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

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**Abstract**

### Aims:

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

### Methods:

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

### Results:

The results showed 85% of the population received supervised CR. The FSM group were significantly older, female predominantly in lower socioeconomic groups. The results showed, all patients on average benefit from CR, independent of mode of delivery, across all risk factors. There was additional benefit for physical activity in the FSM programmes with 13% associated increase in the likelihood of achieving >150 mins post CR (OR 1.137 p <0.001).

### Conclusion:

This is the first study to investigate traditional cardiovascular risk factors with CR mode of delivery using routine clinical data. Both modes of delivery were associated with comparable statistical significant positive outcomes. Despite having equivalent outcomes facilitated self-management CR continues to be underutilised with less than 20% of patient’s receiving this mode of delivery in the UK.

Word Count – 250

**Keywords**

Keywords: Cardiac Rehabilitation, Risk Factors, outcomes, Secondary Prevention.

**INTRODUCTION**

Cardiovascular Diseases (CVD) are the number one cause of death globally,[1] with an estimated 17.7 million related mortalities in 2015. It is estimated in Europe that more than 85 million people are living with CVD.[2] One of the most widely recognised and well evidenced treatments for CVD patients Cardiac Rehabilitation (CR). CR in the modern era of cardiology remains effective.[3-4] The effectiveness of CR include reduction in re-admissions (RR 0.82, 95% CI 0.70-0.96) cardiovascular mortality (RR 0.74, 95% CI 0.64-0.86) in trial populations and in observational studies a reduced overall mortality (HR 0.62 95% CI 0.54-0.70).[3-4]

CR is a multifaceted lifestyle intervention that aims to; influence favourably the causes of CVD, provide the best possible physical, mental and social conditions and result in the slowing or reverse of the progression of disease.[5] CR is included in NICE guidelines for treatment myocardial infraction patients.[6-7] CR in the UK is widely adopted, with 51% of eligible patients participating in 2017 and is the most cost-effective intervention after aspirin.[8-9]

In a recent cost-effectiveness systematic review, CR in a variety of countries and settings was seen to be significantly cost effective.[10]

CR is best delivered by a multidisciplinary team in the form of a multi-component intervention that aims to reduce burden of disease, promote healthy lifestyle improve risk factor management and facilitate optimal recovery.[5, 11] The mode of delivery for CR has long been thought to be an influencing factor in terms of patient’s outcomes. Cochrane in 2017 reviewed the trial evidence for home-based versus centre-based CR modes of delivery, which concluded that; for total mortality (RR1.19 95% CI 0.65-2.16), exercise capacity (SMD =-0.13 95% CI -0.28-0.02) and health related quality of life (figure not estimated), there was no difference between modes.[12] Additionally, two studies using routine clinical populations found no difference in the psychosocial outcomes (hospital anxiety and depression score (HADS) and Dartmouth COOP) and walking fitness (incremental shuttle walk test and 6 minute walk test) of patients attending supervised or self-managed rehabilitation in the UK.[13-14]

Currently, CR in 2017 is predominantly delivered as supervised group-based CR and only a small proportion are other modes, which are often facilitated self-managed (FSM) modes.[8] The recent studies using the National Audit of Cardiac Rehabilitation (NACR) data indicated a fifth of the delivery is from FSM.[13-14] Tradition has been that supervised group-based has long been the assumed best approach for influencing outcomes, however, there is an emerging trend in recent years to offering modes such as the FSM alternatives.[13-15]

The aims of CR in all modes is to facilitate optimal recovery and reduce risk factors. According to the World Heart Federation, four of the highest associated risk factors for CVD are smoking, being overweight or obese, high blood pressure or hypertension and physical inactivity.[16]

Smoking cessation is key to the British Association of Cardiovascular Prevention and Rehabilitation (BACPR) standards and core components encouraging programmes to offer smoking cessation supported by skilled and competent staff.[5] Based on the most recent UK data 6.4% of patients entering CR were smoking and a fifth of this group successfully quit by post assessment which equated to over 300 patients.[8]

Patients who are physically inactive, defined by the Chief Medical Officer guidelines of >150 minutes moderate activity per week makes up 58.4% of patients entering CR services,[17] on average 28.1% of patients (4,448) moved into the higher physically active group by the end of CR which is a trend associated with reduced mortality.[8, 18]

High blood pressure, defined in the CVD population as >140/90 (>130/80 for south Asians) is a major risk factor for CVD.[16] A reduction in systolic blood pressure by 5 mmHg can reduce the cardiovascular mortality by as much as 20-40%. Through successful titration of drugs from the CR staff and increases in physical activity, 6% of previously high blood pressure patients move into <140/90 by the time they finish CR.[8] In the recent EUROSPIRE IV, they found that ~60% of hypertensive patients attending CR were <140/90 post CR.[19]

The final risk factor to be considered is obesity which is defined as >30 BMI. Obesity is an indicator of poor health and is associated with an increased likelihood of developing hypertension, diabetes and atherosclerosis.[5-16] According to recent statistics more than 400 million adults are obese in the world and ~30% of patients entering CR have a higher than 30 BMI. [1, 8] Evidence suggests that patients moving from obese and overweight to normal BMI have a reduction in risk of CVD and cancer.[20]

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

**METHODS**

This study was reported according to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines.[21]

**Data**

The source of data for the study was the National Audit of Cardiac Rehabilitation.[8] The audit monitors and reports service quality, the patient profile and outcomes in patients that complete CR. The NACR covers CR programmes from UK totalling over 200; with 74% coverage through online data entry, however, including the index of multiple deprivation (IMD) this study will only look at England CR programmes.[8] The data collected includes patient characteristics such as age, gender and ethnicity along with services details such as staffing and number of patients seen.

Patients from England with initiating event between 1st Jan 2012-30th April 2018 were eligible. The initiating event was the diagnosis or treatment that deemed the patient eligible for CR. All patient groups were included in the main analysis, such as Myocardial Infarction, Percutaneous Coronary Intervention and Coronary Artery Bypass.[5, 8] Patients needed to have 1) completed CR and 2) have a recorded mode of delivery. To account for reporting bias, the population without a recorded mode of delivery were compared for baseline demographics such as age and gender.

### Mode of Delivery

The modes of delivery recorded in the NACR, includes both supervised and FSM levels.[8] For this study mode of delivery for each patient was coded from NACR variables, including Group-Based into supervised (with staff present) and Home-Based and Web-Based into FSM delivery (contact with CR staff). Patients recorded as receiving delivery classified as ‘other’ were excluded from the study due to lack of descriptive information; this equalled 3% of patients, and these were assessed for differences in demographics to test the extent by which our final sample was representative.

### Outcome Measures

The study’s outcomes included four key CVD risk factors (physical activity, smoking status, blood pressure and obesity) in patents following a cardiac event or undergoing a related cardiac procedure. The patients were all assessed at baseline and followed-up upon completion of the core stage of rehabilitation. The outcomes were all categorized into binary variables, such as achieving 150 mins physical activity per week, not smoking/smoking, having a blood pressure greater than 14/90 (130/80 for south Asian populations) and having a BMI of >30.

### Statistical Analysis

The analyses were conducted in SPSS 25. Baseline characteristics were compared across groups using Chi2 and odds ratios for categorical variables or t-test for continuous variables.[22] To account for missing variables, the data was manipulated using multiple imputation within SPSS. The valid patients, needing to have a recorded age, gender, marital status, ethnicity and recorded IMD score. Imputed values for missing cases in Employment, comorbidities, baseline psychosocial health scores, waiting times, duration and staff at the programme. The imputation was run and 20 imputations were made as per guidance, the results presented are the pooled model results.[23]

Logistic regression models were built to investigate whether, in the fully imputed data, accounting for covariates, the supervised and FSM methods for mode of delivery were associated with outcomes post CR. Relevant important covariates were included in the analysis, where they were evidenced in the literature or significant in preliminary analysis. Age (years), gender (male/female), number of comorbidities and employment status have been shown to influence the outcomes following a variety of different rehabilitation interventions, including CR.[24-26] Employment status was coded as employed/retired or unemployed, this is because previous research found that employed and retired states have similar effects on outcomes.[24] The duration of CR (length of CR) was also included in the analysis along with staffing profile, total staff hours and Multi-Disciplinary Team (MDT) after being evidenced in previous research.[24-25] The staffing information was retrieved from an annual survey, performed routinely by the NACR to gain centre level information such as staff profile, hours and funding type. Because the mode of delivery was a patient-level variable, it was important to take into account the relative size and staffing profile of the centre where the patient received the CR.

The study also utilised the patient’s IMD, based on where they live, as a predictor of outcome post CR. IMD score is a well evidenced socio-economic factor influencing access to health care services and measures of patient’s experience.[27] The IMD used, ranked patients based on where they live; but is only available for England, and thus patients from Wales and Northern Ireland were excluded from the study population.[27]

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

**RESULTS**

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

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

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

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

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

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

The regression model’s independent variable, the mode of delivery, and it’s odds ratio and p value are presented for each outcome in **Table 3**. For three outcomes, smoking, BMI and blood pressure, the significance was larger than the threshold of 0.05 and the 95% CI crossed one, this means that there is no significant association between the type of delivery the patients received and the post CR outcome.

For the physical activity measure the p-value was <0.05 and the 95% CI did not cross one. This means that the association between mode of delivery and physical activity post CR was statistically significant (p value <0.001). The odds ratio indicates that there is a 13.7% increased likelihood of patients being physically active post CR in the FSM group.

The other variables included in the analysis such as age, gender, IMD and MDT were justified as many were statistically significant in their association with the four outcome measures. The model summaries show that the Nagelkerke R square was between 0.185-0.767, and the models accurately predicted between 67.5-97.1% of dependent variable.

**DISCUSSION**

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

The current literature on mode of delivery is a mixture of trial evidence, a robust Cochrane review,[12] and recent observational studies using routine patient populations in the UK and Europe.[13-14, 28-29] The trials and previous observational studies have concluded that for psychosocial health, walking fitness, quality of life and total mortality there is no differences association with the mode of delivery for CR.[12-14,28-29] A recent study conducted using Danish Cardiac rehabilitation, comparing centre-based rehabilitation to Home-based with tele-monitoring found no differences in outcome, physical fitness, activity level and QoL, after a year, and moreover, identified that home-based is more cost effective.[29]

The result of this study is similar for BMI, smoking and blood pressure, which after accounting for the patient’s baseline score and relevant covariate measures both modes had positive and comparable effects. The change is similar to that of the wider population in the 2017 NACR report, which identifies that the study population is representative of the wider CR population in the NACR and Wales and Northern Ireland.

The study, using a large clinical population recruited to CR from within routine practice, adds to the literature by showing that regardless of mode there is improvements made in all outcomes, which further justifies the continued use of CR as an intervention for tackling CVD risk factors for all eligible patients. There was less change in patients from the FSM group for the blood pressure measure, however, looking at the baseline score these patients also started with 2% higher in the target group.

There was a greater likelihood of achieving physical activity status in the FSM CR mode. This outcome was found to be significantly more likely in patients receiving FSM CR compared to supervised. The strength of this association was a 13.7% greater likelihood of achieving the 150 min post CR in self-delivered mode than supervised (p value <0.001).

Within our study population, we found that for all four outcome measures, patients improved between pre and post CR measures in both modes, these changes were equivalent to wider UK CR population.[8] This is similar to previous studies, indicating that patients improve regardless of the mode.[13-14] The most significant change was in physical activity, where the self-delivered group had a 3.1% greater proportional change post CR than supervised group which meant they had more patients active in the follow up assessment. Independent of mode of delivery the extent of change in smoking was also significant with over 700 patients overall quitting smoking and over 200 moved into the target BMI group.

The proportion of patients in the FSM group is similar to recent observational studies and routine patients in that there is around 15% of the population receiving this mode of delivery.[8, 13] This highlights a lack of choice in the offer of CR, especially when the FSM mode is taken up more by females, older patients, those with single status and patients from lower socioeconomic areas. These sub-groups of CVD patients have been shown in routine care to not take up conventional group based CR with a mixture of patient and service factors that are inhibiting engagement and uptake to the offer of CR.[30] The BACPR core components state that CR should be delivered according to patient’s needs, if some eligible patient’s needs are met more so by FSM mode of CR, then CR programmes need to include FSM as part of the CR offer.[5]

**LIMITATIONS**

The first limitation of this study, is the lack of complete data entry. This study used multiple imputation to account for the large levels of missing data, however, the high number of cases having one or more missing fields in demographics or service levels variables is still an issue. Through increasing data within the audit, this will improve the conclusions that can be made on what works in CR routine practice.

Another limitation is that the number of patient’s having a recorded mode of delivery and moreover receiving FSM rehabilitation is still very low and varied in terms of wait times and duration. Although our analysis took account wait time and duration we were unable to take account of dose of CR which is known to be a determinant of outcome following CR and adherence to medications.[28] This would have been calculated from the length of CR and how many sessions a patient received. However, the current recording of sessions in the NACR dataset, reflects huge clinical variability and thus could not be included in the analysis. The BACPR and NACR will redefine sessions and will lead to the sessions being able to be included in future analysis.

**CONCLUSION**

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

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**Conflict of Interests**

The authors have no conflict of interests.

**Author Contributions**

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

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**Figure Legends**

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