoking cessation to

quality is needed. It is important to capture the variation within centres/countries in the future analysis. Due to incomplete data and massive variation in the demographics of the centres which may introduce biases between quality categorises (Appendix 17); future research is needed to investigate the extent to which patients meet outcomes targets among high-, middle- and low-quality CR programmes particularly how can quality categorisation could impact on terms of smoking outcome which when I tried to do that it distorts the results. Programme outcomes based on quality is a recommended area of research for the future. Due to the scale of the challenge in terms of clinical presentation and potential for change, at the point patients start CR, is very different from programme to programme; future methodology research is required due to the complexity of reporting the extent of change.

Our research recommends increasing the number of pre and post CR assessments for all core components, assessment of patients who complete CR should be at 100%, and the frequency and quality of patient assessment before and after CR needs to improve. Exploration and comparison of intensive CR vs standard care using NACR data is needed in future when the NACR will has sufficient information of intensity/dose variables added to NACR database.

Appendices

Appendix 1 Permission to use figures form the NACR authors



University of York

Ahmad Salman <as1816@york.ac.uk>

Permission
2 messages

Ahmad Salman <as1816@york.ac.uk> 25 April 2018 at 16:14
To: Corinna Petre <corinna.petre@york.ac.uk>
Cc: Patrick Doherty <patrick.doherty@york.ac.uk>

Dear Ms. Petre,

May I ask for a permission to copy of figures from the annual report into my Ph.D. thesis, please?

Thanks, Ahmad

--

Dr. Ahmad Salman

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Corinna Petre <corinna.petre@york.ac.uk> 3 May 2018 at 15:28
To: Ahmad Salman <as1816@york.ac.uk>
Cc: Patrick Doherty <patrick.doherty@york.ac.uk>

Dear Ahmad

Thank you for your email seeking permission to use the figures and tables from the NACR Annual Report 2017. I can confirm that we are happy to grant permission for you to use them in your PhD Thesis only. Please ensure that you reference them appropriately.

I have requested high resolution figures but the BHF have said they are with the publishing company. They will try and get jpeg versions but this might not be possible.

Kind regards

Corinna

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Appendix 2 The National Audit of Cardiac Rehabilitation (NACR) assessment questionnaire

NACR Questionnaire Assessment 1

National Audit

THE QUESTIONNAIRES AND THE NATIONAL AUDIT OF CARDIAC REHABILITATION

Cardiac rehabilitation starts with an assessment to see how we can help you and we would be grateful if you would fill in the attached questionnaire. This information is also used for the National Audit of Cardiac Rehabilitation.

We will ask you to fill the questionnaire in again at the end of the rehab programme and then again 12 months later. The reason for collecting the data is to measure what you achieve on this programme, and through combining everyone's information in the National Audit Programme to find ways to improve cardiac rehabilitation. It is also very helpful for us to compare how we are doing here so that, if necessary, we can improve our programme.

WHAT HAPPENS TO THE INFORMATION?

We enter the information into a computer programme in the hospital and this is treated in the same way as all information you provide to your healthcare team.

The data is collected by NHS Digital (formerly HSCIC) who hold data and information relating to health and social care (http://content.digital.nhs.uk/). They anonymise it and send it to the BHF Cardiac Care and Education Research Group at the University of York, who combine the data into an annual report. You can download the previous reports here:

http://www.cardiacrehabilitation.org.uk/reports.htm

Data collected by the audit may be shared for research purposes in an anonymised format. The information will only be shared if the research is related to improving cardiac rehabilitation services for patients.

WHO SEES MY INFORMATION?

The staff who treat you here, and staff at NHS Digital if necessary. Staff of the National Audit in York see the same information but with the name/NHS number/address details removed so they don't know who it is from.

DO I HAVE TO TAKE PART

No you don't, this is completely voluntary. If you don't want to take part it will not effect your treatment in any way. If you start but want to stop later that is fine too.

QUESTIONS?

If you have further questions please ask any of the staff.

THANK YOU FOR YOUR HELP

About You

NHS No. ..... DOB.....

Name ..... Date .....

Gender (please tick)

Male ☐1 Female ☐2

Marital Status (please tick)

Single	☐1	Married	☐2
Permanent partnership	☐3	Divorced	☐4
Widowed	☐5	Separated	☐6

What is your ethnic group? (please tick)

We are collecting this information to check that everyone has fair access to the help that they need. Please tick the one that describes you best, or, if none of them do, tick number 6 (any other).

White - British	☐A
White - Irish	☐B
White - Any other White background	☐C
Mixed - White and Black Caribbean	☐D
Mixed - White and Black African	☐E
Mixed - White and Asian	☐F
Any other Mixed background	☐G
Asian or Asian British - Indian	☐H
Asian or Asian British - Pakistani	☐J
Asian or Asian British - Bangladeshi	☐K
Any other Asian background	☐L
Black or Black British - Caribbean	☐M
Black or Black British - African	☐N
Any other Black background	☐P
Other Ethnic Groups - Chinese	☐R
Any other ethnic group	☐S

Previous Events: Other heart problems you have had, before the current event (please tick all that apply)

MI (Heart Attack)	☐1	Cardiac Arrest	☐2
Pacemaker	☐3	LV Assist Device	☐4
Angina	☐6	ICD	☐7
Bypass Surgery	☐8	Other Surgery	☐9
Congenital Heart	☐10	Angioplasty / PCI	☐11
Heart Failure	☐12	Transplant	☐13
Other	☐14	No/None	☐15
Arrhythmia	☐16	Unknown	☐99

Other Illnesses You've Been Told You Have (Comorbidity)

Have you ever been told by a doctor that you have definitely had any of the following illnesses?

Please answer every question even if they are all NO.

Angina	NO	☐	YES	☐1
Arthritis (osteoarthritis)	NO	☐	YES	☐2
Cancer	NO	☐	YES	☐3
Diabetes	NO	☐	YES	☐4
Rheumatism	NO	☐	YES	☐6
A stroke	NO	☐	YES	☐8
Osteoporosis	NO	☐	YES	☐7
Hypertension	NO	☐	YES	☐8
Chronic bronchitis	NO	☐	YES	☐9
Emphysema	NO	☐	YES	☐10
Asthma	NO	☐	YES	☐11

('Other Illnesses' cont. over…)

Claudication	NO	☐	YES	☐12
Back problems or chronic pain	NO	☐	YES	☐13
Anxiety	NO	☐	YES	☐14
Depression	NO	☐	YES	☐15
Family History	NO	☐	YES	☐16
Erectile Dysfunction	NO	☐	YES	☐17
Hypercholesterolaemia / dyslipidaemia	NO	☐	YES	☐18
Other illnesses	NO	☐	YES	☐99

Weight, Height and Waist Measurements

Weight: ☐ kg *or* ☐ st ☐ lbs

Height: ☐ m *or* ☐ ft ☐ inches

Waist ☐ cm *or* ☐ inches

Smoking

Never Smoked ☐1 Ex-Smoker ☐2

Stopped smoking since event ☐3 Currently Smoking ☐4

Alcohol

How much do you drink a week? [One unit of alcohol is about equal to: half a pint of ordinary strength beer, lager or cider (3-4% alcohol by volume); or a small pub measure (25 ml) of spirits (40% alcohol by volume); or a standard pub measure (50 ml) of fortified wine such as sherry or port (20% alcohol by volume). There are one and a half units of alcohol in: a small glass (125 ml) of ordinary strength wine (12% alcohol by volume); or a standard pub measure (35 ml) of spirits (40% alcohol by volume).]

Units per Week ☐

Physical Fitness and Activity

(Chief Medical Officer (CMO) Physical Activity Questionnaire)

Do you take regular **moderate** physical activity of at least 30 minutes duration on average 5 times a week? *(or equivalent eg. 150 minutes over 7 days).* ***Moderate** activity means anything that takes **as much effort as**: brisk walking or house work/carrying a light bag on level ground/ mowing the lawn/general DIY like painting and decorating/sports like easy swimming, easy cycling, ballroom dancing etc*	Yes ☐ No ☐

Do you do 75 minutes of **vigorous** exercise a week? ***Vigorous** activity means anything that takes **as much effort as**: running/vigorous swimming or cycling/aerobics class/ circuit training/digging in heavy ground/chopping wood/ heavy DIY/sports like football, rugby, squash, netball etc*	Yes ☐ No ☐

(continued over…..)

Quality of Life (Dartmouth Co-op)

PHYSICAL FITNESS. During the past week what was the hardest physical activity you could do for at least 2 minutes? (Place a tick in the box next to the one you feel best describes your fitness)

Very heavy, for example: run at a fast pace or carry a heavy load upstairs or uphill (25 lbs / 10 kgs)		1
Heavy: for example: jog, slow pace or climb stairs or a hill at moderate pace		2
Moderate: for example: walk at medium pace or carry a heavy load on level ground (25 lbs / 10 kgs)		3
Light: for example: walk, medium pace or carry a light load on level ground (10 lbs / 5 kgs)		4
Very light: for example: walk at a slow pace, wash dishes		5

FEELINGS. During the past week how much have you been bothered by emotional problems such as feeling anxious, depressed, irritable or downhearted and blue? (Place a tick in the box next to the one you feel best describes your feelings)

Not at all		1
Slightly		2
Moderately		3
Quite a bit		4
Extremely		5

DAILY ACTIVITIES. During the past week how much difficulty have you had doing your usual activities or task, both inside and outside the house because of your physical and emotional health?

No difficulty at all		1
A little bit of difficulty		2
Some difficulty		3
Much difficulty		4
Could not do		5

SOCIAL ACTIVITIES. During the past week has your physical and emotional health limited your social activities with family, friends, neighbours or groups?

Not at all		1
Slightly		2
Moderately		3
Quite a bit		4
Extremely		5

PAIN. During the past week how much bodily pain have you generally had?

No pain		1
Very mild pain		2
Mild pain		3
Moderate pain		4
Severe pain		5

CHANGE IN HEALTH. How would you rate your overall health now compared to a week ago?

Much better		1
A little better		2
About the same		3
A little worse		4
Much worse		5

OVERALL HEALTH. During the past week how would you rate your health in general?

Excellent		1
Very good		2
Good		3
Fair		4
Poor		5

SOCIAL SUPPORT. During the past week was someone available to help you if you needed and wanted help? For example:

- if you felt nervous, lonely, or blue,
- got sick and had to stay in bed,
- needed someone to talk to,
- needed help with daily chores,
- needed help with taking care of yourself

Yes, as much as I wanted		1
Yes, quite a bit		2
Yes, some		3
Yes, a little		4
No, not at all		5

QUALITY OF LIFE. How have things been going for you during the past week?

Very well: could hardly be better		1
Pretty good		2
Good & bad parts about equal		3
Pretty bad		4
Very bad: could hardly be worse		5

Please check that you have ticked or circled one answer for every question on all 3 pages

(continued over….)

Hospital Anxiety and Depression Scale (HADS)

GL assessment
the measure of potential

Clinicians are aware that emotions play an important part in most illnesses. If your clinician knows about these feelings he or she will be able to help you more. This questionnaire is designed to help your clinician to know how you feel. Read each item below and **tick the reply** which comes closest to how you have been feeling in the past week. Don't take too long over your replies, your immediate reaction to each item will probably be more accurate than a long, thought-out response.

I feel tense or 'wound up'
- ☐ Most of the time
- ☐ A lot of the time
- ☐ From time to time, occasionally
- ☐ Not at all

I still enjoy the things I used to enjoy
- ☐ Definitely as much
- ☐ Not quite so much
- ☐ Only a little
- ☐ Hardly at all

I get a sort of frightened feeling as if something awful is about to happen
- ☐ Very definitely and quite badly
- ☐ Yes, but not too badly
- ☐ A little, but it doesn't worry me
- ☐ Not at all

I can laugh and see the funny side of things
- ☐ As much as I always could
- ☐ Not quite so much now
- ☐ Definitely not so much now
- ☐ Not at all

Worrying thoughts go through my mind
- ☐ A great deal of the time
- ☐ A lot of the time
- ☐ Not too often
- ☐ Very little

I feel cheerful
- ☐ Never
- ☐ Not often
- ☐ Sometimes
- ☐ Most of the time

I can sit at ease and feel relaxed
- ☐ Definitely
- ☐ Usually
- ☐ Not often
- ☐ Not at all

I feel as if I am slowed down
- ☐ Nearly all the time
- ☐ Very often
- ☐ Sometimes
- ☐ Not at all

I get a sort of frightened feeling like 'butterflies' in the stomach
- ☐ Not at all
- ☐ Occasionally
- ☐ Quite often
- ☐ Very often

I have lost interest in my appearance
- ☐ Definitely
- ☐ I don't take as much care as I should
- ☐ I may not take quite as much care
- ☐ I take just as much care as ever

I feel restless as if I have to be on the move
- ☐ Very much indeed
- ☐ Quite a lot
- ☐ Not very much
- ☐ Not at all

I look forward with enjoyment to things
- ☐ As much as I ever did
- ☐ Rather less than I used to
- ☐ Definitely less than I used to
- ☐ Hardly at all

I get sudden feelings of panic
- ☐ Very often indeed
- ☐ Quite often
- ☐ Not very often
- ☐ Not at all

I can enjoy a good book or radio or television programme
- ☐ Often
- ☐ Sometimes
- ☐ Not often
- ☐ Very seldom

Now check that you have answered all the questions

	A	D
TOTAL	☐	☐

Work and Employment

Please complete your employment status as it is at the time of filling in this questionnaire.

If you are in paid work, or currently looking for work and could start in the next 2 weeks, or are retraining for work, choose from the Grey box; If you are not paid, or are on temporary/long term sickness benefits, please choose from the White box

Please choose one item, from one box only:

Employed Full Time	☐1
Employed Part Time	☐2
Self-Employed Full Time	☐3
Self-Employed Part Time	☐4
Unemployed/Looking for work	☐5
Government Training Scheme	☐6

Looking after family/home	☐7
Retired	☐8
Permanently Sick/Disabled	☐9
Temporarily Sick/Injured	☐10
Student	☐11
Other Reason Not Working	☐12

Medication / Drugs

Are you currently taking any of these medicines? Please tick all those you are taking in each drug class. (We are wanting drugs related to your cardiac event, so do not worry about medication that is not included in the list below.)

Drug Class	Drug	Tick ✓
ACE Inhibitors	Captopril	☐1
	Enalapril	☐2
	Lisinopril	☐3
	Perindopril	☐4
	Ramipril	☐5
	Trandolapril	☐6
	Quinapril	☐7
	Other/Not Specified	☐8
Angiotensin Receptor Blockers (ARB)	Candesartan	☐9
	Losartan	☐10
	Valsartan	☐11
	Other/Not Specified	☐12
Heart Rate Meds	Bisoprolol	☐13
	Carvedilol	☐14
	Nebivolol	☐15
	Atenolol	☐16
	Propranolol	☐17
	Metoprolol	☐18
	Ivabradine	☐19
	Other/Not Specified	☐20

Diuretic: loop	Bumetanide Ethancrynic Acid Frusemide Torasemide Other/Not Specified	☐21 ☐22 ☐23 ☐24 ☐25
Diuretic: Thiazide	Bendroflumethiazide Metolazone Other/Not Specified	☐26 ☐27 ☐28
Selective Aldosterone Receptor Antagonist (SARA) Diuretic/Antihypertensive	Eplerenone Spironolactone Other/Not Specified	☐29 ☐30 ☐31
Antiplatelet	Aspirin Clopidogrel Other/Not Specified	☐32 ☐33 ☐34
Antiarrhythmics	Digoxin Amiodarone Other/Not Specified	☐35 ☐36 ☐37
Calcium Channel Blockers (CCBs)	Amlodipine Felodipine Diltiazem Verapamil Other/Not Specified	☐38 ☐39 ☐40 ☐41 ☐42
Therapy for Lipids (Statins)	Atorvastatin Pravastatin Rosuvastatin Simvastatin Other/Not Specified	☐43 ☐44 ☐45 ☐46 ☐47
Anticoagulant	Warfarin Other/Not Specified	☐48 ☐49
Vasodilators	Nitrates (incl GTN Spray) Other/Not Specified	☐50 ☐51
Current Diabetes Therapy	Metformin Sulphonylurea Glitazone Insulin Other/Not Specified	☐52 ☐53 ☐54 ☐55 ☐56

(continued over….)

Total Activity Measure

We'd like to know how active you've been in the last week, and how many minutes one of these activities typically lasts. Please put a score in **all 6 boxes** even is the answer is 0. In this questionnaire the last week refers to the week nearest to the point of starting the formal exercise part of your rehabilitation.

NB: If you are filling in this questionnaire at home, and are finding this question difficult, please leave it, and fill it in when you are at your first rehab appointment or clinic – your clinician will be able to help you with it.

1. In the last week, **how many times** did you do **strenuous** activities? ☐

   Typically, how many **minutes** did **one** of those strenuous activities last? ☐

***Strenuous activity** means anything that takes as much effort as: running/vigorous swimming or cycling/aerobics class/ circuit training/digging in heavy ground/chopping wood/ heavy DIY/sports like football, rugby, squash, netball etc*

2. In the last week, **how many times** did you do **moderate** activities? ☐

   Typically, how many **minutes** did **one** of those moderate activities last? ☐

***Moderate activity** means anything that takes as much effort as: brisk walking or house work/carrying a light bag on level ground/ mowing the lawn/general DIY like painting and decorating/sports like easy swimming, easy cycling, ballroom dancing etc*

3. In the last week, **how many times** did you do **mild** activities? ☐

   Typically, how many **minutes** did **one** of those mild activities last? ☐

***Mild activity** means anything that takes as much effort as: easy walking or very light housework/browsing in shops/slow dancing/hand weeding in the garden/sports like bowls, river fishing, golf etc*

Thank you for your help.
The information you have provided will be used
to improve our services to you.

Appendix 3 The National Certification Programme for Cardiovascular Rehabilitation (NCP_CR) Report

The Minimum Standards for Certification of Cardiac Rehabilitation Programmes: 2016

We will use a combination of the details from the Certification Registration Document and from the NACR/BACPR Certification Report to ascertain whether a cardiac rehabilitation programme meets the following minimum standards.

Minimum Standards (MS)
Standard 1: The delivery of seven core components employing an evidence based approach
Minimum standard (MS) 1.1 Named leads for each of the core components i. Health behaviour change and education iia. Lifestyle risk factor reduction: Physical activity iib. Lifestyle risk factor reduction: Diet iic. Lifestyle risk factor reduction: Smoking cessation iii. Psychosocial health iv. Medical risk factor management v. Cardioprotective therapies vi. Long term management vii. Audit and evaluation
Standard 2: An integrated multidisciplinary team consisting of qualified and competent practitioners, led by a clinical coordinator
MS 2.1: At least three professions in the cardiac rehabilitation team – these are professionals who regularly have input into the cardiac rehabilitation programme. MS 2.2: Named Clinical Coordinator
Standard 3: Identification, referral and recruitment of eligible patient populations
MS 3.1: Cardiac rehabilitation is offered at least to priority groups: MI, PCI, CABG, heart failure.
Standard 4: Early initial assessment of individual patient needs in each of the core components, ongoing assessment and reassessment on programme completion*
MS 4.1: Mean wait time from initiating event to assessment 1 is equal to or less than 48 days MS 4.2: Percent of patients with recorded assessment 1 is equal to or more than 74% MS 4.3: Percent of patients with recorded assessment 2 (end of CR) is equal to or more than 52% MS 4.4: Use of formal risk stratification for exercise
Standard 5: Early provision of a cardiac rehabilitation programme, with a defined pathway of care, which meets the core components and is aligned with patient preference and choice.
MS 5.1: Time from referral to start of main CR programme for MI/PCI is equal to or less than national median of 38 days MS 5.2: Time from referral to start of main CR programme for CABG is equal to or less than national median of 50 days MS 5.3 Duration of main CR programme for MI/PCI is equal to or more than national median of 58 days. MS 5.4 Duration of main CR programme for CABG is equal to or more than national median of 60 days.

Standard 6: Registration and submission of data to the National Audit for Cardiac Rehabilitation (NACR)
MS 6.1: Obtaining of a valid NACR/BACPR Certification report
Standard 7: Establishment of a business case including a cardiac rehabilitation budget which meets the full service costs.
Standard 7 is not measured.

You will see that we are not assessing standard 7 (Establishment of a business case) within the minimum standards. While this standard is vital for meeting the full BACPR standards, it is difficult to assess for certification that a business case is established (what would we use as criteria for a document to be accepted as a business case?).

Assessment of delivery of the core components:

Currently, we are not assessing the efficacy of delivery of the core components – simply that there is a named person to lead on each component and that each component is delivered. In the registration document we ask programmes to discuss their strengths in each of components, and whether there are areas that need to be developed and if so, what plans do they have for this. These plans and goals may be included in the feedback as goals to achieve for re-certification for a cardiac rehabilitation. In future, once the standard of data included in NACR is improved, then we will be able to assess whether these components are being delivered in a way that meets minimum standards for outcomes of the components.

Appendix 4 Risk stratification (adapted courtesy of ACPICR 2015)

Appendix E: Risk stratification

Risk stratification is a multi-factorial measure used to establish prognosis of future major cardiac events and chances of survival. Mortality risk within the first year for an individual assessed as:

- low risk is 2%
- moderate risk is 10 – 25%
- high risk is >25%

It can also help determine the chances of disease progression in terms of arterial, myocardial or electrophysiological function. This tool helps the exercise professional to identify relevant information for individual management, appropriate level of supervision and monitoring.

AACVPR stratification for risk of cardiac events [58]

LOWEST RISK - C	MODERATE RISK - B	HIGHEST RISK - A
Absence of complex ventricular dysrhythmias during exercise testing and recovery Absence of angina or other significant symptoms (for example unusual SOB, light-headedness or dizziness, during exercise testing and recovery) Presence of normal haemodynamics during exercise testing and recovery (i.e. appropriate increases and decreases in HR and SBP with increasing workloads and recovery) Functional capacity ≥ 7 METS **Non-exercise Testing Findings:** Resting EF ≥50% Uncomplicated MI or revascularisation procedure Absence of complicated ventricular dysrhythmias at rest Absence of CHF Absence of signs or symptoms of post-event/post-procedure ischaemia Absence of clinical depression	Presence of angina or other significant symptoms (for example unusual SOB, lightheadedness or dizziness, occurring only at high levels of exertion ≥ 7 METS) Mild to moderate level of silent ischaemia during exercise testing or recovery (ST-segment depression <2 mm from baseline) Functional capacity <5 METS **Non-exercise Testing Findings:** Resting EF 40 – 49%	Presence of complex ventricular dysrhythmias during exercise testing or recovery Presence of angina or other significant symptoms (for example unusual SOB, lightheadedness or dizziness at low levels of exertion (<5METS) or during recovery) High level of silent ischaemia (ST-segment depression > 2mm from baseline) during exercise testing or recovery Presence of abnormal haemodynamics with exercise testing (i.e. chronotrophic incompetence or flat or decreasing SBP with increasing workloads) or recovery (severe post exercise hypotension) **Non-exercise Testing Findings:** Resting EF <40% History of cardiac arrest or sudden death Complex dysrhythmias at rest Complicated MI or revascularisation procedure Presence of CHF Presence of signs and symptoms of post-event/post-procedure ischaemia Presence of clinical depression
All characteristics listed must be present for patients to remain at lowest risk	**Any one, or combination of these findings places a patient at moderate risk**	**Any one, or combination of these findings places a patient at high risk**

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Criteria checklist for use when risk stratifying CHD individuals prior to exercise [105]

Indicators of severity of event	Indicators of LV function	Indicators of ongoing ischaemia	Other considerations
• An anterior rather than inferior MI • More than one previous infarct • High cardiac enzymes or • troponin levels at time of infarct • Complicated recovery	• LV function – moderate (EF = 40-49%) or poor (EF = <40%) • Presence of HF	• Positive ETT • Ongoing angina/ischaemia • Awaiting further investigations	• Arrhythmias (especially ventricular) • Cardiac arrest secondary to event

Supervision level

This relates to potential difficulties when taking part in the exercise component of CR for example hard of hearing, poor vision, poor balance, MSK/neurological problems which may affect the staff to individual ratio or type of exercises prescribed.

1=High supervision needs 2=Moderate supervision needs 3=Low supervision needs.

Appendix 5 The Hospital Anxiety and Depression Scale (HADS)

Hospital Anxiety and Depression Scale (HADS)

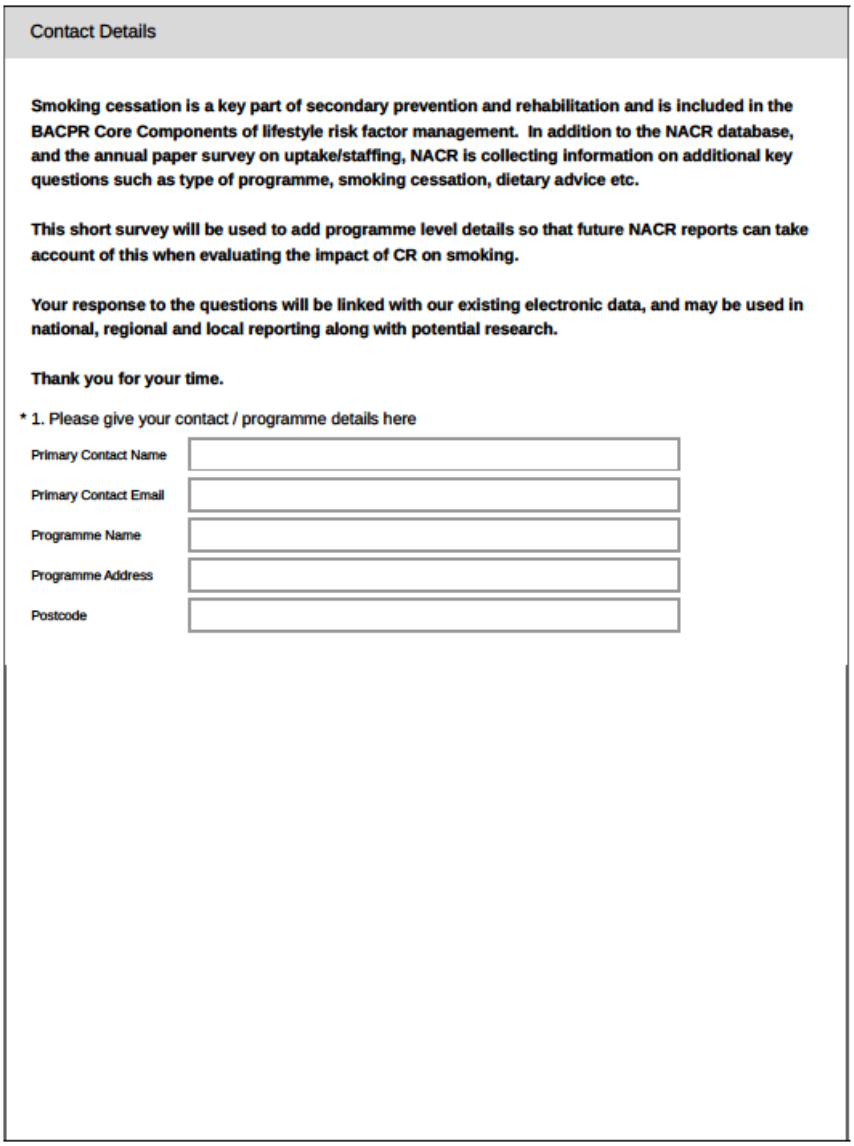
Tick the box beside the reply that is closest to how you have been feeling in the past week.
Don't take too long over you replies: your immediate is best.

D	A		D	A	
		I feel tense or 'wound up':			**I feel as if I am slowed down:**
	3	Most of the time	3		Nearly all the time
	2	A lot of the time	2		Very often
	1	From time to time, occasionally	1		Sometimes
	0	Not at all	0		Not at all
		I still enjoy the things I used to enjoy:			**I get a sort of frightened feeling like 'butterflies' in the stomach:**
0		Definitely as much		0	Not at all
1		Not quite so much		1	Occasionally
2		Only a little		2	Quite Often
3		Hardly at all		3	Very Often
		I get a sort of frightened feeling as if something awful is about to happen:			**I have lost interest in my appearance:**
	3	Very definitely and quite badly	3		Definitely
	2	Yes, but not too badly	2		I don't take as much care as I should
	1	A little, but it doesn't worry me	1		I may not take quite as much care
	0	Not at all	0		I take just as much care as ever
		I can laugh and see the funny side of things:			**I feel restless as I have to be on the move:**
0		As much as I always could		3	Very much indeed
1		Not quite so much now		2	Quite a lot
2		Definitely not so much now		1	Not very much
3		Not at all		0	Not at all
		Worrying thoughts go through my mind:			**I look forward with enjoyment to things:**
	3	A great deal of the time	0		As much as I ever did
	2	A lot of the time	1		Rather less than I used to
	1	From time to time, but not too often	2		Definitely less than I used to
	0	Only occasionally	3		Hardly at all
		I feel cheerful:			**I get sudden feelings of panic:**
3		Not at all		3	Very often indeed
2		Not often		2	Quite often
1		Sometimes		1	Not very often
0		Most of the time		0	Not at all
		I can sit at ease and feel relaxed:			**I can enjoy a good book or radio or TV program:**
	0	Definitely	0		Often
	1	Usually	1		Sometimes
	2	Not Often	2		Not often
	3	Not at all	3		Very seldom

Please check you have answered all the questions

Scoring:
Total score: Depression (D) _____ Anxiety (A) _____
0-7 = Normal
8-10 = Borderline abnormal (borderline case)
11-21 = Abnormal (case)

Appendix 6 Smoking cessation survey



Contact Details

Smoking cessation is a key part of secondary prevention and rehabilitation and is included in the BACPR Core Components of lifestyle risk factor management. In addition to the NACR database, and the annual paper survey on uptake/staffing, NACR is collecting information on additional key questions such as type of programme, smoking cessation, dietary advice etc.

This short survey will be used to add programme level details so that future NACR reports can take account of this when evaluating the impact of CR on smoking.

Your response to the questions will be linked with our existing electronic data, and may be used in national, regional and local reporting along with potential research.

Thank you for your time.

* 1. Please give your contact / programme details here

Primary Contact Name

Primary Contact Email

Programme Name

Programme Address

Postcode

* 2. Does your CR programme offer support for patients with stopping smoking?

- ◯ Yes
- ◯ No

3. Is the smoking cessation delivered at the CR programme or referred out?

- ◯ Delivered at the CR programme
- ◯ Externally referred out
- ◯ Both

Delivered at CR Programme

4. How does the patient receive the service within your programme?

- [ ] One to One Sessions
- [ ] Group Education Sessions
- [ ] Other (please specify)

5. Who delivers the service within your programme?

- [ ] CR Team
- [ ] Other smoking cessation qualified member of staff
- [ ] Other (please specify)

Referred Externally

6. What external service is the patient referred to?

- [ ] Doctor/GP Appointment
- [ ] Community Based Cessation Programme
- [ ] Other (please specify)

Both

7. How does the patient receive the service within your programme?

- [ ] One to One Sessions
- [ ] Group Education Sessions
- [ ] Other (please specify)

8. Who delivers the service within your programme?

- [ ] CR Team
- [ ] Other smoking cessation qualified member of staff
- [ ] Other (please specify)

9. What external service is the patient referred to?

- [ ] Doctor/GP Appointment
- [ ] Community Based Cessation Programme
- [ ] Other (please specify)

10. What might decide whether a patient would attend the CR Programme or be referred out?

- [ ] Availability
- [ ] Patient Preference
- [ ] Funding Constraints
- [ ] Specific Patient Needs (eg. hardened smoker)
- [ ] Other (please specify)

No Smoking Cessation Support

11. Please explain why you don't provide support for stopping smoking.

- [ ] No funding
- [ ] Provided elsewhere
- [ ] No appropriate staff
- [ ] No demand
- [ ] Other (please specify)

Appendix 7 ANOVA with post-hoc results between standards and quality categories

The average of the percentage of programmes meeting the Ax1 criterion increased from the low-quality category (n=31, mean 68.45% (SD 30.73%)) to the middle-quality category (n=78, 76.42% (SD 28.26%)) to the high-quality category (n=52, 89.44 (SD=8.93%)). Heterogeneity of variance, as the ratio of max SD:min SD, was greater than 2 (30.73/8.93=3.44). The difference between all three quality categories was statistically significant (Welch's $F(2,64.91)=12.92$, $p<0.001$, $\eta^2=0.09$). The Games-Howell (G-H) post-hoc analysis found that the mean increases from low- to high-quality (20.99 (95% CI 7.11 to 34.87), p=0.002) and from middle- to high-quality category (13.02 (95% CI 4.86 to 21.19), p=0.001) were statistically significant.

The average of the percentage of programmes meeting the Ax2 criterion increased from the low- (n=26, mean 41.05% (SD 29.35%)) to the middle- (n=78, 52.25% (SD 28.13%)) to the high-quality category (n=52, 63.98 (SD 18.53%)). Homogeneity of variance, as the ratio of max SD:min SD, was less than 2 (29.35/18.53=1.58). The difference between all three quality categories was statistically significant ($F(2,153)=7.47$, $p=0.001$, $\eta^2=0.09$). G-H post-hoc analysis revealed that the mean increases from low- to high-quality category (22.93 (95% CI 7.51 to 38.35), p=0.002) and from middle- to high-quality category (11.73 (95% CI 2.03 to 21.44), p=0.013) were statistically significant.

The average number of days for TRS_CR/MIPCI decreased from the low- (n=31, mean 54.39 (SD 17.31) days) to the middle- (n=78, 42.94 (SD 20.08) days) to the high-quality category (n=52 (31.32 (SD 9.99) days). There was heterogeneity of variance, as assessed by the max SD:min SD ratio (20.08/9.99=2.01). The difference between all three quality categories was statistically significant (Welch's $F(2,74.94)=27.22$, $p<0.001$, $\eta^2=0.19$) G-H post-hoc analysis revealed that the mean decreases from low- to middle-

quality category (11.45 (95% CI 2.21 to 20.69), p=0.01), from low- to high-quality category (23.07 (14.80 to 31.34) days, p<0.001) and from middle- to high-quality category (11.62 (95% CI 5.30 to 17.94) days, p<0.001) were statistically significant.

The average number of days for TRS_CR/CABG decreased from the low- (n=27, mean 61.85 (SD 18.79) days) to the middle- (n=75, 55.61 (SD 24.26) days) to the high-quality category (n=52, 41.99 (SD 13.44) days). There was homogeneity of variances, as assessed by the max SD:min SD ratio (24.26/13.44=1.81). The difference between all three quality categories was statistically significant ($F(2,151)=10.73$, $p<0.001$, $\eta^2=0.12$). G-H post-hoc analysis revealed that the mean decreases from the low- to high-quality category (19.86 (95% CI 9.96 to 29.76) days, p<0.001) and from the middle- to high-quality category (13.62 (95% CI 5.63 to 21.60, p<0.001) were statistically significant.

The average number of days for CR programme duration increased from the low- (n=29, mean 57.59 (SD 20.21) days) to the middle- (n=78, 64.56 (SD 22.53) days) to the high-quality category (n=52, 70.33 (SD 18.26) days). There was homogeneity of variance, as assessed by the max SD:min SD ratio (22.53/18.26=1.23). The differences between all three quality categories was statistically significant ($F(2,156)=3.56$, $p=0.03$, $\eta^2=0.04$). G-H post-hoc analysis revealed that the mean increase from the low- to the high-quality category (12.74 (95% CI 1.83 to 23.66) days) was statistically significant (p=0.02).

Appendix 8 ANOVA with post-hoc results between standards and countries

The average of the percentage of programmes meeting the Ax2 criterion was lowest for Wales (n=17, mean 36.78% (SD 22.71%)), intermediate for England (n=131, 54.53 (SD 27.49%)) and highest for Northern Ireland (n=12, 59.28% (SD 16.85%)). There was homogeneity of variance, as assessed by the max SD:min SD ratio (27.49/16.85=1.63). The difference between all three countries was statistically significant ($F(2,157)=3.76$, $p=0.03$, $\eta^2=0.05$). Games-Howell post-hoc analysis revealed that the mean differences between Wales and England (17.75% (95% CI 2.69% to 38.82%), p=0.02) and Wales and Northern Ireland (22.5% (95% CI 4.28% to 40.73%), p=0.01) were statistically significant.

The average number of days for CR programme duration was lowest for Northern Ireland (n=14, median 57.46 (SD 14.14) days), intermediate for England (n=134, 63.45 (SD 20.23) days) and highest for Wales (n=17, 79.32 (SD 25.71) days). There was homogeneity of variance, as assessed by the max SD:min SD ratio (25.71/14.14=1.82). The difference between all three countries was statistically significant ($F(2,162)=5.48$, $p=0.01$, $\eta^2=0.06$). Games-Howell post-hoc analysis revealed that the mean difference between Wales and Northern Ireland was statistically significant (21.86 (95% CI 3.73 to 39.99) days, p=0.02).

Appendix 9 Demographic characteristics between quality categories

The average of number who started CR increased from the low (n=31, mean 126.16 (SD=126.03)), to the middle- (n=78, 261.15 (SD=186.23)), to the high-quality category (n=52, 289.67, (SD=209.22)). There was homogeneity of variances, as assessed by the max SD:min SD ratio (209.22 / 126.03=1.66). The differences between all three quality categories was statistically significant ($F(2, 158)=8.25$, $p <0.001$, $\eta 2=0.10$). The Games-Howell post-hoc analysis found that the mean increases from low- to high-quality (163.51 (95% CI 75.65 to 251.37), $p<0.001$) and from low- to high-quality category (134.99 (95% CI 61.13 to 208.86, $p<0.001$) were statistically significant

The average of hours of staff members increased from the low- (n=27, mean 60.78 (SD=53.47)), to the middle- (n=75, 91.91, (SD=83.07)), to the high-quality category (n=48, 137.06, (SD=98.05)). There was homogeneity of variances, as assessed by the max SD:min SD ratio (98.05 / 53.47=1.83). The differences between all three quality categories was statistically significant ($F(2, 147)=7.96$, $p=0.001$, $\eta 2=0.10$). Games-Howell post-hoc analysis found that the mean increases from low- to high-quality (76.28 (95% CI 34.41 to 118.14), $p<0.001$), and from middle- to high-quality category (45.15 (95% CI 4.39 to 85.91), $p=0.03$) were statistically significant.

The average of number of MDT increased from the low- (n=27, mean 3.03 (SD=2.10)), to middle- (n=75, 3.71, (SD=2.06)), to high-quality category (n=48, 4.56, (SD=2.10)). There was homogeneity of variances, as assessed by the max SD:min SD ratio (2.10 / 2.06=1.02). The differences between all three quality categories was statistically significant ($F(2, 147)=5.05$, $p=0.01$, $\eta 2=0.06$). Games-Howell post-hoc analysis found that the mean increases from low- to high-quality category (1.53 (95% CI 0.31 to 2.74, $p=0.01$)) was statistically significant.

Appendix 10 Demographic characteristics among countries

The average of number who started CR was lowest for Northern Ireland (n=15, mean 122.47 (SD=68.98)), intermediate for Wales (n=17, 238.71, (SD=140.90)), and highest for England (n=137, 252.58, (SD=202.08)). There was heterogeneity of variances, as assessed by the max SD:min SD ratio (202.08 / 68.98=2.93). The differences between these countries was statistically significant, (Welch's F(2, 35.87)=14.40, p <0.001, η2=0.04). Games-Howell post-hoc analysis revealed that the mean difference between Northern Ireland and England (130.12 (95% CI 70.14 to 190.10, p<0.001) and Northern Ireland and Wales (116.24 (95% CI 19.97 to 212.51, p=0.02) were statistically significant.

The average of hours of staff members was lowest for Northern Ireland (n=15, mean 38.32 (SD=18.08)), intermediate for England (n=124, 102.02, (SD=90.00)), and highest for Wales (n=17, 120.01, SD=94.45). There was heterogeneity of variances, as assessed by the max SD:min SD ratio (94.45 / 18.08=5.22). The differences between these countries was statistically significant, (Welch's F(2, 38.78)=26.82, p<0.001, η2=0.05). Games-Howell post-hoc analysis revealed that the mean difference between Northern Ireland to England (63.69 (95% CI 41.52 to 85.86), p<0.001) and Northern Ireland and Wales (81.69 (95% CI 21.82 to 141.55), p=0.01) were statistically significant.

Appendix 11 Baseline health states of patients in cardiac rehabilitation (CR) programmes classified as having low-, middle- and high-quality service delivery

The average of proportion of high risk patients was not statistically significant different among quality categories (F(2, 107)=1.14, p=0.32, η2=0.02): low- (n=12, mean 16.28 (SD=10.04)), middle- (n=53, 21.84, (SD=15.31)), and high-quality category (n=45, 23.39 (SD=14.38)).

The average of waist was not statistically significant different among quality categories (F(2, 129)=0.82, p=0.45, η2=0.01): low- (n=25, mean 97.47 (SD=7.38)), middle- (n=63, 98.07 (SD=9.93)), and high-quality category (n=44, 101.00 (SD=13.29)).

The average of proportion of patients with BP of 140/90 mmHg or higher was not statistically significant different among quality categories (F(2, 144)=1.46, p=0.24, η2=0.02): low- (n=25, mean 28.69 (SD=11.24)), middle- (n=70, 32.64 (SD=13.05)), and high-quality category (n=52, 33.47 (SD=9.98)).

The average of proportion of smoker patients was not statistically significant different among quality categories (F(2, 123)=2.52, p=0.09, η2=0.04): low- (n=18, mean 8.32, (SD=4.10)), middle- (n=60, 12.68 (SD=8.24)), and high-quality category (n=48, 11.39 (SD=6.87)).

The average of six-minute walk test (6MWT) was not statistically significant different among quality categories (F(2, 62)=1.99, p=0.15, η2=0.06): low- (n=13, mean 342.74 (SD=102.63)), middle- (n=27, 276.66 (SD=111.99)), and high-quality category (n=25, 280.61 (SD=95.71)).

The average of incremental shuttle walking test (ISWT) was not statistically significant different among quality categories (F(2, 59)=0.48, p=0.62, η2=0.02): low- (n=7, mean

374.58 (SD=190.26)), middle- (n=30, 326.18 (SD=123.54)), and high-quality category (n=25, 352.33 (SD=132.30)).

The average of proportion of patients reported exercise 150 minutes over a week was not statistically significant different among quality categories (F(2, 156)=2.15, p=0.12, η2=0.03): low- (n=31, mean 36.49 (SD=27.71)), middle- (n=76, 28.04 (SD=16.92)), and high-quality category (n=52, 29.53 (SD=16.38)).

The average of proportion of patients reported exercise 75 minutes of vigorous exercise a week was not statistically significant different among quality categories, (F(2, 155)=1.18, p=0.31, η2=0.02): low- (n=30, mean 8.38 (SD=9.24)), middle- (n=76, 6.20 (SD=5.66)), and high-quality category (n=52, 6.56 (SD=6.20)).

The average of proportion of patients categorised according to Hospital Anxiety and Depression Scale (HADS) score to borderline abnormal or anxious scores was not statistically significant different among quality categories (F(2, 133)=1.86, p=0.16, η2=0.03): low- (n=18, mean 28.05 (SD=8.83)), middle- (n=68, 32.58 (SD=8.96)), and high-quality category (n=50, 31.54 (SD=8.70)).

The average of proportion of patients categorised according to Hospital Anxiety and Depression Scale (HADS) score to borderline abnormal or depressed scores was not statistically significant different among quality categories (F(2, 130)=1.52, p=0.22, η2=0.02): low- (n=17, mean 18.24 (SD=7.52)), middle- (n=66, 21.89, SD=8.62), and high quality category (n=50, 21.69 (SD=6.91)).

Appendix 12 Baseline comorbidity profiles of patients in cardiac rehabilitation (CR) programmes classified as having low-, middle- and high-quality service delivery

The average of proportion of patients started CR with angina comorbidity was not statistically significant different among quality categories ($F(2, 158)=0.84$, $p=0.43$, $\eta^2=0.01$): low- (n=31, mean 12.23 (SD=11.59)), middle- (n=78, 12.07 (SD=10.00)), and high-quality category (n=52, 14.38 (SD=10.00)).

The average of proportion of patients started CR with arthritis comorbidity was not statistically significant different among quality categories ($F(2, 158)=2.09$, $p=0.13$, $\eta^2=0.03$): low (n=31, mean 7.94 (SD=8.75)), middle- (n=78, 9.72 (SD=7.32)), and high-quality category (n=52, 11.42 (SD=7.23)).

The average of proportion of patients started CR with cancer comorbidity was not statistically significant different among quality categories ($F(2, 158)=2.31$ $p=0.10$, $\eta^2=0.03$): low- (n=31, mean 2.99 (SD=2.78)), middle- (n=78, 4.32 (SD=4.26)), and high-quality category (n=52, 4.73 (SD=3.05)).

The average of proportion of patients started CR with rheumatism comorbidity was not statistically significant different among quality categories ($F(2, 158)=0.85$ $p=0.43$, $\eta^2=0.01$): low- (n=31, mean 1.77 (SD=3.00)), middle- (n=78, 1.61 (SD=1.80)), and high-quality category (n=52, 2.09 (SD=1.77)).

The average of proportion of patients started CR with osteoporosis comorbidity was not statistically significant different among quality categories ($F(2, 158)=3.02$, $p=0.052$, $\eta^2=0.04$): low- (n=31, mean 1.08 (SD=1.70)), middle- (n=78, 1.27 (SD=1.27)), and high-quality category (n=52, 1.86 (SD=1.89)).

The average of proportion of patients started CR with hypertension comorbidity was not statistically significant different among quality categories ($F(2, 158)=0.76$, $p=0.47$,

η^2=0.01): low- (n=31, 31.89 (SD=25.55)), middle (n=78, 31.87 (SD=15.77)), and high-quality category (n=52, 35.58 (SD=15.01)).

The average of proportion of patients started CR with chronic bronchitis pulmonary disease (COPD) comorbidity was not statistically significant different among quality categories (F(2, 158)=0.62, p=0.54, η^2=0.01): low- (n=31, mean 1.22 (SD=1.62)), middle- (n=78, 3.04 (SD=10.89)), and high-quality category (n=52, 2.55 (SD=7.70)).

The average of proportion of patients started CR with emphysema comorbidity was not statistically significant different among quality categories (F(2, 158)=2.06, p=0.13, η^2=0.03): low- (n=31, mean 0.53 (SD=1.01)), middle- (n=78, 1.50 (SD=3.83)), and high-quality category (n=52, 1.80 (SD=1.39)).

The average of proportion of patients started CR with claudication comorbidity was not statistically significant different among quality categories (F(2, 158)=1.70, p=0.19, η^2=0.02): low- (n=31, mean 3.07 (SD=9.18)), middle- (n=78, 1.47 (SD=1.65)), and high-quality category (n=52, 2.41 (SD=2.50)).

The average of proportion of patients started CR with chronic back problems comorbidity was not statistically significant different among quality categories (F(2, 158)=2.13, p=0.12, η^2=0.03): low- (n=31, mean 5.02 (SD=7.10)), middle- (n=78, 6.58 (SD=7.30)), and high-quality category (n=52, 8.33 (SD=7.27)).

The average of proportion of patients started CR with anxiety comorbidity was not statistically significant different among quality categories (F(2, 158)=1.27, p=0.29, η^2=0.02): low- (n=31, mean 4.78 (SD=17.85)), middle- (n=78, 1.96 (SD=3.80)), and high-quality category (n=52, 2.82 (SD=2.59)).

The average of proportion of patients started CR with depression comorbidity was not statistically significant different among quality categories ($F(2, 158)=0.74$, $p=0.48$, $\eta^2=0.01$): low- (n=31, mean 4.92 (SD=17.88)), middle (n=78, 2.73 (SD=4.43)), and high-quality category (n=52, 3.20 (SD=2.72)).

The average of proportion of patients started CR with family history of CVD comorbidity was not statistically significant different among quality categories ($F(2, 158)=0.30$, $p=0.74$, $\eta^2=0.00$): low- (n=31, mean 9.58 (SD=14.50)), middle- (n=78, 11.28 (SD=12.28)), and high-quality category (n=52, 11.69 (SD=11.44)).

The average of proportion of patients started CR with Hypercholesterolaemia / dyslipidemia comorbidity was not statistically significant different among quality categories ($F(2, 158)=0.58$, $p=0.56$, $\eta^2=0.01$): low- (n=31, mean 17.21 (SD=22.94)), middle- (n=78, 15.58 (SD=13.97)), and high-quality category (n=52, 18.74 (SD=15.39)).

Appendix 13 Does cardiac rehabilitation meet minimum standards: an observational study using UK national audit?

openheart

Does cardiac rehabilitation meet minimum standards: an observational study using UK national audit?

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ABSTRACT

Objective: To assess the extent by which programmes meet national minimum standards for the delivery of cardiac rehabilitation (CR) as part of the National Certification Programme for Cardiovascular Rehabilitation (NCP_CR).

Methods: The analysis used UK National Audit of Cardiac Rehabilitation (NACR) data extracted and validated for the period 2013–2014 set against six NCP_CR measures deemed as important for the delivery of high-quality CR programmes. Each programme that achieved a single minimum standard was given a score of 1. The range of the scoring for meeting the minimum standards is between 1 and 6. The performance of CR programmes was categorised into three groups: high (score of 5–6), middle (scores of 3–4) and low (scores of 1–2). If a programme did not meet any of the six criteria, they were considered to have failed.

Results: Data from 170 CR programmes revealed statistically significant differences among UK CR programmes. The principal findings were that, based on NCP_CR criteria, 30.6% were assessed as high performance with 45.9% as mid-level performance programmes, 18.2% were in the lower-level and 5.3% failed to meet any of the minimum criteria.

Conclusions: This study shows that high levels of performance is achievable in the era of modern cardiology and that many CR programmes are close to meeting high performance standards. However, substantial variation, below the recommended minimum standards, exists throughout the UK. National certification should be seen as a positive step to ensure that patients, irrespective of where they live, are accessing quality services.

KEY QUESTIONS

What is already known about this subject?

- Recent clinical review of cardiac rehabilitation (CR) highlights that CR is highly effective but warns that not all programmes are working to the minimum standards.

What does this study add?

- This is the first study in the UK identifying the proportion of programmes meeting national minimum standards for the delivery of CR. Only 30% of the UK CR programmes met the criteria for high performance CR. This study is the first to evaluate CR against minimum standards and report the extent of deficit in UK CR services.

How might this impact on clinical practice?

- This paper shows that high performance is achievable in the modern cardiology era and that many other programmes deemed as being mid-level performance are close to meeting high performance standards. It has also shown that the National Certification Programme for Cardiovascular Rehabilitation (NCP_CR) criteria are able to differentiate the quality of CR delivery.

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INTRODUCTION

Cardiovascular disease (CVD) is the number one cause of death that is globally responsible for an estimated 17.5 million people deaths, 31% of all global deaths in 2012.[1] In 2014, CVD caused 27% of all deaths in the UK.[2] On the basis of international guidelines, underpinned by Class I evidence, cardiac rehabilitation (CR) is recommended as an effective intervention for patients diagnosed with CVDs.[3–6] CR is defined as a structured, multicomponent, tailored intervention that is delivered by a skilled multidisciplinary team.[5 6] The British Association for Cardiovascular Prevention and Rehabilitation (BACPR) recommended minimum standards, National Institute for Health and Care Excellence (NICE) clinical guidance and the National Certification Programme for CR (NCP_CR) seek to ensure that routine provision of CR programmes closely resembles that delivered by effective clinical trials.[4 7–9] The National Audit of Cardiac Rehabilitation (NACR), funded by the British Heart Foundation, is a clinical audit that monitors CR services in the UK in terms of service delivery and patient outcome.[10] According to the 2015 NACR

report, the number of CR programmes delivering core CR in 2013–2014 was 308.[10] Numerous clinical trials and systematic reviews have shown the effectiveness of CR over the last 20 years.[3 11] The updated Cochrane review reported that CR is proved to reduce cardiovascular mortality, hospital admissions in addition to improving health-related quality of life.[3] On the other hand, the conclusion from the largest UK-based randomised controlled trial 'Rehabilitation after myocardial infarction trial (RAMIT)' of comprehensive CR in the modern era of medical management showed that CR does not reduce mortality or morbidity and has no beneficial effect on psychosocial well-being or lifestyle.[12] RAMIT was included in the Anderson *et al*[3] review alongside 62 other trials and did not alter the overall cardiovascular mortality benefit. The negative results of RAMIT appear to differ from those of the latest Cochrane reviews. The negative findings of this trial have also led to scepticism about the delivery of UK-based CR programmes.[13 14] Moreover, a recent clinical review of CR published in the *British Medical Journal* highlights that CR is highly effective but warns that not all programmes are working to the minimum standards.[11] The NACR is committed to promoting and supporting quality service provision based on measurable indicators of successful delivery. The aim of this study was to assess the extent by which programmes meet national minimum standards for the delivery of CR.

METHODS

Data collection

The analyses were conducted using individual patient data collected electronically by the UK NACR which has approval to collect anonymised patient data for a range of clinical variables.[15] Data are collected under 251 approvals that are reviewed annually by the Health and Social Care information Centre (HSCIC). The audit is voluntary, collecting local programme-level data on the delivery of CR alongside patient-level data on patients who undergo CR in the UK, including details of the initiating event, treatment type, risk factors, medication, patient demographics and pre-CR clinical outcomes and post-CR clinical outcomes. The data from 1 April 2013 to 31 March 2014, which relates to the first year of the NCP_CR minimum standards, have been validated and extracted to support this analysis. Patients were included in the analyses if they started CR, had been assessed at baseline and had follow-up data at an assessment post-CR. This observational study was reported following the guidelines of the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE).

Service delivery measures

The BACPR-NACR National Certification Programme for Cardiovascular Rehabilitation (NCP_CR) aims to achieve a minimum level of service delivery across the UK and has clear guidance (available by emailing: education@bacpr.com) which is based on NACR patient-level and programme-level data extracted as the NCP_CR report.[9] The latter was used in this study to assess whether a CR programme met the minimum service delivery standards. Within the NCP_CR report, six field measures, deemed as important for defining the delivery of high-performance CR programmes, were used alongside 95% CI as the part of certification criteria derived from all three countries (England, Wales and Northern Ireland). The NCP_CR minimum service delivery criteria used to define high-performance CR programmes was based on NICE guidance and national UK CR statistics (NACR 2015 report). The criteria included:

- offered to all priority groups (PG):
  - Myocardial infarction (MI)
  - Percutaneous coronary intervention (PCI)
  - Coronary artery bypass surgery (CABG)
  - Heart failure (HF)
- ≥69% of core CR patients with recorded assessment before starting formal CR programme (ax1)
- ≥49% of core CR patients (end of CR) with recorded assessment after completing CR programme (ax2)
- Median waiting time from referral to start (TRS) of CR—MI/PCI (TRS_CR/MIPCI) was within 40 days
- Median waiting time from referral to start of CR—CABG (TRS_CR/CABG) was within 54 days
- Median duration of CR programmes was 54 days for conventional delivery or 42 days where the Heart Manual (an evidence-based 6-week facilitated self-management programme) was the sole method of delivery.[16 17]

NCP_CR scoring

Each programme that achieved a single minimum standard was given a score of 1. The range of the scores is between 1 and 6. The performance of CR programmes was categorised into three groups: high (scores of 5–6), middle (scores of 3–4) and low (scores of 1–2). If a programme did not meet any of the six criteria, they were considered to have failed.

Statistical analysis

The analyses were conducted using IBM Statistical Package for Social Sciences (SPSS) software statistics V.23 (SPSS, Chicago, Illinois, USA). Analyses were conducted using all available data from CR programme centres across the UK, to minimise selection bias. Programmes have been aggregated to identify those who met the minimum criteria. Mean and frequency tables were generated to score the programmes according to the certification categories. A χ^2 test for association was conducted between meeting each minimum standard and where the programme sat in the performance group. Data were analysed by using one-way analysis of variance (ANOVA) test, which was conducted to determine whether the minimum criteria were different among performance groups. Games-Howell method was conducted while performing ANOVA for multiple comparisons. Partial η^2

Table 1 Programme performance categories

Programme performance rating	Frequency	Percentage
Poor	9	5.3
Low	31	18.2
Middle	78	45.9
High	52	30.6

have been reported as an effect size. A value of $p \leq 0.05$ was considered statistically significant.

RESULTS

The analysis was derived from 170 CR programmes in the UK, of which 52 (30.6%) scored 5 or 6, so making them high-performance programmes. Middle performance programmes being the largest group accounting for 78 programmes (45.9%). However, 31 programmes (18.2%) were considered as low-performance programmes. Programme performance categories are presented in table 1.

15.9% was the percentage of programmes (27 programmes) who met all the minimum criteria. 84.1% of the programmes offering CR were below the scores required for meeting all minimum criteria.

The percentage of programmes that met each specific criterion is presented in figure 1.

Assessment 1 (ax1) was the largest percentage meeting field (72.4%) on the criteria while waiting time from referral to start (TRS) of CR—MI/PCI (TRS_CR/MIPCI) was the smallest percentage meeting field (49.4%).

The extent by which CR programmes met each minimum standard among performance categories varied significantly (table 2). Ax1 is the highest minimum standard met among the low (51.6%), middle (71.8%) and high (98.1%) performance programmes. On the other hand, the lowest minimum performance category was for the types of patient priority groups included (9.7%), TRS_CR/MIPCI (43.6%) and Ax2 (84.6%) among low-performance, middle performance and high-performance programmes, respectively.

A χ^2 test for association was conducted between meeting each minimum standard and the three performance categories. All expected cell frequencies were >5. There was a statistically significant association between meeting each standard and performance categories, $p<0.001$ at all. There was moderate to strong association between meeting each standard and performance categories (table 2). The PG standard among performance categories had the largest association ($\phi=0.62$) while the duration of CR programme standard had the lowest association among all categories ($\phi=0.37$).

A one-way ANOVA was conducted to determine whether the mean value of each of the five fields of the criteria (the five fields: % of ax1, % of ax2, median waiting TRS_CR/MIPCI, median waiting TRS_CR/CABG and median duration) were different among performance categories. Table 3 shows that the average of the standards in the low-performance programmes was statistically and significantly different to either the middle performance or high-performance programmes. When comparing the average standards in each group, every standard in the low-performance programmes was outside the criteria. This differed to the middle performance programmes, where some standards were met such as the assessments but both referral times were outside of the boundaries. The high-performance programmes averages all sat within the boundaries.

The effect sizes (partial η^2) were largest for median waiting time from referral to start CR programme for MIPCI (TRS_CR/MIPCI) and CABG (TRS_CR/CABG) (0.19 and 0.12, respectively) while duration had the lowest effect size (0.04).

DISCUSSION

There were 170 CR programmes pooled from the patient-level NACR data to identify those who met the minimum standards of the NCP_CR. Statistically significant differences were found among UK CR programmes regarding meeting the minimum standards in terms of

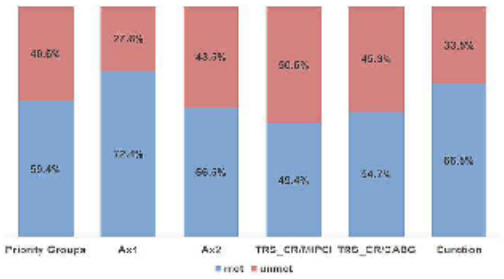

Figure 1 Percentage of total CR programmes meeting and not meeting each of the six fields of the minimum criteria. CR, cardiac rehabilitation.

Table 2 Frequency and percentage of each minimum standard among performance categories

Minimum standard	Low (31)	Middle (78)	High (52)	Cramer's V
PG	3 (9.7%)	48 (61.5%)	50 (96.2%)	0.62*
Ax1	16 (51.6%)	56 (71.8%)	51 (98.1%)	0.39*
Ax2	7 (22.6%)	45 (57.7%)	44 (84.6%)	0.44*
TRS_CR/MIPCI	4 (12.9%)	34 (43.6%)	46 (88.5%)	0.55*
TRS_CR/CABG	7 (22.6%)	38 (48.7%)	48 (92.3%)	0.52*
Duration	14 (45.2%)	51 (65.4%)	48 (92.3%)	0.37*

Ax1, assessment 1; Ax2, assessment 2; PG, priority group; TRS_CR/CABG, median waiting time from referral to start of CR—CABG; TRS_CR/MIPCI, median waiting time from referral to start (TRS) of CR—MI/PCI.
*p<0.001.

delivery of CR in the UK. The principal finding of this study was that, based on the NACR data from 2013 to 2014, only 15.9% (27 programmes out of 170 UK CR programmes) met all the minimum standards included in the NCP_CR report.[10] This result depends on the use of the more lenient interpretation of the report, where we used the 95% CI of the annual averages of the minimum standards. Using the 95% CI increases the data range for meeting a particular minimum standard. Previously, CR programmes were required to meet a particular data cut-point for the majority of the standards within the NCP_CR report. If this latter method had still been in place, fewer programmes would be classed as high performance. This finding agrees with the warning, given in the recent clinical review of CR published in the *British Medical Journal*, that not all CR programmes are working to the minimum standards.[11] The results of this study demonstrate the huge variation in meeting the minimum standards among CR programmes. Also, the analysis showed that, within low-performance groups, CR is being delivered later than recommended, not offered for the PG, not underpinned by preassessment and postassessment and is shorter in duration than the recommended minimum standards suggested by the BACPR, NICE service CR commissioning guide and NICE clinical guidance 172.[4 7 8] Our analysis showed that a large proportion of the variance in the performance groups (38.44% and 19%, respectively) was associated with the minimum standards for offering CR to PG, and with the time from referral to CR start among MI/PCI patients. Despite having tariff-based National Health Service funding and NICE clinical guidelines which define the service specification for the delivery of CR, this study showed that the performance of programmes in the UK varies significantly in terms of meeting the recommended minimum standards. This study is the only UK-specific study that identifies the proportion of programmes meeting national minimum standards for the delivery of CR. This study accounted for six service indicator measures that form part of the NCP_CR report.

This paper shows that high performance is achievable in the modern cardiology era and that many other programmes deemed as being midlevel performance are close to meeting high performance standards. However, substantial unacceptable variation, below the accepted minimum standards, exists. This paper has shown that NCP_CR criteria are able to differentiate the quality of CR delivery and our findings thus support national certification is a positive step to ensuring that patients, irrespective of where they live, are accessing quality services.

LIMITATIONS

The use of an observational approach based on routinely collected patient data is a strength in respect of showing what happens in the real-world, but retrospective observational studies have known limitations in terms of data capture and quality. There are 308 CR programmes in the UK, according to the 2015 NACR

Table 3 ANOVA with post hoc results among performance categories

Minimum standard	Low (26)	Middle (78)	High (52)	(Sig.)	Effect Size
Ax1	68.45%*	76.42%†	89.44%*,†	0.000	0.09
Ax2	41.05%*	52.25%†	63.98%*,†	0.001	0.09
TRS_CR/MIPCI	54.39‡	42.94‡	31.32‡	0.000	0.19
TRS_CR/CABG	61.85*	55.61†	41.99*,†	0.000	0.12
Duration	57.59*	64.56	70.33*	0.031	0.04

Ax1, assessment 1; Ax2, assessment 2; TRS_CR/CABG, median waiting time from referral to start of CR—CABG; TRS_CR/MIPCI, median waiting time from referral to start (TRS) of CR—MI/PCI.
*Post hoc significance between low-performance and high-performance groups, p≤0.05.
†Post hoc significance between middle performance and high-performance groups, p≤0.05.
‡Post hoc significance among low-performance, middle performance and high-performance groups, p≤0.05.

report, but only 170 programmes entered NACR data electronically, which was a requirement of this study. Although it can be argued that there are enough data to carry out the analysis, future work should aim to achieve greater capture of available data across the UK. Although CR programmes are encouraged to provide complete patient records, it was expected that a proportion of patient data would be missing due to non-completion of patient records. On the basis of the NACR data, of all patients who completed CR, 32% did not have a post-CR assessment recorded, which might have affected the representativeness of our sample.

CONCLUSIONS

This study aimed to identify the proportion of programmes meeting national minimum standards for the delivery of CR. Only 30% of the UK CR programmes met the criteria for high-performance CR with a further 18% seen as low performance and 5% failed to meet any of the criteria. This study is the first to evaluate CR against minimum standards and report the extent of deficit in UK CR services. Further research is required to investigate the extent of patient outcomes between high-performance, middle performance and low-performance CR programmes.

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Contributors PD and AS are responsible for conception acquisition, analysis, interpretation of data for the work, drafting the work and revising critically for important intellectual content and approved the final version of the manuscript to be published and agreed to be accountable for errors. GF, HMD and AH are responsible for conception acquisition, interpretation of data for the work, drafting the work and revising critically for important intellectual content, approved the final version of the manuscript to be published and agreed to be accountable for errors.

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Competing interests None declared.

Ethics approval Health and Social Care Information Centre.

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement No additional data are available.

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Appendix 14 Do the demographic characteristics and baseline health state of patients vary in different cardiac rehabilitation performance programmes?

(OR 1.9, 95% CI 1.1–3.2, p=0.017) and living alone (OR 2.9, 95% CI 1.6–5.0, p<0.001).
Conclusion: The benefits of CRP enrollment after an ACS are undeniable. However, dropout rates remain high and are a source of concern in CRP. Identifying those at higher risk of non-compliance, especially those with social and economic disadvantages might steer a redesign of CRP programs, and alternatives to reduce costs and inequities in access to this cost-effective treatment option.

P2496 | BEDSIDE
Aerobic interval versus continuous training in coronary artery disease and chronic heart failure patients: an updated meta-analysis of randomized clinical trials

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Background: Since the publication of our latest meta-analysis in 2014, including only 9 study groups, an increasing number of randomized clinical trials have compared the effectiveness of aerobic interval training (AIT) and continuous training (ACT) in cardiac patients. This allows for a more precise estimate of the effect on peak oxygen uptake (peak VO2) and other relevant secondary outcomes.
Purpose: To update the meta-analysis comparing AIT and ACT including both CAD and chronic heart failure (CHF) patients and examining also secondary outcomes.
Methods: Literature search up to September 2016. Random effects models were used.
Results: We included 21 study groups (11 CAD; 259 AIT, 274 ACT; 59.5±9.6 years / 10 CHF; 113 AIT, 120 ACT; 63.2±8.8 years). Peak VO2 increased more after AIT compared to ACT in both patient groups (p<0.01). Peak HR increased more following AIT in CAD patients, whereas we observed larger improvements in left ventricular ejection fraction, VO2 at first threshold and VE/VCO2 slope in CHF patients.

Mean effect sizes of AIT compared to ACT

	Pathology	Study (n)	Patients AIT vs ACT (n)	Mean effect size (AIT-ACT) (95% CI)	P-value
Exercise capacity					
Peak VO2 (ml/kg/min)	CAD	11	259 vs 274	1.28 (0.52–2.04)	<0.001
	CHF	10	113 vs 120	1.68 (0.41–2.94)	0.009
VO2 at first threshold (ml/kg/min)	CAD	7	194 vs 200	0.73 (-0.25–1.68)	0.14
	CHF	5	88 vs 95	1.16 (0.05–2.27)	0.04
Peak HR (bpm)	CAD	10	231 vs 242	5.11 (1.94–8.28)	0.002
	CHF	7	78 vs 79	-0.10 (-5.68–5.47)	0.97
VE/VCO2 slope	CAD	5	147 vs 153	0.50 (-0.39–1.38)	0.27
	CHF	6	69 vs 74	-1.74 (-3.53–0.04)	0.06
OUES	CAD	3	125 vs 131	79.37 (-69.4–230)	0.36
Cardiovascular risk factors					
Weight (kg)	CAD	6	156 vs 167	0.67 (-0.79–2.13)	0.37
	CHF	2	29 vs 28	0.24 (-3.11–3.60)	0.89
SBP (mmHg)	CAD	5	155 vs 158	2.67 (-2.22–7.56)	0.29
	CHF	3	46 vs 44	-0.25 (-5.27–4.76)	0.92
DBP (mmHg)	CAD	5	155 vs 158	0.27 (-3.33–3.87)	0.88
	CHF	3	46 vs 44	-0.54 (-4.61–3.34)	0.75
HDL-C (mmol/l)	CAD	4	142 vs 155	0.00 (-0.05–0.07)	0.96
	CHF	4	54 vs 52	0.05 (-0.03–0.13)	0.25
LDL-C (mmol/l)	CAD	4	142 vs 155	-0.12 (-0.33–0.09)	0.28
	CHF	4	54 vs 52	0.09 (-0.23–0.39)	0.58
Triglycerides	CAD	4	142 vs 155	-0.02 (-0.19–0.14)	0.77
	CHF	4	54 vs 52	0.01 (-0.21–0.23)	0.93
Glucose (mmol/l)	CAD	3	128 vs 141	0.06 (-0.25–0.37)	0.69
	CHF	3	39 vs 37	-0.34 (-0.89–0.21)	0.22
Rest HR (bpm)	CAD	5	212 vs 224	1.80 (-0.50–3.10)	0.15
	CHF	3	42 vs 45	1.39 (-3.86–6.67)	0.61
Other variables					
Left Ventricular ejection fraction (%)	CAD	3	121 vs 129	-0.56 (-2.49–1.37)	0.57
	CHF	5	66 vs 67	3.97 (1.45–6.49)	0.002
Heart rate recovery 1 min (bpm)	CAD	7	200 vs 211	1.24 (-2.11–4.59)	0.47
	CHF	2	27 vs 27	-2.25 (-15.3–10.8)	0.73
Flow mediated dilation (%)	CAD	3	111 vs 121	0.08 (-0.57–0.73)	0.81
	CHF	3	29 vs 31	1.70 (-0.90–4.29)	0.20

Conclusion: AIT seems more useful to increase exercise capacity parameters. Traditional cardiovascular risk factors, heart rate recovery and endothelial function were similarly influenced by both training methods.

P2497 | BEDSIDE
A randomised clinical trial for an extended cardiac rehabilitation program using telemonitoring

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Background: Despite the known positive effects of cardiac rehabilitation (CR) and an active lifestyle, evidence is still emerging that it is difficult to attain and sustain the minimum recommendations of leisure time physical activity. The long-term benefits are often disappointing due to lack of adherence to the changes in life style.
Purpose: The aim of the TeleCaRe study was to determine if prolongation of a traditional cardiac rehabilitation program with additional mHealth guided CR (mCR) for a period of 6 months results in better long-term effects on physical and mental outcomes, care consumption, and quality of life.
Methods: TeleCaRe was a prospective single centre randomised controlled trial. 122 patients who had completed a traditional cardiac rehabilitation program were randomised in a 1:1 ratio to an intervention group with 6 months 6 mCR or a control group with traditional follow up. Patients in the intervention group were equipped with a Smartphone and connected heart rate monitor dedicated for the use of telemonitoring. Based on a performed spiro-ergometry they received personal exercise instructions. Data were transferred to a secured website. Patients as well as specialised nurses had access to the website which led to weekly feedback by using motivational interviewing.
Primary outcome was VO2peak after 12 months. Secondary outcomes were VO2 peak after 6 months, Quality of life, physical, emotional and social functioning, traditional risk factors, compliance for the use of mCR, MACE and care consumption.
Results: A total of 122 patients were included; 61 in mCR, 61 in standard follow up. The base line characteristics were equally divided in both groups.
Primary outcome: The mean peak VO2/ kg in the telemonitoring guidance group improved from 22.75 to 24.5.
The mean peak VO2/kg in the standard Care group improved from 22.21 to 23.34

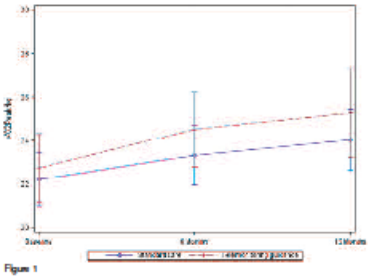

Figure 1

Secondary outcomes: Still under investigation.
Conclusion: There was no significant difference in peak VO2 after 12 months between the intervention group and the control group. Both groups improved.
Acknowledgement/Funding: Astra Zenica

P2498 | BEDSIDE
Do the demographic characteristics and baseline health state of patients vary in different cardiac rehabilitation performance programmes?

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Purpose: To evaluate the extent by which baseline characteristics of patients explain the variation in cardiac rehabilitation (CR) programme performance.
Methods: The analysis used UK national audit of cardiac rehabilitation data for the period 2013–14 set against six of the national certification programme for CR measures. The criteria included: (1) CR offered to all priority groups (myocardial infarction (MI), percutaneous coronary intervention (PCI), coronary artery bypass surgery (CABG), heart failure), (2) recorded assessment of core CR patients at baseline, (3) recorded assessment after completing of CR, median waiting time from referral to start CR (4) was within 40 days for MI/PCI patients and (5) was within 54 days for CABG patients and final (6) median duration of CR programmes was 54 days. Each programme that achieved a single criterion was given a score of 1. The performance of CR programmes was categorised into three groups: high (score of 5–6), middle (scores of 3–4) and low (scores of 1–2). The computed variables included demographics characteristics, cardiovascular risk factors, physical and psychosocial health measures.
Results: Data from 170 CR programmes revealed statistically significant differences among UK CR programmes. The highest performance group made up only 30% of all included UK CR programmes. The analysis showed that a large proportion of the variance in the performance groups (38.44% and 19%, respectively) was associated with meeting criteria of offering CR to priority groups, and with the time from referral to CR start among MI/PCI patients. Also, the analysis showed that within low-performance group CR is being delivered later than recommended, not offered for the priority groups, not underpinned by pre and post assessment and short in duration. However, we found that increases in a total number of patients started the standard core CR (volume), total staff hours worked and total comorbidities patients had in a program were statistically and

significantly associated with an increased likelihood that program would be categorised as a high-performance. Variations were found among UK CR performance groups regarding differing in the patients receiving CR services in the UK. The high-performance programmes have been found to recruit higher proportion of patients with high risk, comorbidities, body mass index score, waist size, with blood pressure >140/80 mmHg, anxious and depressed than low or middle-performance programmes. In addition, high performance programmes also take on patients with lower fitness compared to low-performance programmes.

Conclusions: The study found that increases in the volume, total staff hours worked and the total comorbidities of patients in a programme were associated with programme categorised as a high performing. This represents an important association between service performance and the extent of more multi-morbidity in populations being served.

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P2499 | BEDSIDE

Myocardial infarction patients more often reach treatment goals for low-density lipoprotein at centres where cardiac rehabilitation nurses adjust statins - the Perfect-CR study

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Background: Treating hypercholesterolemia and hypertension are fundamental parts of secondary prevention after myocardial infarction (MI). As the patient's primary contact in cardiac rehabilitation (CR) the nurse has a key position in optimizing treatment. However, the autonomy of CR nurses to adjust medication and the support they receive from CR cardiologists varies widely.

Purpose: To explore associations between aspects of CR nurses' autonomy and support and patient outcomes regarding low-density lipoprotein cholesterol (LDL-C) and systolic blood pressure (BP).

Methods: We performed a survey exploring CR protocols followed in Sweden in 2016. A questionnaire, sent out to and answered by all 79 invited CR centres in Sweden, included questions on which support the CR nurse had from a cardiologist in their daily work and their autonomy to adjust statins and BP medication. T-test and linear regression were performed to compare means and explore associations between reported routines at the centres and proportion of patients reaching goals for LDL-C (<1.8 mmol/L) and systolic BP (<140 mmHg) at one year (data retrieved from the Swedish Secondary Prevention after Heart Intensive Care Admission Registry).

Results: The majority (77%) of the centres reported having a medical director (cardiologist) responsible for the CR clinic. At 40% of the centres, the nurses had regular rounds with a CR cardiologist to discuss patient-related questions. At 57% of the centres, the nurses reported having no round routines but instead having an opportunity to consult a cardiologist when needed. At one centre the nurses reported having no support from a cardiologist at all.

At 81% and 54% of the centres, the nurses independently adjusted BP medication and statins, respectively. At centres where the nurses adjusted statin treatment, 62% of the patients achieved LDL-C goals at one year post-MI, compared to 53% at the centres where nurses did not adjust statin doses (p=0.001). Having a medical director at the centre (61% vs 52%, p=0.004) and regular rounds (62% vs 56%, p=0.02) resulted in a higher proportion of patients reaching LDL-C goals at one year. In a regression analysis including all three routines statin dose adjustment by the CR nurse and having a medical director were independently associated with lower LDL-C at 1 year (β-coefficient=0.33, p=0.009 and β=0.29, p=0.02, respectively). At centres where nurses adjusted BP medication we observed a non-significant trend towards more patients reaching systolic BP goals at one year.

Conclusions: In this nation-wide survey of post-MI patients followed at CR centres, nurse-led adjustments of statin treatment, having a medical director and regular case rounds led to a higher proportion of patients reaching treatment goals for LDL-C at one year follow-up. The results support providing autonomy to CR nurses to adjust statin treatment as well as underlining the importance of adequate medical support for the CR nurse.

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P2500 | BEDSIDE

Walking improvement for patients with intermittent claudication: success of a short 25 days supervised exercise program

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Background: Exercise rehabilitation programs have been shown to increase walking distance in people with peripheral arterial disease (PAD) at intermittent claudication stage. Benefit of supervised rehabilitation programs in walking, in addition to the medical treatment has a I-A grade in ESC guidelines. However, optimal rhythm and duration of a program are not well established, and the more common duration vary between 12 to 24 weeks, with exercises 3 times a week. Applicability of such programs and adhesion of the patients are difficult to obtain. That's why we developed a short duration program consisting of 25 sessions spread over 5 consecutive weeks. We present the results of walk increase of the patients who completed the program.

Method: We prospectively assessed at the first and last days of the program each patient with a 6-minute walk test (6MWT) and tests to measure the walking discomfort maximal speed and the speed allowing a sustained walk of 20 minutes without stopping on a constant speed treadmill with no slop. Supervised exercises were on a daily routine, 5 days week and comprised: stairs climbing, arm bike machine during 30 minutes, and constant speed treadmill walking with no slope during 20 minutes after 10 minutes of warm-up and then followed by 10 minutes for recovery. The initial speed was set up at 80% of the 6MWT. Speed was increased every 2 sessions by 5%, unless the patient preferred to plateau or if he felt able to increase faster.

Results: We enrolled 54 patients, 46 (85%) men, mean age ± standard deviation 63.6±12.3 years. Diabetes mellitus was present in 12 (22%) patients. The body mass index was 26.9±4.7 kg/m^2. LDL-cholesterol was 2.57±1.0 mM with 42% at the target (LDL-c <1.8mM). The glomerular filtration rate was 88.7±20.7 mL/min/1.73m^2, with 55% patients with normal renal function. All patients had statin, ACE inhibitor or ARB, and antithrombotic therapy. Eight (15%) patients quit the program before the end. Between first and last days of the program, from the 46 evaluable patients, the 6MWT increased from 349±86m to 393±68m (+15%, p=0.002), the walking discomfort maximal speed increased from 4.5±0.9 to 6.4±1.0 km/h, (+43%, p=0.001) and the 20 minutes without stopping walk speed increased from 2.6±0.9 to 3.9±1.1 km/h (+ 57%, p<0.001).

Conclusion: Among people with PAD and claudication we obtained a 85% adhesion to a short 25 days rehabilitation program with encouraging results: +15% at the 6MWT and +57% on the walking average speed during 20 minutes. Long-term benefits need to be evaluated yet, because a functional decline during the subsequent year is expected. However, this easy to set-up program was easy to follow for the patients. This kind of program could increase access to such therapy for PAD patients with intermittent claudication.

P2501 | BEDSIDE

Impact of phase 2 cardiac rehabilitation program on obese and non-obese patients with stable coronary artery disease

A.M. Elmissiri, W. Adel, T. Rashid, A.S.A. Almaweri. *Ain Shams University, Cairo, Egypt*

Background: Obesity has significant adverse effects on coronary artery disease (CAD). Cardiac rehabilitation (CR) has proven beneficial effects on cardiac patients Nearly 80% of patients referred to CR program are overweight and obese.

Purpose: To assess the impact of phase 2 CR program on obese and non-obese patients with stable CAD after total revascularization.

Methods: 120 patients with stable CAD referred for phase 2 CR program. Patients were divided into two groups according to body mass index (BMI); non-obese group with BMI <30 kg/m^2 and obese group with BMI ≥30 kg/m^2. Venous blood samples were obtained to measure fasting blood sugar (FBS), triglycerides (TG), total cholesterol (TC), high-density lipoprotein cholesterol (HDL-C) and low density lipoprotein cholesterol (LDL-C). Trans-thoracic echocardiography was performed to measure left ventricular ejection fraction (LVEF) by bi-plane Simpson's method of discs. Patients participated in a 12-week (24 session) CR program of progressive prescribed exercise training. At the end of the program, patients were reassessed for smoking status, functional capacity (in the form of METs achieved), blood pressure (BP) assessment, BMI calculation, follow-up lipid profile and FBS and echocardiography.

Results: At baseline, the obese group (n=62) in comparison to the non-obese one (n=58) had a larger percentage of females 20 (32.25%) versus 6 (10.13%) (p=0.04), a larger percentage of hypertensives (p=0.023) and had higher baseline readings of systolic BP (p=0.008) and diastolic BP (p=0.043) with less METs achieved 7.97±2.4 vs 9.74±2.47 (p=0.007). There was a larger percentage of smokers in the non-obese group 46 (79%) vs 32 (51%) (p=0.025). There was no difference between both groups regarding age, presence of diabetes mellitus and dyslipidemia. LDL-C was higher in the obese group 121.63±36.524 vs 95.73±31.51mg/dl (p=0.005). There was no significant difference between both groups regarding TC, HDL-C, TG, FBS and LVEF.

At the end of CR program, the obese group showed more reduction in BMI -1.7781±1.45976 vs -0.5966±0.70167 kg/m^2 (p<0.001), systolic BP (p=0.016) and

Appendix 15 To what extent is the variation in cardiac rehabilitation quality associated with patient characteristics?

RESEARCH SQUARE INDEPENDENT VALIDATION | BHSR-D-18-01038

RESEARCH QUALITY EVALUATION

MANUSCRIPT TITLE To what extent is the variation in cardiac rehabilitation quality associated with patient characteristics?
AUTHORS AHMAD SALMAN, University of York*; Patrick Doherty, University of York
REPORT DATE Aug 30 2018, 14:59 (UTC -0400)
EVALUATED BY Academic Peer Reviewer

Current Manuscript Version

OBJECTIVE

Does the manuscript have a clear objective?

✔ Yes - there is a clear objective

DESIGN

Is the current approach (including controls / protocols) appropriate for the objective(s)?

✖ No - there are minor issues

EXECUTION

Are the experiments and analyses performed with technical rigor to allow confidence in the results?

✖ No - there are minor issues

INTERPRETATION

Is the current interpretation of the results reasonable and not overstated?

✖ No - there are minor issues

Manuscript Potential

Could an appropriately REVISED version of this work represent a technically sound contribution?

✔ Probably - with minor revisions

REVIEWER COMMENTS

The overall impression of the study was fair. The objectives of this study was clear which the authors have done well. The statistical analysis was reasonable, but the reporting of results is unclear. For example, they do not report CIs when the report a x-fold increased risk.

REQUESTED REVISIONS:
The authors reporting of results needs to be improved and the 95% CIs need to be reported
ADDITIONAL REQUESTS/SUGGESTIONS:
The future implications of this work are not clear

Appendix 16 The New Investigator Award from the British Association for Cardiovascular Prevention and Rehabilitation (BACPR).

Health Sciences

PhD student wins New Investigator Award

Posted on 31 October 2017

A PhD student from the Department has received an award for research as part of his studies

Dr Ahmad Salman (right) receives his award from Professor Patrick Doherty (left)

Dr Ahmad Salman, a PhD student within the Department of Health Sciences, has been awarded the New Investigator Award from the British Association for Cardiovascular Prevention and Rehabilitation (BACPR).

The award is given in recognition of research that shows clear evidence of sound scientific background, originality and content which recognises novel, important work by new researchers in the field.

Ahmad recently attended the 2017 BACPR conference, which was held in London in October. Supervised by Professor Patrick Doherty, Professor of Cardiovascular Health and Deputy Head of Department (Research), and supported by the National Audit of Cardiac Rehabilitation (NACR) team, Ahmad presented an oral presentation entitled 'Determinants of smoking cessation in patients attending cardiac rehabilitation'. He received this prestigious award in recognition of the research he conducted with Professor Doherty as part of his PhD. He also received a prize for his oral presentation.

Ahmad said: "I am pleased that the BACPR chose my abstract for presentation and I feel extremely privileged to receive the BACPR award. It was an amazing and very important experience for my research and career. It was quite unexpected, and it just goes to show that, after a very challenging three years, hard work pays off and it's great to have it acknowledged. It's given me the motivation I need to continue researching and do well in my PhD."

Patrick said: 'This research helps us better understand which factors determine patient outcome and enables clinical teams to use this to tailor rehab for individual patients'.

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Appendix 17 Smoking outcome results between quality categorises

Quality groups: 95% criteria using NACR 2017 averages for (2013-2016)

Quality groups	Number of smoker patients	Percent
Low	346	10.5
Middle	1805	54.9
High	1043	31.7
Total	3194	97.1
Missing	96	2.9
Total	3290	100.0

Smoking categorisation groups among quality groups

Quality groups	Smokers	Quitters	Total
Low	217 (62.7%)	129 (37.3%)	346
Middle	1089 (60.3%)	716 (39.4%)	1805
High	670 (64.2%)	373 (35.8%)	1043
Total	1976 (61.9%)	1218 (38.1%)	3194

Summary of multiple regression analysis clustered by quality groups ((high quality as reference)

Variable (N)		Unstandardised coefficients		Standardised coefficients		95% CI		Effect size
		B	S.E.	Beta	Sig.	Lower	Upper	
Weight (n=2,299)	Constant	0.32	0.29		0.27	-0.25	0.89	0.01
	Baseline weight	0.99	0.00	0.99	0.00	0.99	1.00	
	Smoking	0.42	0.11	0.01	0.00	0.21	0.63	
	Low quality	0.20	0.19	0.00	0.29	-0.17	0.57	
	Middle quality	-0.05	0.12	0.00	0.67	-0.28	0.18	
BMI (n=2,204)	Constant	0.22	0.12		0.06	-0.01	0.45	0.01
	Baseline BMI	0.99	0.00	0.99	0.00	0.98	0.99	
	Smoking	0.17	0.04	0.02	0.00	0.09	0.25	
	Low quality	0.04	0.07	0.00	0.53	-0.09	0.18	
	Middle quality	0.02	0.04	0.00	0.68	-0.07	0.10	
Waist (n=915)	Constant	4.41	0.85		0.00	2.75	6.06	0.00
	Baseline waist	0.95	0.01	0.97	0.00	0.94	0.97	
	Smoking	0.01	0.23	0.00	0.95	-0.44	0.46	
	Low quality	0.16	0.36	0.00	0.65	-0.54	0.87	
	Middle quality	0.06	0.23	0.00	0.78	-0.38	0.51	
Alcohol consumption (775)	Constant	5.30	1.16		0.00	3.03	7.58	0.01
	Baseline alcohol consumption	0.55	0.02	0.72	0.00	0.51	0.59	
	Smoking	-1.20	0.69	-0.04	0.08	-2.55	0.15	

	Low quality	-1.12	1.33	-0.02	0.40	-3.73	1.49	
	Middle quality	-0.16	0.76	-0.01	0.84	-1.65	1.34	
HADS anxiety score (1558)	Constant	1.62	0.28		0.00	1.07	2.17	0.02
	Baseline HADS anxiety score	0.77	0.02	0.76	0.00	0.74	0.80	
	smoking	-0.73	0.15	-0.08	0.00	-1.03	-0.44	
	Low quality	0.19	0.24	0.01	0.42	-0.27	0.66	
	Middle quality	-0.09	0.16	-0.01	0.58	-0.41	0.23	
HADS depression score (1527)	Constant	1.30	0.26		0.00	0.79	1.80	0.01
	Baseline HADS depression score	0.74	0.02	0.74	0.00	0.71	0.78	
	smoking	-0.56	0.15	-0.07	0.00	-0.85	-0.28	
	Low quality	0.26	0.22	0.02	0.25	-0.18	0.70	
	Middle quality	-0.31	0.15	-0.04	0.04	-0.61	-0.01	

B=unstandardised regression coefficient; Beta=standardized coefficient; BMI, body mass index; CI=Confidence Interval for unstandardised regression coefficient; CR, cardiac rehabilitation; HADS, hospital anxiety and depression scale; n=Number of patients; S.E.=standard error of the coefficient. *p≤0.05 (bold text).

Summary of multiple regression analysis clustered by quality groups (physical activity outcome)

Physical activity outcomes	Smokers (%)			Quitters (%)		
	Improve	No change	Worsen	Improve	No change	Worsen
Low						
Δ 150 mins/week (moderate) (N=241)	16.7	79.4	3.9	57.4	39.3	3.3
Δ 75 mins/week (vigorous) (N=134)	14.0	81.4	4.7	37.5	56.3	6.3
Middle						
Δ 150 mins/week (moderate) (N= 1025)	34.9	61.3	3.9	44.2	52.1	3.7
Δ 75 mins/week (vigorous) (N= 930)	19.5	78.1	2.5	27.1	69.3	3.6
High						
Δ 150 mins/week (moderate) (N= 599)	34.7	56.7	8.6	36.8	58.5	4.7
Δ 75 mins/week (vigorous) (N= 531)	17.0	80.6	2.4	21.3	76.3	2.5

Δ, change; %, percentage

Appendix 18 Summary of binomial logistic regression analysis (original data) clustered by centre (adjusted for 86 clusters)

	B	**Robust SE**	**p**	**OR**	**95% CI for OR**	
					Lower	**Upper**
Age	–0.01	0.01	0.21	0.99	0.97	1.01
Marital status (single)	–0.52	0.16	**0.00***	0.60	0.43	0.82
Employment status (Retired as reference)						
Employment status (employed)	0.10	0.26	0.69	1.11	0.67	1.84
Employment status (unemployed)	–0.20	0.28	0.48	0.82	0.48	1.42
Cardiovascular risk (high as reference)						
Cardiovascular risk (low)	0.54	0.21	**0.01***	1.71	1.14	2.57
Cardiovascular risk (moderate)	0.14	0.19	0.45	1.15	0.80	1.66
Comorbidities	–0.13	0.06	**0.02***	0.88	0.79	0.98
Weight	0.01	0.00	0.18	1.00	1.00	1.02
HADS anxiety score	0.03	0.03	0.32	1.03	0.97	1.09
HADS depression score	–0.06	0.03	0.06	0.95	0.89	1.00
Constant	–0.63	0.92	0.50	0.53	0.09	3.23

B=unstandardised regression coefficient; CI=Confidence Interval for odds ratio; HADS, hospital anxiety and depression scale; OR, odds ratio. S.E.; standard error of the coefficient. *p≤0.05 (bold text).

Appendix 19 Summary of binomial logistic regression analysis (expectation maximisation data) clustered by centre (adjusted for 90 clusters)

	B	Robust SE	p	OR	95% CI for OR	
					Lower	Upper
Age	–0.01	0.01	0.31	0.99	0.97	1.01
Marital status (single)	–0.52	0.15	**0.00***	0.60	0.44	0.81
Employment status (Retired as reference)						
Employment status (employed)	0.13	0.22	0.58	1.13	0.74	1.73
Employment status (unemployed)	–0.09	0.29	0.77	0.92	0.52	1.62
Cardiovascular risk (high as reference)						
Cardiovascular risk (low)	0.61	0.21	**0.00***	1.83	1.23	2.74
Cardiovascular risk (moderate)	0.27	0.19	0.17	1.31	0.89	1.91
Comorbidities	–0.16	0.05	**0.00***	0.86	0.77	0.95
Weight	0.01	0.00	0.06	1.01	1.00	1.01
HADS anxiety score	0.02	0.03	0.41	1.02	0.97	1.08
HADS depression score	–0.05	0.03	0.07	0.95	0.90	1.01
Constant	–0.90	0.81	0.27	0.41	0.08	1.98

B=unstandardised regression coefficient; CI=Confidence Interval for odds ratio; HADS, hospital anxiety and depression scale; OR, odds ratio. S.E.; standard error of the coefficient. *p≤0.05 (bold text)

Appendix 20 Summary of multiple regression analysis clustered by centre

Variable (N)		Unstandardised coefficients			95% CI	
		B	Robust S.E.	Sig.	Lower	Upper
Weight (n=2,380) adjusted for 133 clusters	Constant	0.75	0.25	0.00	0.26	1.24
	Baseline weight	0.99	0.00	0.00	0.99	1.00
	Smoking	0.43	0.12	**0.00***	0.20	0.66
BMI (n=2,275) adjusted for 130 clusters	Constant	0.41	0.10	0.00	0.22	0.61
	Baseline BMI	0.99	0.00	0.00	0.98	0.99
	Smoking	0.18	0.05	**0.00***	0.10	0.27
Waist (n=929) adjusted for 90 clusters	Constant	4.52	0.68	0.00	3.17	5.86
	Baseline waist	0.95	0.01	0.00	0.94	0.96
	Smoking	0.05	0.23	0.83	-0.40	0.50
Alcohol consumption (784) adjusted for 103 clusters	Constant	3.85	0.69	0.00	2.50	5.21
	Baseline alcohol consumption	0.56	0.05	0.00	0.45	0.67
	Smoking	-1.34	0.84	0.11	-3.01	0.33
HADS anxiety score (1592) adjusted for 122 clusters	Constant	0.86	0.12	0.00	0.62	1.11
	Baseline HADS anxiety score	0.77	0.02	0.00	0.73	0.80
	smoking	-0.75	0.17	**0.00***	-1.08	-0.42
HADS depression score (1562) adjusted for 125 clusters	Constant	0.64	0.13	0.00	0.38	0.89
	Baseline HADS depression score	0.74	0.02	0.00	0.69	0.78

	smoking	-0.58	0.15	**0.00***	-0.88	-0.28

B=unstandardised regression coefficient; Beta=standardized coefficient; BMI, body mass index; CI=Confidence Interval for unstandardised regression coefficient; CR, cardiac rehabilitation; HADS, hospital anxiety and depression scale; n=Number of patients; S.E.=standard error of the coefficient. *p≤0.05 (bold text)

Appendix 21 Abbreviations

%	*Percentage/Proportion*
AACVPR	*American Association Of Cardiovascular And Pulmonary Rehabilitation*
ACC	*American College of Cardiology*
AHA	*American Heart Association*
ARR	*Absolute Risk Reduction*
Ax1	*A Recorded Assessment Before Starting Formal CR Programme*
Ax2	*A Recorded Assessment After Completing CR Programme*
BACPR	*British Association For Cardiovascular Prevention And Rehabilitation*
BHF	*British Heart Foundation*
BMI	*Body Mass Index*
BP	*Blood Pressure*
CABG	*Coronary Artery Bypass Surgery*
CATs	*Critical Appraisal Tools*

CHD	*Coronary Heart Disease*
CI	*Confidence Interval*
CVD	*Cardiovascular Disease*
DBP	*Diastolic Blood Pressure*
ESC	*European Society of Cardiology*
HF	*Heart Failure*
HR	*Hazard Ratio*
JBS3	*3rd iteration of the Joint British Societies*
LVEF	*Left Ventricular Ejection Fraction*
Max	*Maximum*
MDT	*Multidisciplinary Team*
MI	*Myocardial Infarction*
Min	*Minimum*
NCP_CR	*National Certification Programme For Cardiovascular Rehabilitation*

NHS	*National Health Service*
NICE	*National Institute For Health And Care Excellence*
NNT	*Number Needed To Treat*
OR	*Odds Ratio*
PCI	*Percutaneous Coronary Intervention*
PEDRO	*Physiotherapy Evidence Database*
PG	*Priority Groups*
POST-CR	*After Cardiac Rehabilitation*
PRE-CR	*Before Starting Cardiac Rehabilitation*
PTCA	*Percutaneous Transluminal Coronary Angioplasty*
RAMIT	*Rehabilitation After Myocardial Infarction Trial*
RR	*Relative Risk*
SBP	*Systolic Blood Pressure*
SD	*Standard Deviation*
SE	*Standard Error*

TRS_CR/CABG	*Median Waiting Time From Referral To Start Of Cardiac Rehabilitation After Coronary Artery Bypass Surgery*
TRS_CR/MIPCI	*Median Waiting Time From Referral To Start Of Cardiac Rehabilitation After Myocardial Infarction Or Percutaneous Coronary Intervention*
U.S.	*United States*
UK	*United Kingdom*
WHO	*World Health Organization*

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