Feasibility of chair based exercise in a group based setting for patients with systolic heart failure.

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Abstract

Background – Clinical guidance recommends that patients with heart failure (HF) should be offered exercise based cardia rehabilitation (CR) in a group setting. The NHS long term plan reiterates these recommendations and has set an ambitious target for much greater uptake through a broader range of modes of CR delivery. In the UK 80% of patients attending cardiac rehabilitation do so through supervised exercise in groups yet fewer than 15% of patients with heart failure (HF) take up any form of CR. This shortfall in uptake is partly due to existing CR being dominated by exercise that requires patients to stand and walk for long periods which is something many HF patients are unable to do.

Purpose - This study aimed to evaluate the feasibility of Chair based exercise (CBE) delivered in a group setting, as part of routine clinical practice.

Design and methods – A prospective feasibility study was approved by the NHS and undertaken by recruiting a cohort of HF patients from routine clinical practice. A pre assessment including an incremental shuttle walk test was carried out before the start of the exercise programme which was delivered two times per week over an eight week period. Prior to study commencement ethical approval was obtained from an NHS ethics committee.

Results- The study recruited 10 patients with an average age of 73 years with equal 50/50 % being male and female. The chair based exercise intervention was safe with participants exercising at 65-70% of their maximum without any adverse events. With a caveat around a small sample size descriptive analysis of outcomes indicates slight positive trends in physical, psychological and quality of life measures. Patient feedback on carrying out chair based exercise using a DVD in a group setting was mixed with an overall positive sense of group exercise alongside some perceived challenges in tailoring the exercise levels to the different levels of fitness in the group.

Conclusion- The research study was successful in achieving approval from NHS ethics and achieved its aim in that patients with HF were recruited to a chair based exercise programme as part of routine practice. The exercise intervention was delivered safely and at an appropriate intensity in a group setting without any adverse events.

Authors Declaration

This thesis has been submitted to the University of York, England to fulfil the requirements of the qualification Masters in Philosophy (MPHIL). I declare that this thesis is a presentation of original work and I am the sole author. The work that has been conducted under the supervision of Professor Patrick Doherty. This work has not previously been presented for an award at this, or any other, University. The work within this thesis has not been used for other research or presented elsewhere. All sources are acknowledged as references.

Contents

Abstract 2

Chapter one: Introduction 8

Aims: 9

Chapter two: Review of literature 10

What is Heart Failure? 17

Exercise type, effectiveness and safety 22

Mode of CR delivery 24

Barriers to exercise 28

Chapter three: Methodology 32

Type of research 32

Sample size 32

Participants and recruitment Process 33

Design 34

Non clinical intervention by patients 38

Data Collection 44

Inclusion 44

Exclusion 45

Participants information and consenting 46

Ethical Considerations 46

Meaningfulness of the study 48

Chapter four: Results 56

CBE sessions and progression 56

Shuttle walk test 57

Safety of CBE 60

Discussion 60

Fitness and the shuttle walk test 62

Patient observations around the exercise classes 63

Groups 64

Incremental shuttle walk test (ISWT) 67

Self-Assessment tools 68

Limitations: 69

Conclusion 75

References: 76

Appendices 99

Appendix 1: How the idea was formed 99

Appendix 2: Literature Search 101

Appendix 3: Patients Participation 105

Appendix 4: Consent Form 107

Appendix 5: Hospital and Anxiety Depression Scale 108

Appendix 6: Dartmouth Quality of life 109

Appendix 7: GP letter 112

Appendix 8: ISWT CBE 113

Appendix 9: General themes and responses from the R&D lead and research panel. 114

Appendix 10: Letter from University 117

Appendix 11: University letter of insurance 118

Appendix 12: Chair based exercise DVD questionnaire 119

Appendix 13: HRA approval information sheet..... 121

Appendix 14: NLAG letter 129

Appendix 15: CRIGs Comments..... 131

Appendix 16: IRAS form 132

17: Abbreviations 161

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Thank you one and all!

Chapter one: Introduction:

The origin of this thesis was based on a gap in clinical service and a gap in the literature highlighted by NICE CG108 (2010), and DOH (2013) Cardiovascular Outcomes Strategy (2013), which recommended group based cardiac rehabilitation (CR) exercise should be made available in a group setting for patients with heart failure (HF). The original NICE guidance (NICE CG 108 2010) has been updated and reiterates the recommendation that group based CR is the most evidence based mode of delivery (NICE NG106 2018) in HF patients. The new guidance placed a lot of emphasis on CR, however the guidance has not been followed in terms of offering a menu of approaches in the delivery of rehabilitation programmes for HF patients as shown through the National Audit of Cardiac Rehabilitation (NACR 2018). The need for greater variation in CR modes of delivery that are feasible in routine practice is reiterated by the recent NHS Long-term Plan (2019) which states: -

"By 2028 the proportion of patients accessing cardiac rehabilitation will be amongst the best in Europe, with up to 85% of those eligible accessing care."

Page 63 NHS Long-term Plan (2019). https://www.longtermplan.nhs.uk/publication/nhs-long-term-plan/

In order to achieve these national targets CR services, need to improve the CR offer through a comprehensive menu including group settings. NHS England (2019) suggests social prescribing of exercise through GP surgeries and other agencies to support long term conditions improving outcome. Very few absolute contraindications to exercise exist and most of the older generation could benefit from exercise (Nied, Franklin 2002). CR is proven to be both a clinically and cost effective treatment for the long term management of cardiovascular disease showing improvement in both physical and psychological health (BACPR 2017, Blum-Schimid et al 2013). Recent evidence by Sabbag, Mazin et al (2018) suggests that HF patients after participating in a CR programme showed improved cardiovascular fitness that is related to reduced mortality or cardiac hospitalisation risk during long term follow up, irrelevant of baseline fitness. Physical inactivity in the older adults is associated with an increased all-cause mortality risk, reduced bone health, reduced function and increased risk of falling (Sexton, Taylor 2019). In comparison to being inactive just 15 minutes of daily activity as part of a structured form of activity can increase life

expectancy by 3 weeks and reduce the risk of all-cause mortality by 14% (Das, Horton 2016). Seated exercise programs enable the older adult with co-morbidities to safely partake in exercise (Sexton, Taylor 2019).

REACH-HF trial which used a chair based exercise (CBE) approach concluding that CBE delivered in a home setting as clinically effectiveness and cost effective. The study failed to show increases in physical fitness and highlighted certain limitations most notably that it is difficult to ensure the appropriate CR exercise intensity dose of CR in a home setting. The research question shaping this thesis asks, "Is it feasible for NHS CR services to deliver a group based exercise intervention at the appropriate intensity for patients with heart failure?" utilising an NHS practice.

Aims:

This study aims to evaluate the feasibility of a chair based exercise (CBE) training programme delivered in a group setting, as part of routine clinical practice to improve service delivery to patients with heart failure.

This will be achieved by developing a hospital based opportunity to deliver a previously established CBE programme and test patients' willingness to take part and ability of CBE to meet the needs of heart failure patients. The idea to pursue this study was strongly influenced by clinical service demands and patient preference (See Appendix 1).

Chapter two: Review of literature

The literature search was undertaken probing as widely as possible, using electronic journals and data bases. Three search strategies were run in CINAHL uncovering 136 results, EMBASE 200 results, and Medline 168 which is 504 results in total (See Appendix 2). Supplementary techniques were also used looking at citations and reference lists. Free text search terms and phrases were used to undertake both thesaurus and phrase mapping. Care was taken when running the search in different data bases as they all have different thesaurus and mapping terms, which would cause a syntax error making the search ineffective. Duplicates were removed across the three searches using the Endnote software leaving 286 unique records. Out of the 286 records only 11 were relevant and suitable to be used in the study. The unique records were checked by both the student and the supervisor who agreed that 11 were relevant for the study (Figure 1).

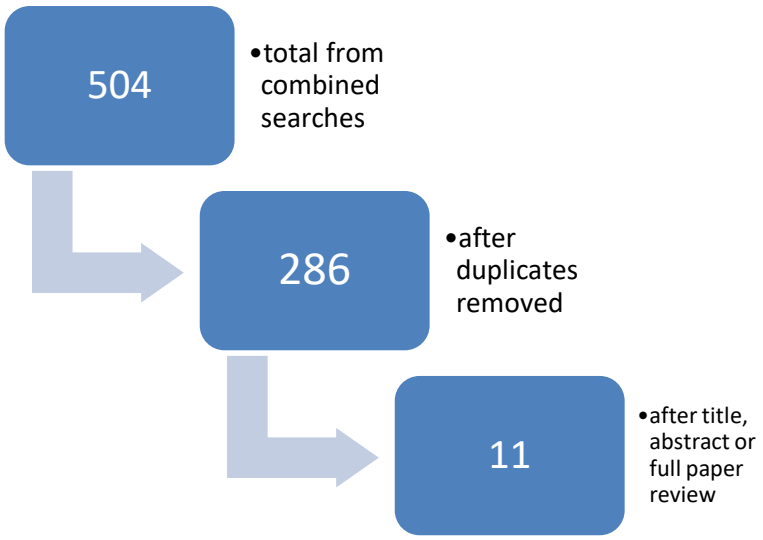

Figure 1. Review flow diagram

NICE (2010) had already carried out a literature search up to 2009, the search for this piece of work covered 2009 up to the present day. The search confirmed a gap in the literature as no evidence of group based CBE in HF was highlighted. Table 1 summarises the key papers included in this review.

Table 1. Summary of key papers

Author, study type & year	Population & sample size	Age	Gender proportion	Intervention
1. Yamoda M Aoyama T et al 2011. RCT	Elderly Adults 146 people screened N=93 (DVD=48 UC=45) met the inclusion criteria.	65 years and over	DVD group. Gender Female 33 (80.5%) Control group 32 (74.9%). P value0.606	DVD group, 20mins group based exercise twice a week for 24 weeks. Control group had no exercise prescribed.
2. Anthony K, Robinson K , et al 2013 Systematic Review.	Frail Older people.	70 to 99 years of age.	Not Stated	A systematic search was performed for CBE-controlled trials in frail populations published between 1990 and February 2011 in electronic databases.
3. Robinson K, Leighton P, et al 2014 A Delphi study	Frail Older Adults		Not stated	Expert consensus to define CBE for elderly people. The framework for consensus was constructed through a team workshop identifying 42 statements within 7 domains. A 4 round electronic Delphi study with multidisciplinary health care experts was undertaken. 25 experts invited to take part 17 accepted to take part in the modified Delphi process.
4. Robinson K, Masud T, et al 2016. Qualitative data cross sectional survey and a Delphi consensus study on CBE.	Older adults	22-90	378 took part 329 women (87%)	731 exercise instructors. 378 delivered mostly seated exercise and 223 of those instructors provided qualitative data. 155 instructors who did not provide any qualitative comments.
5. Robinson K, Gladman S, et al 2015. Quantitative study	13 older people		Not stated	13 community dwelling older people were recruited to CBE. A researcher maintained field notes and recorded barriers and facilitators to delivering the programme from the participant and therapists perspective.
6. Lui C, Chang W, et al 2017	23 eligible trials were identified	The mean age was	Not Stated	Appraised randomised-controlled trials from published systematic-reviews.

Author, study type & year	Population & sample size	Age	Gender proportion	Intervention
Meta-analysis study	from 22 systematic reviews.	75 years or older		
7. Cancela Carral J, Pallin E, et al 2017	People older than 80. 36 participants	80 or older (87.91+/-4.70 years)	Group A (n13) 84.61% women Group B (n12) 91.66 Women Group C (n11) 63.63	The participants were randomly allocated to 3 chair based exercise programmes. The participants exercised for 3 days per week during a 3 month period.
8. Robinson K, Long A et al 2018 A Feasibility study with a cluster randomised controlled trial component.	Older People	65 years and over Mean age 84	66% female 60% with dementia	CCBE delivered once a week in 4 day centres and 4 community centres, and twice a week in 4 care homes for 12 weeks.
9. Razoab N, Rahman N et al 2018 Preliminary study	18 older women	Mean age 66.7 +/- 4.	100% Women	CBE twice a week for 8 weeks
10. Sexton B, Taylor N 2019. Systematic review and Meta-Analysis.	Older Adults	>65	Not stated	A systematic search of health databases. 14 Randomised controlled trials met inclusion.
11. Dalal H, Taylor R, et al RCT REACH 2018	216 Participants men and women	Average 70 years of age	Mostly Men	Self-help manual for HF Multicentre Centre parallel two group randomised superiority trial. Home based exercise 12 week

1. Yamoda M, Aoyama T, et al (2011) carried out a randomised controlled trial (RCT) on older participants to evaluate the effectiveness of using a seated DVD and dual-task (DT) stepping exercise. All of the participants were female, 33 in the DVD group and 32 in the control group. To improve the DT exercise, participants were also asked to perform a verbal fluency task while stepping as quickly as possible. The trial was undertaken screening 146 people, out of which 93 met the inclusion criteria. The researchers excluded 53 patients

from the study, stating most of the participants had exercised regularly in the previous six months, and 6 people met the criteria but refused to enter the study. The researchers acknowledge that a larger study needs to be undertaken.

2. Anthony k, Robinson k et al (2013) carried out a systematic review looking at chair based exercise for frail older people. Out of 2631 papers only 6 studies were relevant to be included. The search uncovered various studies not relevant to the study for example, wheelchair athletics, high intensity programmes, duplicates and healthy subjects. The objective was to examine the benefits and harmful effects of exercise. They found the studies highlighted were small ranging from 20-82 participants and single site studies, this made the findings limited. The review was difficult due to the fact not all researchers referred to CBE or seated exercise in their titles or abstracts, so not all studies may have been included.

3. Robinson, Leighton et al (2014) carried out a qualitative study of CBE using the Delphi approach. Forty two statements within seven domains were analysed using a framework to reach consensus. They reached a conclusion on a set of principles for CBE in older people. Devising a model for implementation which still needs further work. This study uses experts from CBE who have already invested time and engaged with the concept, which may influence their responses making them give a more favourable biased response to CBE. It could be argued that using experts from any area has the potential for bias. A limitation to the study was there was no patient participation.

4. Robinson, Masud et al (2016) under took a piece of work using surveys looking at the use of CBE from the instructors' perspective. There are approximately 3000 instructors on the register, 731 instructors replied to the survey, which is approximately a quarter of all fitness instructors. Unfortunately, the author does not state how the survey was carried out whether it was postal or computer generated, although the paper states that fitness instructors were able to add free text comments so it is presumed it was computer generated. The study offers some important insights into how CBE is being utilised

(Robinson, Leighton et al 2014). Surveys such as that conducted by Robinson, Masud et al (2016) have shown that CBE should not be a default exercise for all elderly adults and should be targeted at the less mobile population allowing for progression within the group. The findings from the study were based on qualitative exploratory research so cannot objectively determine the health benefits of CBE.

5. Robinson, Gladman et al (2015) carried out a qualitative study looking at barriers and facilitators to CBE exercise. The exercise was carried out in nursing and care homes. Surveys were completed by the homes which highlighted 19 facilitating and 18 barriers to CBE exercise. Although the findings make for an interesting read, only a small number, of 13 participants in care homes were included in the study meaning that the findings cannot be generalised to the wider HF population. The findings of the study suggest further work needs to be carried out in CBE.

6. Lui C, Chang T et al (2017) carried out a Meta-analysis study looking at 23 eligible trials identified from 22 systematic reviews. The goal of this meta-analysis was to look at the evidence of progressive resistance strength and multimodal exercise in older adults, against no intervention on improving muscle strength. They found that positive effects of multi modal exercises including muscle strength, balance, and gait. A limitation of the review is the inability to detect newer more recent significant current trials as no current studies were identified. The populations in each of the reviews were different which could be seen as a weakness of meta-analysis (Nobel 2006).

7. Cancela-Carral J, Pallin E et al (2017) carried out a study of older people who were eighty and above, looking at the effect of 3 different low cost CBE programs in groups of older people with cognitive impairment. Overall the percentage of women in the study was higher than men. The groups of exercise were aerobic exercise, muscular resistance and joint mobility exercise. They concluded that in the older population there was no significant change in mobility or functional independence, although the Thera-band exercise group had a positive effect on strength and balance. Cancela- Carral, Pallin et al (2017) do not state

the type of research they have undertaken in their paper. Out of 50 participants who started the research only 37 attended more than 80% of the sessions completed. One male patient was unable to complete the final assessment so the final sample was composed of 36 participants resulting in a 28% drop out rate which is slightly higher than previous studies which are typically around 20% (Anderson et al 2016).

8. Robinson K, Long A, et al (2018) carried out a feasibility study before a definitive trial undertaken to understand how best to evaluate the feasibility of running a cluster programme in these settings. The programmes were undertaken in 4 day centres, 4 care homes and 4 community groups. Participants were allocated to either consensus chair based exercise (CCBE), active control, group reminiscence or usual care. The Recruitment was challenging as more staff were needed, originally one staff member was allocated when in fact 3 members of staff were needed. Not all participants completing the CCBE were interviewed due to capacity issues which could have had an overall effect on the findings. As 60% of the participants had dementia it could be argued that depending on the severity of their dementia, it would be difficult at interview to get a true picture of their experience (Beatie 2009).

9. Razaob N, Rahman N, et al (2018) carried out a preliminary cohort study looking at CBE on physical performance and quality of life of older women in Kuala Lumpur, Malaysia. The CBE took place twice a week for 8 weeks using a CBE DVD. The study showed that CBE at an appropriate level, in women without co morbidities can enhance exercise tolerance and QoL in this population. The main limitation of the study is the findings cannot be generalised to a patient population as it was only under taken using older healthy women with no co morbidities attending a recreational club in Kuala Lumpur.

10. Sexton, Taylor (2019) carried out a Systematic review and Meta-Analysis using 14 randomised controlled studies. The studies used did not include exercise bikes or recumbent seating exercises. The overall number of participants used was 921 with a mean age of 81, 77% of the participants were women. Nearly half of the participants were categorised as frail older adults. 44% had recently been inpatients, 6% described as having

dementia, and 3% had undergone hip operations in the previous 2 weeks. The sample sizes they used were relatively small, and they state the evidence used was of low quality so they recommended a fully powered trial. They found that seated exercise had the highest rate of adverse events when participants exercised at moderate to high capacity independently. Due to the participant's characteristics of undergoing surgery and frailty, they would be more at risk of sore muscles and adverse events as Sexton et al (2018) found.

11. Dalal H, Taylor R et al (2018) carried out a multi-centred randomised controlled trial, REACH-HF. The study was undertaken in a home setting, using trained facilitators. Technological challenges around use of DVD players and laptops to view the CBE were evident in many of the participants. Personnel experience of nursing older participants is that they struggle with technology and only the minority have mobile and internet connection. They also found that proof of adherence to exercise in the home environment was challenging which might explain why there was no significant change in physical fitness measured using an incremental walk test. It is much easier to measure outcomes in exercise undertaken in a group based programme. Despite these issues the trial was significant at improving participants' quality of life.

There have been numerous trials and studies undertaken on seated exercise in the older population. Although there is no specific study found carrying out seated exercise in a group setting using a DVD. REACH-HF (2018) used the same DVD and carried out exercise on a one to one basis. Most of the studies have used the elderly participants 65 and over. The mean age of patients with heart failure in the UK is 78 years based on national heart failure audit data (NICOR 2019). The only study which reported adverse events was in the Sexton et al 2018 study, but some of the participants they used were recently discharged from hospital, and others had recently had a hip operation.

What is Heart Failure?

Heart failure (HF) is a complex condition often described in lay terms as defect to the hearts ability to either fill or empty causing congestion of the heart and lungs with symptoms such as severe breathlessness and swollen lower limbs (Ambrosy, Fonarow et al 2014). It is the end point of most cardiovascular diseases including valvular disease, coronary artery disease and hypertension (Coates, Forman et al 2017). HF is a complex syndrome and despite the numerous advances in medical care still has a poor prognosis, with 30-40% of patients dying in the first year of diagnosis (Cowie 2017).

HF has a substantial negative effect on all aspects of physical function, due to decreased cardio respiratory fitness and muscle strength in the older population with HF (Coats, Foreman et al 2017). These changes result in a deficit in capacity effecting function and quality of life in daily activities, ultimately leading onto a poor quality of life.

The European Society of Cardiology (ESC) (2012) state typical symptoms of heart failure consist of breathlessness, ankle swelling and fatigue, due to a low ventricular ejection fraction and increasing diastolic volume. Sosin, Bhatia et al (2010) add that HF is characterised by a reduced cardiac output that is unable to meet the body's needs, it has traditionally been viewed as a phenomenon of the left side of the heart known as HF with reduced ejection fraction (HFrEF). In HFrEF the chambers of the heart contract poorly, as a result less blood is pumped around the body (Dunlay, Roger et al 2017). Recent advances in our understanding of HF has led to the recognition of a different form of HF known as preserved ejection fraction HF (HFpEF) which, is evident in over 50% of patients with HF. In HFpEF the chambers contact well but do not relax efficiently so a smaller amount of blood is pumped around the body (Dunlay, Roger et al 2017). HFpEF presents with differing clinical signs usually an overload of fluid, it still has a poor prognosis and a massive burden to the health service (Abebe, Gebreyohannes 2016). A meta-analysis stated a mortality of 32% in HF with preserved ejection fraction HFpEF, compared to 41 % mortality in reduced ejection fraction HFrEF. Showing that even though HFpEF contributes to more than 54% of all patients with HF most trials thus far have mostly been undertaken in HFrEF (Lam, Donal et al

2011). For the purpose of this work as most of the evidence base in the literature is in HFrEF this will be the focus of the work.

HF per se is a major cause of morbidity and mortality and places huge economic burden on health providers throughout the world. Cowie (2017) states the burden of heart failure can only be described as an epidemic as it affects many people simultaneously in our community. Ambrosy, Fonarow et al (2014) points out that 26 million people worldwide are living with this syndrome, and half a million of those are in the United Kingdom.

The National Institute of Health and Clinical Excellence (NIHCE 2010) stipulates that 900,000 people in England suffer with HF, and predict a large proportion of society are walking around undiagnosed with heart problems but as yet not displaying signs due to the hearts ability to compensate. Sykes, Simpson (2011) highlighted the severity of heart failure by comparing one year survival rates for heart failure against common cancers, they concluded one year survival rate for HF is on par with cancer of the colon but poorer than breast, prostate and bladder cancers.

Pharmacological advances and device therapies in HFrEF have developed substantially over the past decade, with more emphasis being put on health related quality of life (HRQoL) rather than quantity of life (Braunwald 2015). A Cochrane meta-analysis of exercise based cardiac rehabilitation in patients with HF revealed improvement in HRQoL and reductions in rehospitalisation (Taylor, Sagar, et al 2014).

Despite many advances in the treatment for heart failure as of 2017 the numbers are still rising for hospital admissions (Cowie 2017). Statistics from the British Heart Foundation (2018) show over 500,000 people are living with HF in the UK (BHF 2018). The prevalence of HF rises steeply with age, the British Heart Foundation statistics database estimated ten years ago in 2009 that 13.7% of men and 12.5% of women aged over 75 years suffer from the condition (Scarborough, Bhatnager et al 2010). A large burden is placed on the NHS by HF, accounting for one million in patient bed days which equates to 2% of the NHS total and 5 % of all emergency admissions (NICOR 2017-2018). Global Burden Disease study (2017) state that an estimated 64.3 million people are living with HF worldwide. The prevalence of

known HF is estimated at 1-2% worldwide adding that internationally more than 14 million Europeans suffer from heart failure, with the cost reaching 2% of healthcare expenditure in Western Europe Groenewegen, Rutten et al (2020).

The burden of HF in the UK is increasing as work by Conrad, Judge et al (2017) has highlighted by looking at trends and patterns in 4 million individuals between 2002 and 2014. They found HF incidence decreased for both male and female by 7%. However, the estimated absolute number of newly diagnosed HF in the UK increased by 12% and the absolute number of prevalent HF cases in the UK increased by 23%.

The trajectory for heart failure is such that patients experience periods of either wellness or illness, clinically known as compensation when symptoms are stable, and de-compensation, when the patient's condition deteriorates (Johnson, Lehman 2006). Experiencing these episodes of wellness after the decompensation periods patients do not recognise the severity of HF, because after each serious decompensation they tend to bounce back having periods of wellness. HF patients are not routinely labelled palliative although they fit the criteria, which could mean these patients miss out on specific care which would benefit their health journey. Heo, Lennie, et al (2009) work reflects personal experience of working with HF showing this disease leads on to quality of life being dramatically affected, many patients unable to carry out daily activities of living, unable to hold a conversation without becoming breathless, incapable to move from one room to the next without assistance. This has a massive psychological effect on the patient leading on to anxiety and depression in many cases (Hallas, Wray et al 2011).

Maintaining functional ability in these patients is the key to enable adults to carryout activities they value for healthy ageing (WHO 2015). As people age they naturally lose intrinsic capacity, which is muscle strength and skeletal muscle, making everyday activities such as climbing a flight of stairs more difficult (Fielding, Vellas et al 2011). To help improve and preserve intrinsic capacity exercise at an appropriate level should be undertaken (Lui, Chang et al 2017)

A usual hospital admission for patients with HF is routinely less than five days which is not sufficient to adequately manage the disease and patient effectively (Dzubur, Poronsky 2018). Hospital trusts are increasingly under pressure to turn patients around as quickly as possible often resulting in substandard care as patients are being discharged too early, then end up being quickly readmitted. Dzubur, Poronsky (2018) stress that these readmissions are significant in the care of HF patients as frequent readmissions tend to predict a poor outcome with increased mortality in these patients and greater risk of death. Williams, Pozehl (2015) point out that HF is a progressive disease, one of the most common symptoms is poor exercise tolerance which presents as fatigue and dyspnoea.

According to more recent work by Dzubur, Poronsky (2018) focusing on HF patients under taking exercise to help improve quality of life not just prolonging survival, exercise is a cost effective intervention in a disease process that is costing the health service billions. Work by Cowie, Buckley et al (2019) agree, adding that optimising medications and cardiac intervention can add years to life, CR “add life to years”. However, for exercise to work patients need to engage, it sounds easy but the true answer lies in the will to act. A lot of patients with HF are old and frail making it more difficult for these patients to engage in exercise Kosmala, Rojek et al (2016).

Historically previous medical advice for centuries for cardiac patients was confinement to bed rest and no exercise, until chair therapy was introduced in the 1940s (Al Quait, Doherty 2018). It is now understood that physical deconditioning plays a massive role in the advancement of symptoms and poor prognosis (Royal Australian College of General Practice 2019). Exercise is now encouraged and recommended by national and international guidelines including ESC (2016) and NICE (2018) guidelines as they recommend regular aerobic exercise for heart failure patients, to improve symptoms and functional capacity, also to reduce the risk of hospitalisation. Cardiac rehabilitation (CR) is seen as a safe intervention in cardiac patients (BACPR 2017). Issues of an ever growing ageing population (65 years and over), with increasingly longer life expectancy, make it paramount that the older generation exercise (Lees, Clark et al 2005). The health benefits of exercise follow a hyperbolic response curve, patients who go from no exercise to some exercise receive the

greatest benefits than those who already exercise and increase their activity levels as they show progressively smaller improvements (Pate, Pratt et al 1995).

However, with that acknowledged although exercise is recommended it is not being taken up by the HF population. Dalal, Wingham et al (2012) believes a key driver is the lack of funding and exclusion from previous HF commissioning agreements. Analysis by the NICOR audit of patients with HF, who were referred to CR, found a mortality benefit of 21% following referral to CR services compared to 33% for them not referred to CR (National Heart Failure Audit, NICOR 2019). An Explorative study by Tang, Lars et al (2017) whereby participants were allowed to choose whether they entered the home or centre based setting for exercise. They offered the same structured exercise in both groups. Whilst they found on average both groups were equally preferred, they found that participants preference was likely to be influenced by their diagnosis and co morbidities. Work by Cowie Throw et al (2012), admit that home based exercise is somewhat under researched, a positive is that it does not involve an arduous return journey to a hospital site so many patients who are less able and frail could carry out exercise at a time to suit themselves. A counter argument is that patients may lack the motivation they may gain from a group setting and never feel the time is right to exercise.

In contrast work carried out by the BACPR and NACR (2017) highlighted that the overall mean uptake, for conventional CR patients (none HF) has reached 51%, which indicates the UK is in the top 2% of all countries in Europe (Cowie, Buckley et al 2019).

NICE (2018) maintain that exercise training carried out in many variations should be available to the heart failure patients, yet few programmes offer such a service. NACR data shows that 4,723 HF patients started CR in 2016 and they made up 5.3% of the total CVD patient population receiving CR (NACR 2018).

CR services are comprehensive, the BACPR standard recommends factoring in seven core disease modifications, including education and counselling, the services are designed to limit physiological and psychological effects of cardiac disease (BACPR 2017, Balady, Williams et al 2007).

Exercise type, effectiveness and safety

To date a vast number of studies looking at the safety and efficacy of exercise training in HF patients have been under taken. Traditionally patients with HF tended to be viewed as high risk and excluded from exercise programmes, ignorant to the fact that without exercise this patient group is at a higher risk of complication and deterioration as they become embroiled in inactivity which then leads onto obesity and depression (Shepherd, While 2012). Nicholson (2014) supports the previous statement highlighting that patients with a NYHA classification of 111-1V are assumed as high risk but feels this cohort of patients have the most to gain from any health improvements, perhaps benefiting from CBE. CBE is widely used throughout a multitude of settings, to help engage the less mobile of the population into exercise, perhaps those who are unable to stand, or with mobility problems. However, it is difficult to find a robust evidence base of literature in this area for clinical practice.

Landmark trials (Sullivan 1988, Coates 1992) acted as a catalyst for other studies to be undertaken which demonstrate the benefits of exercise in HF. These studies were only small and not representative of the HF population as the study by Lee et al (1979) was undertaken on 25 male participants in their fifties not the usual demographics for HF patients.

Interestingly evidence from a study carried out in the United States on 68 patients listed for heart transplant who were severely symptomatic with poor ejection fractions, showed there was such an improvement in their conditions after completing an exercise programme that 31 patients were in fact removed from the transplant list (Ades 2001).

Flynn, Pina et al (2009) report on the controlled trial by HF ACTION which started in 2002. Over 2,300 patients were randomised in to two groups;

- Routine follow up
- Or routine care, plus at least one year initially supervised CR followed by home based exercise. The trial showed that exercise improves clinical outcome.

If CHD patients do not exercise, they run the risk of deterioration of aerobic fitness, muscle wasting, increased symptom management and elevated risk of thromboembolism (Gianuzzi, Tavazzi, et al 2001). Patients seem to benefit when they receive CR in the form of exercise

management, education and emotional support. Gottlieb (1999) found that patients who only received exercise management without any education or emotional support did not see any improvement in their quality of life. Psychological support in CHD patients is paramount as depression is commonly recognised throughout the literature which can have a negative effect on exercise compliance, adherence morbidity and mortality.

Jolly, Taylor et al (2009) carried out a randomised trial of home based walking and resistance exercise programme plus specialist nurse care, versus specialist nurse care only. Patients were eligible if they have Left Ventricular Systolic Dysfunction (LVSD) and NYHA of at least 2. The patients were highlighted from the specialist nurses workload, it was difficult to recruit to, as many of the participants had co morbidities so were not stable enough to take part in the study. A principle limitation of the study was monitoring adherence to the programme as this was undertaken by the participants themselves. The BRUM-CHF study hypothesized that the addition of a home based exercise programme and HF nurses input would improve the outcome in the community based HF population, unfortunately they failed to confirm their hypotheses. Although a meta-analysis carried out by Chien, Lee et al (2008) carried out in Taiwan concurred that home based exercise did have a significant benefit to patients with HF, showing improved exercise capacity.

Work by Long, Mordi et al (2019) in the most recent Cochrane review, looked at exercise-based rehabilitation on mortality, hospitalisation admissions, morbidity and quality of life of patients with HF. They looked at 44 studies that included 5783 people with HF, focusing on the effectiveness of exercise based rehabilitation compared with no exercise in participants aged over 18 with HF. The mean age of the participants was 52-81 years of age and showed that studies predominantly recruited more men (median 79%) than women. The mode of exercise they looked at was hospital, Community and home based exercise. Long, Mordi et al (2019) looked at HFrEF as at the time of their work no large studies had been undertaken into HFpEF, the findings were broadly comparable with previous work. The review concluded unanimously that patients with HF benefited from under taking exercise.

Mode of CR delivery

The mode of delivery of CR continues to be dominated (80%) by group based exercise with home based CR being taken up by around 10% of patients (Table 2) adapted with permission from NACR 2018). The table 2 shows that group base is taken up by more HF patients compared to home based, and the older HF patient are just as likely to take up group base as younger HF patients.

Table 2 Mode of delivery split by age, gender and diagnosis/treatment groups (NACR 2018)

	All diagnosis/treatment groups			Heart failure patients		
	Mode %	Mean age	Age range	Mode %	Mean age	Age range
Group-based	77.2	65	18-100	78.4	67	18-97
Home-based	7.9	67	18-97	5.7	72	19-94
Web-based	0.1	57	19-83	-	-	-
Home visits	8.0	68	19-98	8.2	74	35-94
Telephone	17.3	66	18-100	17.8	69	19-93
Other mode	5.0	64	19-95	4.8	67	29-88

Figure used with permission from NACR Director.

According to Palmer (2018), many eligible patients who have had a MI are not engaging with CR programmes. Access to services taking more than 28 days was shown in the report to be a problem as patients tended to disengage with the services putting them at high risk of another MI or readmission. Previous research has shown that if patients are assessed early after an event and take up rehabilitation services, mortality risk is reduced by 18% and readmission cut by a third (Palmer 2018). Although numbers have slightly improved over previous years, there are still patients needlessly putting their lives at risk by not engaging in the uptake of exercise. The report was carried out by University of York and suggests it is worrying that the barriers to exercise still need to be addressed, perhaps with more access to programmes in the home and community as suggested by NICE (2018) numbers will improve. The time scale patients are approached by health professionals seems to play a role in the uptake, as participants may not see the need for rehabilitation when they have a busy life and feel reasonably well. Different programmes have different criteria to access

and at present it is fair to say it is a post code lottery as to what outcome a service user will achieve (Palmer 2018).

Rengo, Savage et al (2018) work has shown that a one size fits all rehabilitation session is not suitable for all heart failure patients so perhaps more work needs to be completed in delivering a more varied approach to CR in the HF population. Six weeks is perhaps too long to leave patients before commencing CR as it has been pointed out in other work in the literature.

One question that needs to be asked of Rengo, Savage et al (2018) however, is whether the outcome of uptake to the study would have been different if patients with more complex admissions to hospital with Chronic heart failure (CHF). NYHA IV had been used in the study, as these patients are less likely to engage in exercise due to severe unstable symptoms, whereas patients able to attend an outpatient clinic appointment with NYHA class 11 or 111 on the whole are usually more stable and fitter, so are more likely to attend exercise sessions.

Rengo, Savage et al (2018) fail to show any numbers to indicate how many patients had been approached to join the rehab from the outpatient department. This could have an effect on the total numbers enrolled and the overall percentage for uptake. Their work had support from the local cardiologist and the eligible patients were brought to enrol by cardiologists and told it was part of their recovery management plan to attend exercise. Getting a cardiologist on board may well influence numbers, in reality it would not be possible to physically have a Cardiologist speak to each CR patient. This could be done in the form of a pre written and signed letter from the cardiologist explaining CR is part of their prescribed treatment and the importance of attending CR. NACR data has shown that patients referred to CR by practice nurses are more than 4 times more likely to take up rehab than those referred by consultants (NACR 2018).

To date, no research appears to have been undertaken in HF using a DVD in CBE in a group setting. However, several previous studies have demonstrated the effectiveness of various DVD, video or internet based exercise in older adult (Haines, Russell et al 2009, Yamoda, Aoyama, et al 2011, Russell, Buttrum et al 2011, Eriksson, Lindstrom 2011, and Cowie, Moseley 2014).

Work by Cowie, Moseley (2014) carried out an economic analysis looking at both hospital and home based exercise. They delivered one hour interval training and an aerobic circuit twice a week for 8 weeks in a hospital setting. The exercise was monitored by a senior cardiac rehabilitation physiotherapist, physiotherapy technical instructor and a senior cardiac nurse. The home based exercise contained one hour interval training, an aerobic circuit DVD and ran twice a week for eight weeks. The participants were contacted by telephone twice overall by a senior physiotherapist throughout the eight weeks of the programme. Overall, they found that the cost of delivering the exercise was similar in both home and hospital, although adherence and benefits were higher in the hospital group. This could have been due to the support of peers and staff. Most of the cost in the home group was due to development of the DVD, and if the sessions ran for 5 years this group would become most cost efficient.

Haines, Russell et al (2009) study the Kitchen Table Exercise Programme, was undertaken in the participants' home and consisted of a DVD and workbook, the programme was structured of 6 types of exercise each with 6 levels of difficulty. The exercises were aimed at both muscle strength and balance (Haines, Russell et al 2009). After the initial input from the researchers the study participants were left to motivate themselves. Haines, Russell et al (2009) carried out an exercise programme in the community with elderly patients. The intervention was the use of a DVD which the participant used in their own home following instruction from a therapist. "The table top exercise programme," which entails the participants undertaking exercise on their own using a DVD on their kitchen table. This could raise problems and anxieties in this cohort, as not all of the older generation are able to use electrical devices. Haines, Russell et al (2009) agreed after the study had completed they would suggest that further studies should incorporate more time to teach the older participant how to work the DVD. Haines, Russell et al (2009) found that they had a poor compliance with the programme over time, as the participants felt isolated. It could be argued that it is more difficult to motivate yourself as an individual exercising, group exercise could help with the isolation and motivation of participants.

Several previous studies have demonstrated the effectiveness of various video or internet based exercise in older adults (Haines, Russell et al 2009, Russell, Buttrum, et al 2011 and Eriksson, Lindstrom 2011).

The REACH-HF (Rehabilitation Enablement in Chronic Heart Failure) trial was carried out from 2013 to 2018 using the same CBE DVD albeit under taken on an individual basis at home. The study was derived from health behavioural change theory theorising that after receiving facilitated care through the REACH-HF health related quality of life (HRQoL) at 12 months would improve compared to usual care alone. REACH-HF looked at facilitated self-care and home based exercise programme against usual care received in adults with HFrEF. They recruited 216 participants the majority were men with an average age of 70, any participants who had undertaken CR in the last year was excluded. All participants had evidence of HFrEF confirmed by echocardiogram showing an ejection fraction of 34% or less. In total 185 participants submitted data for the primary outcome. The participants were randomised into two groups the intervention plus usual care (REACH HF Group), and usual care alone (Control group). Randomisation was undertaken using computer generated numbers in strict sequence, using a web based randomisation system which was password protected. The study was under taken in a home setting in the HF population, including significant care givers no previous study has looked at including significant others. The REACH-HF was a multicentre randomised trial.

They hypothesised that the REACH-HF intervention compared to usual care in HF-REF at twelve months using the Minnesota living with HF questionnaire would improve disease specific HRQoL compared to usual care only (Dalal, Taylor et al 2018). At the 12 month mark there was a significant and clinically meaningful difference in HRQoL but no significant differences were found in respect of patient fitness levels between intervention and control groups. The authors stated that achieving an accurate prescription of exercise in a home setting through phone calls was a limitation (Dalal el al 2018).

Recent work by Sexton, Taylor (2019) Highlight the importance of exercising in a supervised environment as it is safer, than individual exercise done alone at home in patients with HF. Adverse events were noted when participants were not supervised in moderate to high intensity whilst undertaking CBE exercise. Supporting the fact that CBE is safer when undertaken in a supervised group, so that instructors can closely monitor technique.

Barriers to exercise

Work by Menezes, Lavie et al (2014) found that certain groups of the population have poor referral rates into CR, including people from ethnic minority groups, elderly people, living in a rural setting and people in lower socioeconomic classes. Although the work of Menzes, Lavie et al (2014) is based on a different healthcare model it translates into British society regarding referral rates as found in the literature. Hazelton, Williams et al (2014) found that women are less likely than men to be referred to CR groups, or complete the course this can be is for many reasons. This has been explored by Grace, Gravely-Witte et al (2009) who list co-morbidities including age, muscular skeletal, depression, family commitments and diabetes as the more common barriers to uptake and participation in exercise by women. Women do not appear from the literature to have more barriers to exercise than men although it seems the nature of their barriers are deep rooted in family responsibilities and commitments. Perhaps to engage this female cohort of patients as Supervia, Medina-Inojosa et al (2017) advocate encouraging more home programs may be the answer.

Gender differences illustrated show 44% of men and 52% of women are less likely to engage in CR services than men, this data was produced from the National audit of cardiac rehabilitation (2015 NACR). This is not a new finding, and has been seen in the previous literature Supervia, Medina-Inojosa et al (2017) amongst others. The negative impact of such a vast treatment gap is emphasised by the fact that women benefit as much as men from exercise (Anjo, Santos et al 2014). The literature highlights that there is a definite gender divide when it comes to partaking in CR after cardiac surgery women are still less likely than men to partake (Feola, Garnero, et al 2015).

Interestingly Dunlay, Witt et al (2009) found that obesity was not a barrier to uptake of CR in women, but it was a factor for not completing the sessions of the programme. Many participants are not aware that exercise is prescribed and part of their recovery process, they are misinformed and unaware of the importance of participating in their local rehabilitation class.

Umberson, Montez et al (2015) state traditionally older adults are more accustomed to groups, tending to participate in group activities such as church activities, women's

Institute, guilds and different community groups. Wallace, Theou et al (2015) feels that attending group activities is important to engage in healthy ageing and says that two widely known factors need to be incorporated in everyday life, that is social relationships and physical activities.

Sepúlveda Loyola, Augusto Camillo et al (2018) claims re-education in the older patient group may be needed to inform them if exercise is not part of their daily routine it can add to frailty and sarcopenia. Muscle strength declines by 15% per decade after the age of 50, and 30% per decade after 70, this is more common in women than males (Nied, Franklin 2002). Bowles, Paton et al (2018) conclude that it is not so much the exercise itself, the problem is convincing the older patient to partake in exercise, adding that barriers first need to be overcome before they participate in the rehabilitation. A study by Lees, Clark et al (2005) looking at specific barriers to exercise found five themes significantly apparent to the older person, fear of injury or falling, inertia, time constraints, negative effect and physical ailments. These findings are consistent throughout the literature. Most of the elderly population have lived through times when exercise was not deemed important or necessary as part of daily living, they need re-educating as they are not aware of the health benefits (Chao, Foy et al 2000). Chao, Foy et al (2000) go on to say that the elderly often perceives the symptoms associated with exercise as negative due to sweating, increased breathing and muscle soreness, in-fact some of the older ladies perceived it as not lady like to perspire. Although contrastingly Cohen-Mansfield, Marx et al (2003) note that barriers to exercise can serve as motivators to engage the elderly in exercise, some participants can be frightened to exercise due to experiencing symptoms similar to when they had their cardiac event, (sweating and shortness of breath). But as there is a health professional present at the exercise class reassurance is given and confidence can grow. Conraads, Spruit et al (2014) found that by increasing a HF patient's activity by 10 minutes a day led on to a 4% lower mortality and hospitalisation rate.

One of the main barriers to exercise in the elderly population throughout the literature is the fear of falling not to exercise itself (Lees, Clark, et al 2005). Grossman, Stewart (2003) stress if this barrier could be overcome the elderly population may well see that exercising in fact increases their overall fitness levels and strength making a fall less likely. Work by Cohen-Mansfield (2003) has provoked the author's thoughts process that it is clear that a

one size exercise regime does not fit all, exercise programmes need to be prescribed and tailored to individual needs. Devereus-Fitzgerald, Powell et al (2016) found that the older population are more likely to engage in exercise if it is a sociable and enjoyable activity with relevant short term benefits to their lifestyle. Half a MET improvement can make the difference of being able to walk to the kitchen from the room and stand and make a cup of tea (Devereus-Fitzgerald, Powell et al 2016).

Work by Jones, Kirby et al (2001) looked at reasons for non-attenders to exercise programmes. They found that more people who had a spouse were more likely to attend and complete exercise sessions than single older participants. Participants mentioned that they would prefer same sex sessions or sessions with others from a similar age group. But whether a person attends the sessions or not is due to where they are psychologically and whether they ready to make the shift and change. Throughout the literature focusing on leisure in later life it is no secret that older people begin to disengage rather than engage with new activities. Thurston, Green (2004) explore this concept more and suggest that as people retire, most actually lose a sense of purpose and daily routine and tend to give up hobbies. Evangelista, Berg et al (2001) pointed out that patients with HF find adhering to an exercise programme more challenging than under taking smoking cessation or reducing alcohol intake. To encourage change the focus needs to be on the individual patient goals, concerns and barriers to exercise, to increase compliance the activity needs to be enjoyable and geared towards the individuals' health needs and beliefs (Nied, Franklin 2002).

This review of literature clarifies the barriers to exercise training in patients with CVD and HF looking to make health behaviour changes as part of the management of their condition. Ambulatory group based CR exercise is very popular as part of conventional CR for patients with less complex conditions yet this option is rarely taken up by patients with HF (NACR 2019).

Chair based exercise is cost effective as it is reasonably easy to provide and requires little equipment making it an appealing option to the providers and commissioners of rehabilitation services. It could be argued that home based exercise is equally cost effective,

although that being said home based is harder to monitor possible technique problems and non-adherence issues (Fleg, Cooper et al 2015).

This study will address the identified gap in the literature around CBE delivered in a group setting to patients with HF. This will take the form of a feasibility study evaluating if it is possible to deliver a CBE training programme in a group setting in patients with HF in a hospital setting as part of routine care.

Chapter three: Methodology

Type of research

The feasibility study was decided upon as it involves the exploration of a research idea exploring the elements involved to determine whether carrying out a larger study (in this case chair based group exercise using a DVD) would be practical, viable and realistic (National Institute for Health Research NIHR 2013).

The initial idea was discussed with the supervisor at the university after identifying a gap in the literature for CBE in a group setting, for patients with LVSD using a DVD. The DVD had previously been used in a validation study (Razaob, Doherty 2012) and large study (Dalal, Taylor et al REACH-HF 2018) with patients on a one to one basis not in a group. No other study to date had been undertaken using a DVD in a group situation. For the hospital service to be in line with NICE (2018) guidelines exercise uptake needs to be increased in this cohort of HF patients. At present the most hospital trusts in the UK offer CR exercise to patients after coronary artery bypass graft surgery, angioplasty and MI, but it is not routinely available to HF patients with uptake less than 10% in routine practice (NACR 2019).

Sample size

The sample size of the feasibility study was based on figures from the National Audit of Cardiac Rehabilitation (NACR 2014/15) report which showed that 3,744 patients with a primary diagnosis of HF accessed exercise based rehabilitation. The NACR data in 2017 showed that an average uptake for the cardiac rehabilitation across all patient groups equated to 47% uptake, however the HF population is unlikely to achieve this level hence a lower expectation of recruitment for this study was anticipated. The aim was to recruit patients with a range of exercise capacity (fitness) to ensure we cover the different levels of the CBE programme badged under two categories for group exercise (high and low) who would carry out the chair based exercise DVD.

The local service was reviewed for up take to assess the number of potential participants eligible to participate in the study. Based on local service data for years 2014-15, 220

patients with left sided HF accessed the cardiac specialist nurse led HF service that year. Given a recruitment period of 4 months a 33% recruitment success over 4 months give us a total of 24 participants (mix of both male and female) who would be available to be recruited through the service during the time scale of the study. This assumes a 33% up take from those patients offered exercise, which will give us 12 participants in each of the two exercise categories of low and high fitness. The estimated uptake figure comes from the NHS CVD Outcomes Strategy (2013) which sets an ambition to increase uptake from 4% to 33% minimum in patients with HF.

Participants and recruitment Process

The target population were representative of the adult participants aged 18 or older suffering with HF using the hospital nurse lead HF service who were made aware of the study by the HF nurses to participate in the study. If interested and subject to meeting inclusion criteria and giving consent and willingness they became participants in the study. It was hoped that enough patients would come through the study to enrol in both the high and low level groups.

The main inclusion criteria to enter the study was diagnosis of stable left sided HF, patients that were decompensated or had recently been admitted to hospital were considered too high a risk for exercise intervention and not enrolled into the study.

Consideration was given to participants if English was not their first language. A telephone translation service was available to translate, called the “Big Word” Family members could also translate and staff members graded their language.

As part of routine service delivery when patients attended the nurse led clinics, they were made aware of the study, at the end of the clinic consultation. They were given the opportunity to take away a patient information sheet explaining the study in full (See Appendix 3) after several days they were contacted by the site investigator to see if they wished to participate in the study, if not usual care was not affected. Usual care is follow up by their cardiology team and HF nurse. CR is not offered at present in the HF service, this is not unusual as the majority of CR teams in England do not routinely offer CR to their HF

population. The recruitment and enrolment into the study took place over a four month period

The participants were also pre assessed by the site investigator, (her details were on the main patient's information sheet), this was to avoid participants already known to the HF service feeling obliged or compelled to take part in the study avoiding bias or cohesion. The principle investigator stayed on the peripheries not inviting participants into the study or becoming solely involved in the incremental shuttle walk tests or data input. If participants had any further questions or concerns about the study they were directed to and also addressed by the site investigator.

Informed consent was gained by providing a written patient information sheet about the study to potential participants, so any queries or concerns could be addressed (See Appendix 4). They were given a minimum of 48 hours to decide if they wanted to take part. The site investigator undertook this role and a consent form was signed by the participant, the paperwork was filed in a locked cupboard for confidentiality.

The study was undertaken in a trust in the North of England forming part of an MPhil qualification. The student was supported by supervisor Professor Patrick Doherty. The study seeks to test the feasibility of a group chair based exercise programme delivered as an innovation in service provision as part of routine practice within a local heart failure service. This may be more attractive to patients with lower fitness levels. It is the first study to test the feasibility of CBE in a group setting with patients with HF using a supervised DVD led exercise protocol.

Design

The design of the study was a prospective feasibility study using a cohort of participants. A feasibility study was required as the DVD had never been used in a group setting before only used on a one to one basis.

A feasibility study is an exploration of a research idea exploring the elements involved to determine if carrying out a larger study would be practical, viable and realistic (National Institute for Health Research NIHR 2013). It is usually a small piece of work undertaken

before the main research is conducted, highlighting any problems and gathering information to contribute to the main study (Fain 2010). NIHR (2013) points out that feasibility studies do not evaluate the usefulness of an intervention this is identified in the main study it is more the practicalities. Fain (2010) add that a feasibility study should always be completed before a new service is introduced to help determine whether the service will succeed or fail.

Throughout the literature search the terms feasibility study and pilot study were used interchangeably by some authors to suggest they are one and the same (Arain, Campbell et al 2010; Leon, Davies et al 2011). NIHR (2013) clarify that a pilot study should be thought of as a miniature version of the main study, and stipulate that a feasibility study focuses on particular aspects such as quality data whereas the pilot study is undertaken to ensure all aspects of the main study will work together. Lancaster (2019) adds that the debate is still ongoing regarding the interchangeable usage of the terms pilot and feasibility studies, they hope to publish their findings sometime in the future. A Similarity of both feasibility and pilot studies are they are designed to establish the safety of specific interventions before commencement of a major clinical trial (Thabane, Ma et al 2010). Thabane, Ma et al (2010) go on to say it is usual practice before any major study that a feasibility or pilot study is under taken to ensure smooth running of the main trial and highlight early any potential problems. Pilot studies are also referred to as vanguard trials intended to test the safety and efficacy of interventions (Tavel, Fosdick et al 2001).

Leon, Davis et al (2011) believe both pilot and feasibility studies should be seen as an important part of the research process, although they do not appear in great depth in the literature, the outcomes are very useful to both researchers and others conducting similar work. Morin (2013) state that not all feasibility studies are successful with the outcome not being as expected, this should not be seen as a waste of time as the findings still need be published so that other researchers can learn from the findings and overall time is saved.

Feasibility studies take time to complete and have their place in the research arena. Work by Arain, Campbell et al (2010) focusing on current practice and editorial practice concluded that if a pilot study shows significant results, researchers may feel there is no need to complete a larger study. Or if the results are unfavourable the main study may be considered less likely

to be useful. Ioannidis (2005) suggest that if only significant results are published this can lead to considerable error in future studies and feel that any results which are obtained from well conducted studies should be published regardless of the outcome. Morin (2013) comments that nurse investigators in particular may be tempted not to publish the findings from a pilot study they have undertaken. Perhaps feeling their work is not valued academically, nurses need to be encouraged to publish their results as it may prevent unnecessary duplication of work and have an impact on future research. Thabane, Ma et al (2010) state all researchers have an ethical obligation to try and publish work and share findings.

Bowen, Kreuter et al (2009) stipulate pilot studies can either be internal or external, internal is the first phase of the substantive study and data collected from the pilot study may contribute to the final analysis. Data from an external pilot may be analysed but set aside in respect of the main study. Wittes, Brittain (1990) believe that feasibility studies should be randomised to exclude bias and informed consent should be gained to evaluate the acceptability of prospective participants. Lancaster, Dodd et al (2002) disagrees and feel that feasibility studies do not need to be randomised which highlights how views in the last 29 years have changed.

Tickle-Degnen (2013) strongly believe that both pilot and feasibility studies have their place in the research process although it is does not appear common practice for the outcomes to be published. Arnold, Burns et al (2009) suggest this could be due to how the data is found and published the sample sizes used in this type of study are usually small and lack statistical power for generalizations to the broader population. Fain (2010) highlights the sample size used needs to characterize the target population and should be a significant number to represent the study being assessed as feasible. Lancaster (2019), feel that although pilot studies will not produce significant results they still have an important place in the research arena. Arain, Campbell, et al (2010) agrees and adds that studies of this nature will not have the power to test clinically significant hypotheses. Lancaster (2019) believes that pilot and feasibility studies are not powered to report on the effectiveness of an intervention. This is teased out in the main study. This can lead on to confusion of the reasons why feasibility and pilot studies are under taken, feasibility and pilot studies should be concerned with feasibility and uncertainty. Tickle-Degnen (2013) see feasibility and pilot studies are critical building blocks set in the foundation of randomised controlled trials,

when carried out correctly researchers are confronted by critical facts to share with stake holders before the main study is conducted.

Linguist (1999) highlight pilot studies tend not to be published due to Publication bias, because journals on the whole only accept papers that show statistically significant results and do not report the non-significant effects. Doody, Doody (2015) acknowledges that selective publication of research results is a known problem papers which highlight methodological issues usually identified during a pilot study are less appealing to publishers. Doody, Doody (2015) goes on to say and has influenced the authors own thought process that not publishing pilot studies is an injustice to the service users as problems highlighted early on could enhance the future participants experience. Teijlingen, Hundley et al (2001) add that even when a pilot study is acknowledged in the literature only one element is usually focused upon, or researchers will acknowledge they have learnt from the feasibility study but do not expand and share the knowledge from the study in the literature as to what has been learnt.

Lindquist (1991) identifies a common theme throughout the literature regarding using the same participants in both the main study and those exposed to the pilot study, as both groups of participants will not have the same experience as those who have not been exposed to the intervention which could lead onto bias. Leon, Davies et al (2011) suggest using data already presented in the pilot study then included in the main study could be seen as contamination of data, as modifications can be made to study methods, participants could have been recruited randomly so may not truly represent the target population to be used in the main study.

Feasibility studies used for randomised controlled trials may or may not always be randomised themselves, they do not evaluate the outcome of interest that is left to the main study. Arain, Campbell et al (2010) adds feasibility studies look at the main components needed to undertake a study. NIHR (2013) Pilot studies are smaller versions of the main study and test whether all the components of the study will work together. Muoio, Wolcott et al (1995) conclude that improved patient care is the end product of any pilot or feasibility study.

Arnold, Burns et al (2009) criticize feasibility studies stating that because of the low numbers used any findings are not significant and they lack statistical power for generalizations to the broader population. Fain (2010) has provoked my thought process as they argue feasibility studies do not evaluate the usefulness of an intervention as this is done by the main study. But add that a feasibility study should be completed before any research is undertaken to determine whether the research will succeed or fail as any issues or weaknesses may be highlighted and addressed at this early stage.

A pre assessment was undertaken to consider any contraindications or precautions before the study was commenced (Association of chartered Physiotherapists in Cardiac Rehabilitation A.C.P.I.C.R 2009), BACPR (2017). The study was carried out in a hospital setting. Participants followed the exercise by watching a DVD, the sessions were over seen by two senior cardiology nurses and a qualified fitness instructor trained to level 4 BACPR with expertise in CR. FI who work with older people in the UK have to at least hold a LEVEL 3 older person qualification which is the minimum level that health services and local councils expect (Robinson, Masud et al 2016).

Before the enrolment of participants, the chief investigator arranged a meeting with the FI and the two nurses to go through the DVD and explain technique, and to answer any issues regarding the study. Perhaps it would have been beneficial to include the participants in this meeting to familiarise them with the DVD and equipment. Razaob, Rahman et al (2018) in their recent study included the participants in their study at this stage.

Non clinical intervention by patients

The participants attended the hospital before the start of the feasibility study to carry out a pre assessment, involving seven non-clinical interventions as part of the research protocol. This included consent being undertaken by the site investigator not the principle investigator so that no bias was introduced. Before attending for the pre assessment an information sheet was given before consent took place, the participants had the sheet for several days so that they could discuss taking part with their partners family members or significant others. The pre assessment included an incremental shuttle walk test, (ISWT) to gauge if the participant would be in the low or high group of exercise. Before the walk

commenced, a full set of observations were taken including blood pressure pulse and oxygen levels. To gauge participants psychological and exercise tolerance two questionnaires were given to complete, the Dartmouth and HAD. Overall the time allocated to fill out the paperwork and complete the ISWT was one hour. The pre assessment was undertaken on the hospital grounds in the room which was to be used for the exercise program.

A visit to another hospital trust was undertaken by the research team in the North of England already carrying out heart failure exercise, the staff at that time observed the incremental shuttle walk test being executed in the patient group.

All participants with a documented diagnosis of LVSD confirmed by Echocardiography were eligible for consideration of entry into the study which ran twice weekly for an 8 week period. Recent evidence by Deka, Pozehl et al (2017) suggests that studies which ran for an 8 week period had better adherence from HF patients than those that ran for 12 or more. Similarly, Duncan, Pozehl et al (2011) found the same in their earlier study.

If participants exercise levels altered during the 8 weeks the plan was to change between the seven levels of exercise on the DVD. Ultimately there were only the low exercise group that ran, as the ISWT showed that all the participants' fitness levels were less than 5 METS. As already mentioned there was only one female whose walk test assessment achieved the criteria above 5 METS who was eligible for the high exercise group. (Unfortunately, it was group exercise and she would have been the only person in that group. She was referred to usual CR classes run at the hospital).

Study protocol:

- Prior to the exercise programme participants had to undertake an incremental shuttle walk test (ISWT) to determine their physical fitness which was used to prescribe the appropriate starting level of CBE;
- The ISWT level achieved was converted to METs abd this value was used to allocate the appropriate CBE level. A single MET is defined as the amount of oxygen a person consumes or the energy expended per kg unit of body weight during 1 minute of rest. Typically, one MET is 3.5 ml/kg/min at seated rest (ACPICR 2016)

- An end of programme ISWT was carried out to evaluate post rehabilitation fitness change. This is a routine practice measured that is also used by the national audit team (NACR 2019).

- Participants were then given a hospital and anxiety (HAD) questionnaire (See Appendix 5) and the Dartmouth quality of life questionnaire (See Appendix 6) before undertaking the shuttle walk test. Consideration was given to use the Minnesota living with heart failure questionnaire which would have been the preferable choice. However due to copy rights and time constraints it was decided to use the HAD score and the Dartmouth questionnaire which is already used in the NACR database and permission already gained.

- GP's were only notified of participants' involvement in the study with permission from the patient (See Appendix 7).

- Observations was taken at baseline prior to and following each exercise session, including manual blood pressure, Oxygen saturations and pulse checks.

- The patients rested 15 minutes before commencing the walk test. Due to patients low exercise tolerance it was agreed that only one walk test would be undertaken. (Other studies have undertaken 2 walk tests this will be discussed later in the paper).

- The incremental walk test was carried out by the participant walking between two cones which were placed 10 meters apart. The start of the test was indicated by a triple bleep. Thereafter the CD emitted a single bleep at regular intervals. The participant was played the triple bleep before the start of the test.

- As the participant walked a CD issued standard prompts. Each time the bleep sounded the participant had to increase their speed. The bleep test quickened at the start of each incremental level. Each minute the test increased by 0.17 m/s which was noted to the participant by a triple bleep, indicating they had reached the next level.

- Using the same prompt on the CD if the participant was more than 0.5 metres away from the cone when the bleep sounds they were told they are not going quick enough and to try to make up their pace. They were observed for untoward signs and symptoms of fatigue and lethargy. The number of shuttles the participant had to complete increased by 1 in each consecutive level. If the participant reached the cone before the bleep they were instructed to wait until the bleep sounded before they continued. The operator informed the participant when the triple bleep sounded that the speed would increase, other than that no encouragement was given.

- The ISWT ended when the patient was more than 0.5 metres away from the cone when the bleep sounds, one lap is allowed for the participant to catch up, or if the participants became fatigued and symptomatic and were unable to make up the pace the test was terminated

- At the end of the test a chair was made available so the participant could sit or if they preferred they could stand.

- Observations of the blood pressure, oxygen saturations and pulse were repeated post exercise to ensure participants observations had returned to baseline. If the observations had not returned to baseline the participant would stay at the centre until the observations were back within an acceptable range.

- The Borg Scale was used to measure perceived exertion during the ISWT.

- A cohort of patients both male and female with left ventricular systolic dysfunction attended twice weekly over an eight week period. The participants were then allocated into the low or high group of exercise, which ran twice weekly for 8 weeks.

- The ISWT walk test was repeated at the end of the 8 weeks the HAD Questionnaire and the Dartmouth Quality of life questionnaires were also re-administered.

- At the end of the twice weekly sessions after an 8 week period, Participants returned to usual care. (Usual care consisted of evidence based medical management as recommended by NICE (2018) and ESC (2016) guidelines, and the specialist heart failure team).

- A copy of the DVD was not given as the study was testing feasibility and had to be sure no adverse events would occur, before allocating the DVD to participants if they required one.

- If patients wished to be referred onto the local phase 4 programme at the leisure centre they were referred on.

After completing the ISWT the patients were then allocated a chair based exercise (CBE) level depending on the ISWT results and the METS. The patients would be prescribed exercise at 65-70% of the ISWT MET test. There are 12 ISWT stages each stage lasts one minute and has a different distance measured in metres, which allows the participant to complete a number of shuttle walks (Parreira, Janaudis-Ferreira et al 2014). The speed is calculated and the average METS worked out using a table (See Appendix 8) which in turn highlights the proposed CBE level. Stage 1 of the ISWT is 10-30 meters long, completing 3 shuttles at a speed of 1.12-1.8 (mph) (kph), average METS of 1.75, proposed CBE level 1. This increases as far as level 12 with the participant completing 890-1020 meters, 14 shuttles at a speed of 5.30-8.5 (mph) (kph), MET average 5.0 proposed CBE level 12. Alotaibi, Doherty (2017) produced reference values in their work that showed age and gender were the main factors in the distance CR patients walked in the ISWT, especially age.

For example;

ISWT stage 5-participant walked 190-250 metres, completing 7 shuttles at a speed of 2.64-4.3, average METS 3.5 proposed CBE level 3. At baseline assessment if the participant should complete 3 of the ISWT shuttles into the next stage then the higher level of CBE would be prescribed.

The low and high groups were differentiated depending on the level of the participants ISWT and MET level. The low group was categorised from the ISWT levels 1-5 with METS of 1.75-3.5. The high group ISWT levels 6-12 with METS from 3.6- 5.0 METS. If any of the participants had achieved level 12 in the ISWT they would start the CBE on level 6, level 7 of the CBE is for progression only. It would be very unlikely that any of the HF patients would reach level 12 on the CBE as the table was actually devised for patients with COPD (Razaob, Doherty 2012).

A BORG chair based effort scale was used to work out the participants RPE. The BORG test is used for measuring individuals' exertion, breathlessness and fatigue during physical activity (Williams 2017). Williams (2017) says the score is a very simple numeric list 0 – 10 with 10 being the hardest exercise imaginable and 0 nothing. Participants are told to focus on the whole body as it was important they understood their level of exertion on the whole body and can work at a level they find comfortable. The scale takes seconds to perform and can be researcher or self -administered. Health professionals tend to enforce their scale of exertion on the patient the scale is what the patient says it is (Williams 2017).

NYHA Classifications symptoms of Heart Failure

Class l: Patients with cardiac disease but without resulting limitation of physical activity. No symptoms at rest, symptoms only at levels of exertion that would limit a healthy individual. Usual physical activity dos not cause any fatigue, palpitations, dyspnoea or angina pain.

Class ll: Patients with cardiac disease resulting in slight limitation of physical activity. No symptoms at rest or mild exertion, symptoms on moderate exertion

Class lll: Patients with cardiac disease resulting in marked limitation of physical activity. No symptoms at rest, symptoms at mild exertion

Class IV: Patients with cardiac disease resulting in the inability to carry out physical activity without discomfort. Symptoms of HF at rest, if any physical activity in undertaken discomfort increases.

The New York Heart Association (NYHA) is a subjective test, the patient is clinically assessed by a doctor or nurse as to which class the clinician feels their symptoms fit, judging exertion and shortness of breath. The NYHA is an indicator of the reserve a patient has, there is a decline in functional capacity the higher the NYHA (Miller-Davis, Marden, et al 2006). It could be argued that the NYHA classification as a test is not a true picture of physical function but is used by many clinicians in clinical practice to gauge exercise capacity (Morales, Martinez, et al 1998). A piece of work by Holland, Rechel et al (2010) asked patients to rate themselves as to what classification they felt was appropriate to them, the study found a clinically significant predictive value when used by patients.

Data Collection

Pre and post assessment data using the hospital anxiety and depression measure (HADS), ISWT data and QoL Dartmouth Coop tool was collected and described using means or median values as appropriate. The sample size derived from this feasibility study was too small to carry out a thorough analysis of pre and post differences but the data helped define future expectations in terms of the differences between pre and post intervention outcome measures and to help inform future sample size estimations in this population.

Patients were allocated a number on entry into the study to be included on all paper work for confidentiality. A database with password sensitive access was used to document all patient information, and only the two nurses' had access to the encrypted memory stick.

The following guidelines for entry into the study are based on national guidance for training in patients with Cardiac disease which includes the BACPR (2017) and ACPICR (2015).

Inclusion

- Patients with documented heart failure
- Evidence of Heart Failure with a recent echocardiogram undertaken in the last year.
- Stable on medication
- Both male and female participants
- Patients aged 30 and above

Exclusion

- Unstable angina
- Cognitive impairment
- MI (heart attack) in previous month
- Hypertension at rest more than 180mm Hg systolic and 100 mm Hg diastolic
- Recent cardiac related hospital admission in the past two weeks
- De-compensation of heart failure within the last month before commencing the exercise programme
- Introduction of a new medication within a month of starting the exercise programme (up titration acceptable)
- Weight gain of >2kg over two days which had not resolved in the past week.
- Recent significant deterioration of exercise tolerance or increase in breathlessness
- Recent surgery or on a waiting list for significant surgery
- Resting heart above 120bpm
- Acute myocarditis or Pericarditis
- Thrombophlebitis
- Recent embolism
- Acute systemic illness or fever
- Uncontrolled Diabetes
- Significant ischemia as low risk rates <2 METS
- Progressive worsening of exercise tolerance over past 2-3 days
- Decrease in systolic blood pressure with exercise
- Supine resting heart rate >100 bpm
- Pre-existing significant co -morbidities

A flare up of condition or adverse reaction due to exercise being too hard, was minimised by completing a baseline fitness test on all participants, and a risk assessment the prescribing of the exercise intensity was based on their ability. A joint statement by the Resuscitation Council (UK) and the British Association Cardiovascular Prevention Rehabilitation (BACPR) (2018) state all staff involved in supervising CR in the structured exercise component should complete regular resuscitation training and hold the appropriate skills required. All venues

should provide a defibrillator, and oxygen available to be delivered by trained staff if necessary should any participants experience an untoward event.

Before the study took place, a meeting was arranged with the resuscitation staff in the trust to inform them of the programme taking place and the room to be used. The crash team was also notified of the room and times of exercise so that if there had been any eventualities there would be no delays in attending. The team could be contacted by ringing the emergency number through the switch board using a phone in the room.

The local ambulance station was also notified of the site and room to be used and informed of the exercise times. The location venue was chosen with the emergency services in mind so that ambulances had easy access for themselves and any equipment needed (Resuscitation Council, BACPR 2018)

Participants information and consenting

Participants were given the opportunity to take away an information sheet explaining the study in full, to see if they would like to partake in the study. They were advised after having the sheet for several days to contact the named nurse on the information sheet to inform them whether they would like to participate in the study. The direct care team will use hospital notes to identify patients suitable to enrol in the study. The team will be the custodians for all data generated by the study. Informed consenting took place at the pre assessment session, participants were made aware at that time that if they changed their mind and didn't want to enrol on the study, or complete once enrolled it would not affect their future care. The principal investigator of the study did not become involved in the recruitment process to reduce or eliminate bias.

If any patients who had given their consent lost capacity they would have been withdrawn from the study and any data collected would have been withdrawn and destroyed.

Ethical Considerations

Ethical principles have been applied during the feasibility study to guide the conduct throughout, respecting the dignity rights and safety of all participants and staff members. The study will abide by the ethical principles underlying the Declaration of Helsinki and Good

Practice guidelines. The research has been peered reviewed and will meet with ethical approval before the start of the study or enrolment of participants. No children will participate or be involved at any time in the study, only adults that do not lack capacity will be included.

This work will present a research proposal which forms part of a Master's dissertation that will incur no fees for the researcher time. The study to be undertaken is the benefits of CBE in the elderly HF population using a DVD. The research will be completed in a hospital trust in the North of England, permission gained from the head of nursing and business managers to carry out the study.

To ensure no breach of confidentiality to participants or service users all participants were allocated a number on entry into the study which was used on all information and data used throughout the study. GP's were only notified of involvement in the study if permission was gained from participants. The fitness instructor did not have access to the individuals' notes only the direct nursing care team involved in the study had access to any identifiable patient information.

NHS and university computer systems were used throughout the study, all paper documents were stored in a locked filing cabinet at all times, the filing cabinet was in a room which had a pin code access. Data was shared with the university as the information was being used for an MPHIL qualification. All data was handled and analysed by the chief investigator and strict confidentiality applied. The General Data Protection Regulation (GDPR) (2018) was used throughout the project which supersedes the Data Protection Act (1998). Other physical security arrangements for storage of the data was a password encrypted memory stick that only the research team had the password for.

Current CV's of all members of the research team were submitted with the IRAS form to highlight levels of training and professional accomplishments. The chief investigator of the study is the students' supervisor from the university. The study has no link to any previous or any current work being undertaken.

At the end of the study all data was analysed by the supervisor at the university. The data was kept for a maximum of three months at the end of the study, research data generated by the

study was kept safely and confidential for 5 years, after this time it will be safely disposed of as per trust policy.

The study is to be undertaken as a service innovation as the local hospital trust does not routinely offer exercise training to heart failure patients. The study seeks to test the feasibility of a CBE in patients with heart failure (e.g. lower exercise tolerance), making this the first study to test feasibility in a group based DVD led exercise in this population.

Meaningfulness of the study

Patient involvement was sought through the local Cardiac Rehabilitation Interest Group (CRIG). They were consulted throughout from inception through to completion of the study to gain their views and comments from a patient/ service users' perspective.

Historically the CR and HF teams have worked closely with patient groups such as CRIG. CRIG as a group works tirelessly as fund raisers for the local area and are always looking for new projects to support. The principal investigator approached CRIG to see if they could support the study financially, and give advice from a service user's perspective. NIHR (2019) feels working with a service group demonstrate an openness, engagement and transparency of the planned study helping to enhance and enrich the research process. This method of sharing ideas was carried out by Borek, Abraham (2018), they found that by engaging their research ideas with groups of people, barriers were broken down between themselves and the participants. Borek, Abraham (2018) go on to say that it allows researchers to highlight the significance of participation from patients and raises the awareness of the importance of taking part in studies, without which research service provision would stand still.

CRIG invited the principle investigator to attend the monthly CRIG meetings enabling the principle investigator to keep them in the loop regarding commencing the feasibility study also supporting their fund raising by attending their events.

At the first meeting a full explanation and presentation was given to explain to the whole group of 50 members (not only the committee) what would be involved and how cardiac patients could benefit from the feasibility study. After the presentation ended the group

discussed the study at their committee meeting for all members to vote to support or reject the idea. The committee met in private and voted to support financially and to give a lay person's perspective on all the study documents that were to be used by the participants in the study. Generously they donated the funds to pay for the British Association for Cardiac Rehabilitation and Prevention (BACPR) level 4 trained fitness instructor (FI).

The potential benefits for participants are to hopefully increase fitness levels, confidence, quality of life and physical activity levels. After completing the exercise and receiving advice from the FI they gained the ability to exercise safely and rate their own levels of exertion. Moving forward the participants have the tools to recognise their own limitations. Which in turn should lead on to reduced hospital admissions, longevity and quality and of life, as well as improved activities of living. Many participants because of restricted exercise tolerance struggle to socialise attending the sessions twice weekly mixing with their fellow peers may improve camaraderie and forge new friendships. Overall their fitness levels may not improve but it is believed they may become more efficient.

Early on and throughout the research process the patient group CRIG was involved in the design of the study and their opinions sought. A group committee meeting was attended by the site investigator and Principle investigator and with permission from all those attending, the meeting was recorded so that their views and comments could be recorded when the study was written up at a later date. Six members of CRIG team visited the first room in the hospital which had been offered by trust to see if it would be fit for purpose from a service user's perspective.

The DVD was watched by CRIG and they were impressed by the exercises. Although they too commented on the seriousness of the lady in the DVD. CRIG highlighted that parking at the hospital may be a problem that was why they stopped holding their meetings at the hospital. They expressed that some of their members didn't know how to catch the park and ride and would be weary initially due to lack of confidence. The principle investigator visited the bus station to find out which bay the bus would be parked at and also a time table to give all participants in the study. The route of the bus stopped directly outside the hall that was used in the study.

All participants in the study were treated with dignity and respect from the outset of the study whether they agreed to participate or not. The group of patients studied were all cardiovascular patients the study had a generic health relevance. The cohort of participants were both male and female, the lower age limit was set from 30 to the higher limit of 85 years of age. The participants had to meet all the inclusion criteria listed earlier and if any one principle exclusion criteria were met they will not be allowed to enter the study. As part of clinic preparation, the team checked past medical history and reports which allowed them to identify suitable participants based on inclusion and exclusion criteria.

As mentioned earlier a pre assessment was undertaken before the study commencement with patients and significant others, using their hospital notes to help verify suitability for inclusion in the study. Risk of harm through exercise was minimised by tailoring exercise to the ability of participants and they were not asked to exercise harder than 70% of their maximum effort based on their walk test values. The incremental benefits of exercising patients at >90% capacity is small and is not recommended as it can lead to build of lactate acid accumulation and fatigue, increasing the chance of physical injury and cardiovascular complications (RACGP 2018). Contra-indication to exercise based on published guidance informed participant inclusion and exclusion. In addition, the study was undertaken in a hospital building with access to the crash team if a problem should have arisen, oxygen and a defibrillator were in the room, two senior nursing staff and a qualified FI attended each session. The risks of CR based exercise are low as shown by the following two studies; A French study observing 25, 000 heart patients undergoing CR, reported one cardiac event for every 50, 000 hours of exercise training, which is equivalent to 1.3 cardiac arrests per million patient hours (Pavy, Lliou et al 2006). An American study conveyed one case of ventricular fibrillation per 111, 996 patient hours of exercise and one MI per 294, 118 patient hours (Van Camp, Peterson 1986). Historically HFrEF with an ejection fraction < 35% and an NHYA level of 3 or 4 have been considered high risk, a Cochrane review in patient with an NHYA 1-3 found no evidence that exercise training can cause harm or risk of death in the long or short term (Taylor, Sagar et at 2014). CR programmes are designed to try and slow down and reduce the progression of heart disease ultimately improving patient's quality of life (Al Quait, Doherty 2018). Anderson, Thompson, et al (2016) add CR has been defined as looking holistically at patients' needs helping them to modify behaviours to help

slow down or even reverse the disease process. By making changes to their daily behaviours exercise is seen as an integral part of the rehabilitation process.

The participants were expected to commit to be in the study for 10 weeks in total which included assessment pre and post the intervention. The potential risk to participants of the study could have been a flare up of their condition or adverse reaction due to exercising to hard which was minimised by completing a baseline fitness test based on their ability. There could be a perception that exercising participants with restricted mobility and low exercise ability could lead to discomfort and distress. This was minimised by the mode and delivery of seated exercise. When patients first begin exercise they may experience symptoms of exercise induced dyspnoea which can cause fear of being active and they may interpret it as worsening of their symptoms which can be frightening to them. Supervised training reassures patients that some signs and symptoms of exercise can be similar to cardiac symptoms shortness of breath sweating and pulse increasing (RACGP 2018).

The first tap meeting was undertaken in January with a presentation of the research given to the supervisor and another member of the academic team and a 3000 word document of the research protocol was submitted. Training needs were discussed which highlighted visiting another trust carrying out the ISWT. Also attending a course on thesis writing was advised and booked. A Gantt chart was completed and presented at the meeting to guide the research, giving structure and time scales and presented at the TAP meeting. This meeting had to be successful for the study to progress.

Part of the criteria by the hospital trust R&D department is that all staff involved in research have to undertake the Good Clinical Practice module course run by the NIHR. On completion of the module a certificate showing completion was submitted to the R&D department by both the principle investigator and the site investigator involved in the study.

The Initial contact with the governance officer in the trust R&D was made in Nov (2015) and the first step was to fill out a research proposal form outlining the basis of the study protocol. All documentation to be used in the study was created at this time which included GP letter, Chair based DVD questionnaire. Patient's Participation information sheet patient

consent form, and which were submitted in April (2016) to the head of research and the supervisor at the university.

A meeting was arranged with the head of research at the trust to discuss the documentation, for the study, including the feedback from the trusts research panel which was received electronically at the end of June (2016). The trust research committee made constructive comments on the research proposal, which helped small adjustments to be made which did not change the study protocol over all.

General themes and responses from the hospital R&D lead and research panel

The research panel and lead queried why the study was for 8 weeks, this had been decided as the REACH-HF (2018) protocol followed the same time period. Initially the protocol was not clear as to which HF participants would be included in the study. The feedback helped to clarify other areas such as who would approach the participants to avoid bias (See Appendix 9). They were concerned which type of participants would be enrolled, this was clarified by emphasising that all participants would have to meet the whole inclusion criteria.

The panel was assured that from the beginning of the feasibility study the patient group was involved. All paperwork and documentation were given to the group for a service user's opinion, and any areas for concern was discussed. The safety of the participants and investigators were paramount.

At this time the university supervisor was also contacted to provide a sponsor letter for the study (See Appendix 10).

In October (2016) the insurance documents from the university (See Appendix 11) were emailed to the R&D department along with the completed paperwork including the questionnaire, consent form and participants information sheet. All participants completed a declaration giving informed consent before entering the feasibility study. A letter from the university confirmed they would sponsor the study within the meaning of the Research Governance Framework for Health and Social Care (Second Edition 2005).

In November 2016 the Integrated Research Application System (IRAS) application form was electronically submitted to the Health Research Authority (HRA) and reviewed by London

City and East NHS Research Ethics Committee (REC). This submission included all the paperwork needed for the study:

- Participant information sheet (Appendix 3)
- Participant consent form (Appendix 4)
- HADS (Appendix 5)
- Dartmouth Co-op (Appendix 6)
- GP information sheets (Appendix 7)
- Letter from the University sponsor (Appendix 10)
- University insurance letter (Appendix 11)
- Non-validated questionnaire (DVD questionnaire Appendix 12)
- Letter of HRA Approval (Appendix 13)
- Letter from North Lincolnshire and Goole (NLAG) (Appendix 14)
- IRAS application form (Appendix 16)

The original application to IRAS was put on hold and the HRA application frozen as notification was received they had installed a new system which included a new registration process. Once HRA had updated their new system the whole application process had to be repeated and re-submitted from scratch. I worked with the governance manager in the R&D department at the hospital trust and together we resubmitted the paperwork.

Concurrently at this time all funding from the nursing confederation was recalled by the government which meant all nursing post graduate education at master's level and above was to lose funding. This was a particularly difficult period, but with support from my supervisor and nursing administrator which was exemplary, the fact that I had initially enrolled at the university for 5 years my funding and place on the course was honoured.

In January 2017 a reply was received from HRA and REC that changes needed to be made to the IRAS form. A provisional opinion from the subcommittee of the London City and east NHS research ethics committee (REC) was a favourable ethical opinion, however they highlighted that the researcher needed to be aware that even though the patients will only exercise at 70% of the maximum exercise tolerance, they felt surely patients who have not exercised for a long time would have sore muscles, aches and pains.- **This was to be addressed by having**

two qualified nurses and a fitness instructor at each session to give advice and support to participants if any problems should arise at the time of exercise. Participants will also be given a contact number of the heart failure team if they should have any issues at any time during or after exercise.

Further clarifications were also needed for the HRA application to comply with HRA approval standards. They specified; (**Response written in bold)**

1. All documentation should have the IRAS application number on-**Amended and both documents attached.**

2. Clarification if any funding will be available to the NHS organisations participating in the study. -**Clarity on this has been added to A65 in the IRAS application form, IRAS pdf form attached.**

3. Disclose if there is any intention to transfer personal identifiable information as opposed to anonymised research date from the participants to the university at any point during the study. How will the information be stored and the purpose for this? **A36 has been amended as requested and the PIS attached.**

4. The IRAS application form states that information will be kept for the minimum time of 3 months. If any identifiable information or data is to be retained details must be documented in the patient information sheet (PIS) informing the purpose of this and how the data will be stored and the time it is to be retained for **A43.**

5. The IRAS form states that participants will be sent a copy of the study results. Clarification is needed if any personal identifiable data will be included. If it is this will need to be included in the PIS, and also a date you would expect the study results to be available. A53 has been amended as requested and the PIS.

These changes were checked by the supervisor and he agreed that the changes were non-substantial, just minor queries, the alterations were e-submitted. The end of January 2017

approval letters on behalf of the ethics committee were received confirming a favourable ethical opinion from REC, and HRA (See Appendix 13).

A copy of the research proposal was discussed at the trust research meeting and all agreed with support from the R&D the work could be undertaken. A letter from the trust confirming to support the feasibility study was obtained at this time so the study could be initiated (See Appendix 14).

Validity was accomplished as it was designed with patients as well as the team members' safety therefore the risk-benefit ratio was favourable. All members of the team were aware of the purpose and their role in the study.

Arrangements for monitoring and auditing the conduct of the research will be undertaken by routine monitoring in line with the trust policy for research and governance. The study will be over seen by the supervisor from the University of York.

Arrangements for insurance and indemnity to meet the legal liability of the sponsors for harm to participants arising from the management of the research, will be undertaken by the university, as they are the sponsor for this feasibility study.

An integrated research application system (IRAS) application had to be under taken before the study or any study is under taken in England or UK health departments. Until the application is granted no contact with the participants is allowed. Included in the application is HRA approval, and a review by NHS research ethics committee (REC).

A statutory requirement of the UK policy framework for Health and Social Care Research which covers all research undertaken in the NHS England, is that the Good Clinical Practice (GCP) course needs to be undertaken by any health professional in the NHS partaking in research (http://www.crn.nihr.ac.uk/learning-development accessed 08/02/2019). GCP is the international ethical scientific and practical standard to which all clinical research is under taken. Compliance with GCP ensures that the rights, safety and wellbeing of research participants are protected and that the research data is reliable. All members of the research team undertook the training in GCP.

Chapter four: Results

The total number of patients with heart failure taking up the offer of CBE in a group setting was a ten. The ratio of number of patients joining CBE against the number approached was 1 in 5. The mean age of patients in this feasibility study was 71 years plus or minus 5 years which is representative of other HF exercise based studies (Table 3). Patients presented with one or more of the following comorbidities including; diabetic, ischaemic heart disease, pulmonary disease, atrial fibrillation, breast cancer, cardiac myopathies and hypertension. As per protocol only patients with a diagnosis of HF with reduced ejection fraction were recruited. Mean systolic blood pressure was 123.33mmHg (SD 13.13) with a mean diastolic blood pressure of 61.00 mmHg (SD 5.47) for the group.

CBE sessions and progression

Sessions ranged from 4 to 16 over the study period (Table 3) with a mode of 15 sessions. The ability of patients to progress was evident with patients moving up three levels above the starting level.

Table 3. Patient characteristics alongside CBE sessions and Progression.

Patient age Years	Gender	Comorbidity	Sessions	CBE levels Achieved
66	M	Diabetic, IHD, AF	16	4
69	M	COPD, IHD, CABG, AF	16	4
72	F	Diabetic, AF, Arm fracture	8	3
74	M	AF, IHD. MI X2	16	4
68	F	MI, AF, Cancer, IHD	16	4
74	M	MI X3, IHD, Diabetic, Stent, COPD	16	4
59	M	MI, IHD, HTN	16	4
75	F	MI	16	4
78	F	DCM	16	4
77	F	COPD, CABG, Diabetes, AF, MI	4	4
DCM-Dilated Cardio myopathy				

Shuttle walk test

Physical fitness was measured using the ISWT which, as a sub-maximal exercise test, was well tolerated by the HF patients in the study and yield a mean walking distance of 95.0m at baseline and 113.12m resulting in change in walking fitness of 18.12m by the end of the study (Table 4).

Table 4. ISWT distances at baseline expressed in respect of age and gender.

Mean incremental shuttle walk test (ISWT) distance by age and gender

Gender		Age (years)	Baseline ISWT distance (metres)	Post CBE ISWT Distance (Metres)
F	Mean	74.00	80.00	103.75
	N *	5	5	4
	SD	4.06	45.45	68.3
M	Mean	68.40	110.00	122.5
	N*	5	5	4
	SD	6.26	46.36	44.3
Total	Mean	71.20	95.00	113.12
	N*	10	10	8
	SD	5.78	59.48	62.38

*Caution required when interpreting mean values based on small sample size

Women in the feasibility study were on average older by 6 years than the men and the proportion of male and female participation was 55:50 (Table 3). The relationship between age and fitness was analysed at the start of the exercise (Figure 2) and following the programme (Figure 3). The figures show that age was poorly related to fitness in patients with HF, as measured by a walk test (ISWT), with less than 2% of the variance in walking distance explained by age. As an example, two patients age 74 years and 75 years old had higher fitness levels than a 59 year old patient.

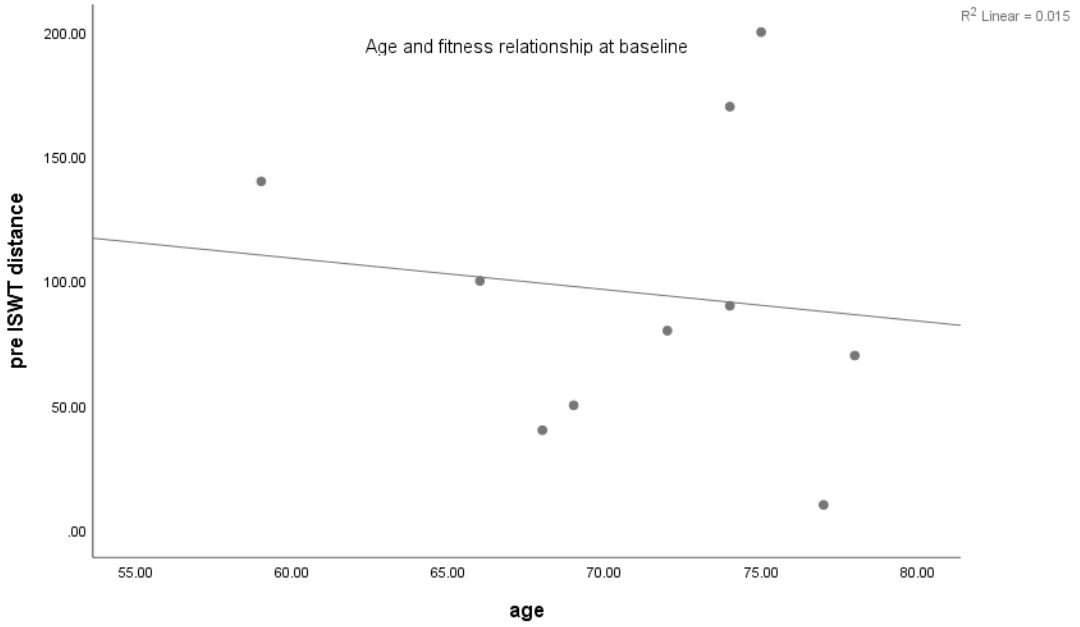

Figure 2. Relationship between age and fitness pre exercise as measured by ISWT

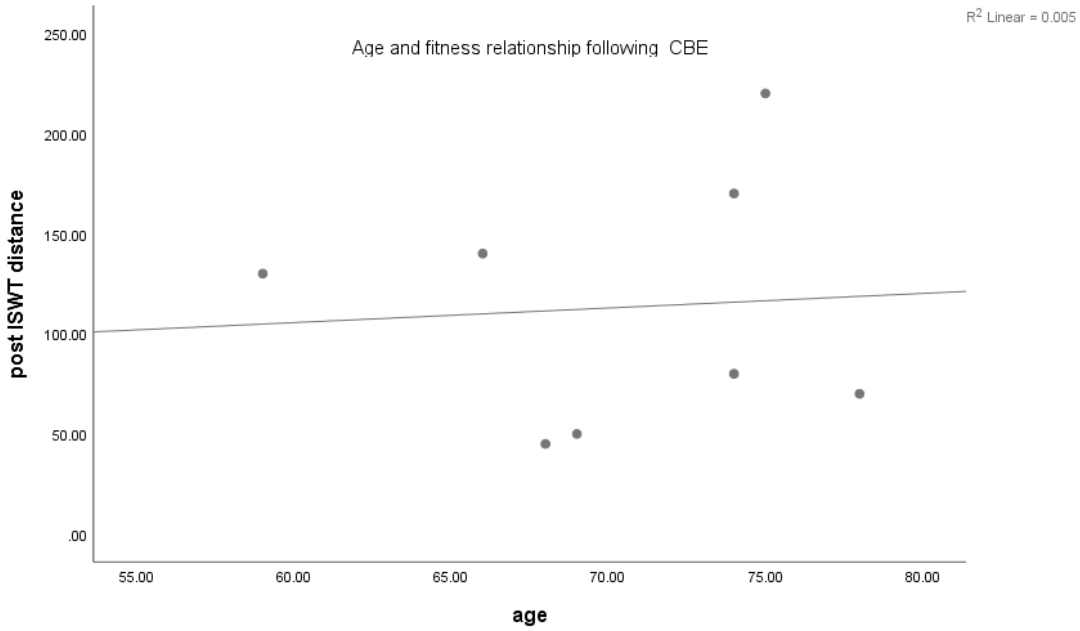

Figure 3. Relationship between age and fitness post CBE measured by ISWT

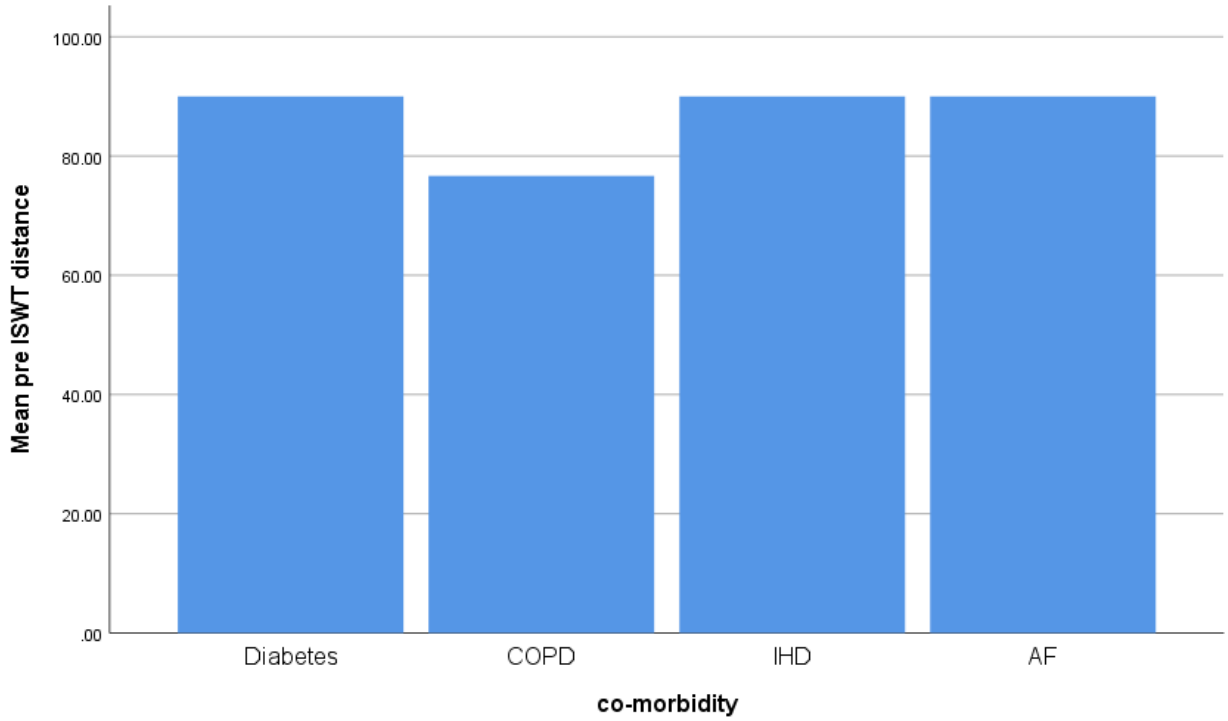

Figure 4. Incremental shuttle walk test distance by co-morbidity

Albeit for descriptive purposes only (due to small sample size) figure 4 shows that the co-morbidity of COPD was linked with the lowest ISWT distance overall exercise fitness which aligns with national audit reports on the impact of COPD on walking fitness in patients with HF.

Quality of life was measured using Dartmouth Coop Questionnaire which although well used in national cardiac audits was associated with poor return rates in this feasibility study with only five of the 10 patients completing pre and post CBE questionnaires. The following values are based on 5 patients and should be seen as low level description of QoL for patients with HF included in this study. Mean QoL went from 24.4 to 18.8 where lower scores indicate improved QoL.

Anxiety and depression measured by HADS also suffered from poor return rates (i.e. 6 out of 10). As above the following data is purely for low level descriptive purposes. Mean anxiety reduced from 6.4 to 3.3 for pre and post CBE respectively. Mean depression reduced from 9.4 to 7.5. The interpretation of HADS is that lower scores equate to less anxiety and depression.

Safety of CBE

During the study there were no adverse events associated with patients taking part in CBE.

Two of the most important measures of cardiovascular demand in patients with HF systolic blood pressure and heart rate.

Systolic blood pressure was on average 123.13mmHg prior to exercise and slightly lower at the end of CBE at 120.75 mmHg (SD 13.09). Mean change in pre to post CBE systolic blood pressure was 2.58mmHg lower following exercise.

Heart rate prior to exercise averaged 74 bpm (SD 7) and was 77 bpm (SD 7) at seated rest immediately following CBE.

Rate pressure product (RPP) is a measure that combines heart rate and systolic blood pressure as an estimate of load on the heart per minute. Encouragingly the mean RPP prior to exercise was 91 mmHg/per minute and remained similar (92mmHg/minute) immediately following exercise.

A rate of perceived exertion (RPE) scale was used by patients to express the effort required of them during each exercise session and was recorded on a zero to ten scale half way through the session and at the end of each exercise session. The RPE scale was integrated into the CBE DVD. Mean RPE in the middle portion of the exercise period was 4 (SD 1.2) which suggests that patients felt comfortable with the exercises.

Collectively, the above measures suggest that patients with HF were able to carry out CBE without creating excessive load on the cardiovascular system and their perception of the effort required to CBE was within a tolerable range.

Discussion

As stated previously a feasibility study is an exploration of a research idea exploring the elements involved to determine if carrying out a larger study would be practical, viable and realistic (National Institute for Health Research NIHR 2013). It is usually a small piece of

work undertaken before the main research is conducted, highlighting any problems and gathering information to contribute to the main study (Fain 2010). NIHR (2013) points out that feasibility studies do not evaluate the usefulness of an intervention this is identified in the main study it is more the practicalities. Fain (2010) add that a feasibility study should always be completed before a new service is introduced to help determine whether the service will succeed or fail.

In this present study the ratio for the number of patients joining the actual study against the number approached was 1 in 5 which is not unusual for trials in HF (Taylor, Sagar et al 2014) but is an issue clinically as this would mean most patients wouldn't take up the CR service. The age range in the feasibility study was 59-79 a usual age range is for HF patients (NICOR 2019).

Schutzer, Graves (2004), found that time constraints on the older adult was a reason for not enrolling into studies, not only the study time needs to be taken into consideration it is the travelling to and from the venue. The time commitment increases even further if participants have to travel on public transport. Most patients used the park and ride service although the R&D department offered to pay for all the participants parking.

Minotto et al (2018) make an interesting point in regards to the effect that diuretics can have on patient's fitness level. It is not the actual diuretics that effects fitness levels it is the factors associated with taking them such as excess fluid retention, obesity and HF severity. The authors show that patients with more severe HF (e.g., NYHA Class III or IV) are diuretics for symptom control. Minotto et al (2018) also analysed the impact of comorbidities using based on similar clinical categories including muscular skeletal commodities such as arthritis rheumatism and back pain as they all share the same common inflammatory process for chronic disease; Metabolic including diabetes hypercholesterolemia, and COPD and asthma; the most deliberating was COPD and Asthma.

It is well-documented that women have a much lower adherence to CR than men, due to family commitments and responsibilities identified as some of the barriers women face (Oosenbrug Marinho et al 2016). Poor adherence and poor outcomes for women is concerning as it may be having a negative impact on their outcomes, which strengthens the

argument for more tailored approaches to CR for all especially women's CR. (Supervia et al 2017).

Fitness and the shuttle walk test

The assessment of functional capacity (fitness) prior to starting an exercise based cardiac rehabilitation programme is a recommendation of all major British and European guidelines (BACPR 2017, Piepoli et al 2012) in patients with CVD. National audit data for the UK suggests that around 30% of patients undergo a baseline fitness tests and of these a third do not complete an end of rehab test (NACR 2019). Data from this NHS routine practice CBE feasibility study show that 8 of the 10 participants complete the CBE which represents a high level of data completion. Physical fitness was measured using the ISWT which, as a sub-maximal exercise test, was well tolerated by the HF patients in the study. The feasibility data yielded a combined mean ISWT walking distances at baseline of 95m which was lower than the mean reference value previously published where patients with HF plus an additional comorbidity had a mean walking distance of 197m but did align with the 25th percentile value of 90m (Doherty, Hossain & Harrison 2019). This shows that the patients included in the study had a low functional capacity which is possibly why they wished to try a CBE rather than an ambulatory circuit based rehab programme which is more typical in slightly fitter patients underpinning the NACR reference values.

Albeit the small sample size limits any generalisation it was nevertheless encouraging to see a slight improvement in the distance walked at the end of the CBE programme equivalent to 18.12m. A larger study is needed to evaluate the effect of CBE on fitness in patients with HF.

All of the participants in the feasibility study were retired, Sutherland et al (2018) found that retirement was found to significantly limit a patient's opportunity to improve their walking ability. Perhaps this could be due to the slowing down or decline in physical activity during the transition into retirement, although that being said not all people retiring see it as a slowing down process (Sunderland et al 2018).

The participants on the feasibility study had the support of their significant others to support them in CR. Molloy, Hamer et al (2008) interestingly found the opposite that being

married or in a relationship had a significant negative impact on patients walking ability, could be due to lack of motivation if one partner is resistant to lifestyle change.

Clinical guidelines recommended that functional capacity (fitness) should be assessed prior to starting cardiac rehabilitation and a follow up tests should be carried out after rehabilitation (BACPR 2017). National audit data shows that fitness tests are not always undertaken in participants with low capacity possibly due to a lack of resources (e.g. 10 metre walkways in an area where audio can be heard) or concerns by health professionals about putting patients with HF, many of whom become breathless with mild exertion, under physical stress through an exercise test. Sutherland et al (2018) encourages the 6MWT to be undertaken in routine practice, even in patients with co morbidities and low capacity. The participants in the feasibility study all undertook the ISWT without any adverse effects with some participants reporting feeling more confident after completing the ISWT.

Patient observations around the exercise classes

At the start of the first session all the participants were choosing three on the Borg scale, three on the Borg scale denotes that the exercise effort is comfortable. In the first session the patients were asked to vocalise the effort rating they felt they were using. All of the group said that they felt the exercise was easy. After the session the nurses and fitness instructor spoke together and it was decided that the scores would be better written down not said out loud in case the patients felt they were in competition with each other and perhaps felt a little intimidated. When the scores were written down the group numbers started to vary in following sessions.

The chairs used in the study were commandeered from the department boardroom as the exercise venue had no chairs with arm rests. Although the chairs were all uniform, but the size and shape of the participants varied considerable in terms of girth and leg length which made it difficult to carry out some of the exercises to the quality seen on the DVD. We did manage to source another chair for the participant with very long legs. This does however show that acquiring the right chairs requires planning and extra resources.

As the sessions progressed over the eight weeks the abilities between the participants started to vary at different rates in respect of moving onto the next level of the DVD which did not present a problem in the small groups but may be an issue with larger groups. One option that we tried was for all the participants to move through the levels of exercise at the same time which worked to an extent. A potential problem started to emerge as the sessions progressed it was difficult to separate the differing abilities as not all the group could advance to the next level at the same time. Some participants in a group thought it would have been a step back in their recovery if they could not keep up with the rest of the group, perhaps losing interest in the exercise. Overall the two groups in the feasibility study managed to progress at the same levels which may not be the case with other larger cohorts where the range of fitness is wider.

At the end of every other CBE session discussions took place around their own rationale and attitudes to exercise. Most expressed feelings such as being frightened to undertake exercise in case it brought back or made worse their symptoms of HF. Albert, Forney et al (2015) found after completing their study that patients fear the physical activity related symptoms which to them are reminiscent of decompensated HF, such as dyspnoea, tachycardia as well as a potential negative effect on the physical activity on the heart. Zores, Lliou et al (2019) add that clinicians' removing psychological blocks and false beliefs, encouraging patients to make exercise a part of their daily routine, just like eating a meal or taking a shower can have a massive impact on the patients' behaviour.

Groups

Interestingly when the group first formed the participants were anxious and uncertain about their role in the study group and nervous as to what was expected of them. One member of the group had a strong personality and appeared to take the lead in the group. Sweet, and Michaelson (2007) add this is usual in group formation, as the group matures other group members may seek to define individual roles more clearly it is at this stage conflict may ensue within the group. There was no conflict in the group in fact there was evidence of

supporting each other in sessions and from this a camaraderie became evident (Pereles, Lockyer et al 2002).

Working in a group setting rather than individually appeared to lift morale, mood and demeanour of the group members which visibly improved in the group after two sessions. They reported carrying out jobs around the house and activities they had not done for a long time. Instead of sitting on the sofa they began re engaging in social activities and building up activities, going for regular walks.

There was also playful competition in the group amongst certain members. Although some participants less confident compared themselves to others when their self-regard was already low. The effectiveness of a group depends on the size, a group can be as small as two people to 400 (Schreurs, Van Emmerik et al 2014). Group dynamics involves the influence of personality, power and behaviour (Pereles, Lockyer et al 2002).

In the first instance if participants were unable to keep pace with the rate and quality of the exercises on the DVD the instructor would address the whole group so as not to target an individual. If the issues continued the instructor made subtle gestures in sight of the individual to emphasise the correct movement patterns. There was a sense from the group and staff that coordination visibly improved in all participants throughout the exercise programme. This possibly relates to the quality of the DVD as it incrementally adds higher level coordination tasks with each level.

Some partners and significant others tended to join in, whilst sat down, with a lesser version of the exercise from the side lines. They were made aware that this was at their own risk and if they should have an injury whilst exercising they would not be covered on the hospitals insurance policy. When the study had finished most of the participants and their significant others moved onto exercise at the local council run exercise venue.

The participants felt that the deep breathing (aka belly buster) exercise on the DVD, was very helpful to use in daily life, as it taught them how to breathe more easily especially during bouts of breathlessness that occur during their daily lives. The CBE was designed to avoid breathlessness by only using the primary muscles whilst the remainder of the muscles are at relative rest. In the study breathlessness was not a major feature as participants

gained experience of belly breathing early on as it was introduced at the end of each exercise training session. Participants reported it helped in their daily lives.

All participants were allocated 16 sessions to run twice weekly over an eight week period. Patients with Heart failure tend to have other co morbidities and they can be unstable as the trajectory for heart failure shows (NICOR 2019). They may not be well enough to attend two sessions each week. Cardiac rehabilitation patients tend to generally improve their fitness levels and progress whereas heart failure patient's condition tends to deteriorate over time as they are multifaceted patients with complex needs. They acknowledge that they become more efficient able to carry everyday activities (REACH-HF 2018).

Before the start of the first session of the feasibility study the DVD was played to the participants, and a demonstration given by the nurses and the fitness instructor, so that they knew what to expect at their first session.

The DVD was not given at the end of the sessions as initially planned, due to the fact that the study was testing feasibility of the group based exercise which may highlight any adverse events. Even though the participants had become skilled in using the DVD through the twice weekly sessions and taught to self-pace and self-regulate it was not felt appropriate by the team to give out the DVD. The participants would have to move appropriately between the higher levels of the DVD as they progressed.

Guidelines in the A.C.P.I.C.R (2015) state ratio of patients per staff member in an exercise session with cardiac patients should be 5-1 this guidance is built on expert opinion. The ratio in the study was higher than this as 2 nurses and 1 FI was at every session. Initially it was considered if under taking the feasibility study using the HF team would be safe, as the hospital CR staff were not involved in the study. This was deliberated and it was concluded that it would be safe to deliver the study within the heart failure team as both nurses had previously worked in the CR service so had experience in CR.

Interestingly studies undertaken on centenarians and other long lived individuals found that four common themes emerged for their longevity exercising regularly, maintaining a social network, keeping a positive mental attitude and a healthy lifestyle (Seeman, Berkman et al 1995, and Spirduso, Francis et al 2005). There is growing evidence that regular exercise

reduces the risk of developing many chronic conditions diseases such as cardiovascular, stroke, hypertension, type 2 diabetes, colon cancer, breast cancer the list goes on (Fletcher, Balady et al 2001, Pollock, Franklin et al 2000, Thompson, and Crouse et al 2001). Exercise is also invaluable in treating other conditions including those mentioned plus many others such as anxiety, depression, Osteoarthritis, COPD, Dementia and of course HF (Wojtek, Chodzko et al 2009).

CBE is widely used throughout a multitude of settings, to help engage the less mobile of the population into exercise, perhaps those who are unable to stand, or with mobility problems. However, it is difficult to find a robust evidence base of literature in this area for clinical practice. Interestingly Robinson, Masud et al (2016) under took a piece of work using surveys looking at the use of CBE from the instructors' perspective. The study offers some important insights into how CBE is being utilised (Robinson, Leighton et al 2014). Surveys such as that conducted by Robinson, Masud et al (2016) have shown that CBE should not be a default exercise for all elderly adults and should be targeted at the less mobile population allowing for progression within the group. The findings from the study was based on qualitative exploratory research so cannot objectively determine the health benefits of CBE.

Shoemaker, Oberholtzer et al (2017) highlighted an interesting finding in their study that most research prior and since their work places little focus on participants being ready for behavioural change before they partake in studies. When participants were enrolled into the CBE none of them were asked if they felt ready to commit to behavioural change. It was presumed that as they wished to partake in the study they must have considered the commitment to exercise and lifestyle change. Shoemaker, Oberholtzer et al (2017) also found that the season had an impact in HF patients' ability to exercise. This is definitely true in the HF population in practice as patients' symptoms vary depending on the time of year they tend to be more symptomatic in peak summer and winter months.

Incremental shuttle walk test (ISWT)

The ISWT is used in clinical practice as field test that correlates reasonably well with peak oxygen consumption (fitness), is reliable, are easy to perform (Rostagno, Gensini 2008). Prognosis in HF is strictly related to the severity of impairment of the functional capacity of

the HF patient (Rostagno, Gensini 2008). According to earlier work by Rostagno, Olivio et al (2003) the distance covered during the ISWT is an independent indicator of survival in patients with mild to moderate HF. HF patients that cover less than 300 metres during the walk test have a significantly higher mortality than those that are able to walk further (Rostagno, Olivio et al 2003). Despite the known benefits from assessing fitness in terms of HF prognosis and the prescription of a tailored exercise intervention this is a poorly assessed aspect of pre and post conventional cardiac rehab services (NACR 2018) and even more so in heart failure services where their priority is on optimising medication and trying to reduce symptoms burden. Clinical guidelines recommend assessment yet only a small proportion of eligible heart failure patients are seen for CR and even fewer have a fitness test prior to starting CR (BACPR 2017, Dalal Doherty, Taylor 2015).

The DVD consists of seven levels of exercise, which gradually increase in difficulty, the participant pace themselves throughout. Initially they may not be able to keep up with the DVD, this should improve over time. The first 3 levels all contains seated exercise, Level 1 lasts for approximately 15 minutes and involves warming up and cooling down, using the arm rests for support for some participants this may be all they can achieve. Level 2 lasts for 20mins using alternate arms. Level 3 resting arms on thighs or chair arms lasts for approximately 20minites. Level 4 progresses to a sitting forward position in the chair leading onto a standing near the chair and carryout exercises uses the chair for stability. Lasting for approximately 25 minutes. Level 5 introduces sit to stand exercises moving onto standing exercise lasting 28 minutes. Level 6 included more repetitions and lasted approximately 30 minutes. The final level 7 involved combinations of sitting, sit to stand, and finally standing exercise lasting 38 minutes. From Level 5-7 the arms were gradually held higher to increase the difficulty of the exercises.

Self-Assessment tools

The subjective self-assessment tool chosen for analysing activity and physical fitness was the Dartmouth COOP questionnaires measuring patients QoL, emotional status, level of pain, social support and overall health status (Jenkinson, Mayou et al (2002), (Van Weel, Konig-Zahn et al (2012). The Dartmouth COOP tool has been used routinely in clinical practice so

and is the main QoL measure used by the national audit team (NACR 2018). This measure was completed by half the participants showing a slight improvement in QoL but was not tested for statistical significance due to the very small sample size (N=5).

The study also included Hospital Anxiety and Depression Score (HADS) which is important to measure as it is sensitive to change based on CR interventions and is seen as an associated mechanism to help explain changes in QoL (Rees, Bennett et al 2004, French, and Lewin et al 2005). The HADS scores are based on only 6 patients returning pre and post CBE questionnaires showed average lower scores for both anxiety and depression following the CBE intervention. These findings should be treated with caution and seen as non-generalisable as there was insufficient data to test statistical significance.

Brennan, Warrell-Davies (2010) have suggested a weakness of the HADs Scale in that it does not include any physical symptoms so the ability to detect depression is decreased, although they add that HADs is a good tool to measure distress in non-psychiatric patients. Cosco, Doyle et al (2012) recommend using HADS for measuring emotional distress rather than just anxiety. Supported by Hunt-Shanks, Blanchard et al (2010) they feel that they HAD scale gives a clear brief structure to users and is widely used in the general medical population particularly in cardiovascular patients. Coyne, Van Sonderson (2012). It has been confirmed in the literature that the HADs score is a powerful predictor of one year mortality and morbidity in the evaluation of cardiovascular patients, better than any other scale in use (Doyle, Mc Gee et al 2006, Hunt-Shanks, Blanchard et al 2010). Coyne, Van Sonderson (2012) agree adding this cannot be disputed at this time, it is the tool of choice for the NACR database.

Limitations:

The first limitation was the small sample size, which is too small to be an accurate representative of all eligible HF patients. That, being said the study was testing feasibility of running a group based exercise using a DVD hence it could be argued not compromised by the number of participants enrolled. However, the study intended to recruit 24 participants but due to staffing issues we only managed to recruit 10 participants. Unfortunately, the target number of participants was not achieved as the FI was taken ill and the feasibility study was stopped prematurely. Whilst this highlighted the fact that there was no scope in

the study to cover sickness, the study itself was not looking at numbers enrolled it was focused on the feasibility of undertaking CBE exercise in a group setting using a DVD which was still achieved with low numbers.

It is difficult to say what level of fitness the participants enrolling on a study would be, we found that all but one of the participants were in the low group of exercise. Perhaps with hind sight the cut off point for the low level exercise group should have been lower, to enable two exercise groups to run.

The Borg rating of perceived exertion (RPE), which is recommended as part of clinical guidance (BACPR 2017), was used to measure intensity of exercise which proved challenging for the participants as it was very subjective. Greater emphasis should have been placed on training staff and participants in then use of RPE. Heart rate could have been incorporated more but that too created difficulties related to the use of beta-blockade medications and diuretics which collective alter load on the cardiovascular system through a blunt heart rate response and excessive fluid volume respectively. In some cases, it was difficult to know when to move participants between the levels of the DVD but overall most participants did progress (see table 3). How to progress was discussed with the fitness instructor and nurses before the sessions began, then as a group to see if they felt ready to move to the next level. Some participants may have felt pressure to agree to move to the next level as they would not want to hold their peers back. Time was given at the start of each exercise session so that Individuals had chance to speak to either the nurses or the fitness instructor to discuss progress.

There was a problem at one of the sessions as the electrics shorted and the DVD was unable to be played. Although the electrics were fixed, it highlighted that a hard copy of the exercises were needed as well as an aide memoir.

Before the start of the feasibility study it was considered to use the exercise approach used in practice which tends to be ~~as~~ a rolling programme (i.e. new patients join each session as others leave). Due to participants moving through the CBE programme at a similar pace and the staffing numbers associate with the feasibility study it was considered better to adopt a cohort approach (i.e. same patients from start to finish).

Two participants were unable to complete the 8 week exercise programme, one lady broke her arm (not at the exercise classes), and the second had a chest infection and needed hospital admission. Some of the participants experienced minor muscle soreness in the first couple of sessions, the possibility this had been discussed at the initial consultation.

One limitation that appeared more noticeable was varying abilities became amongst the participants. It was not considered at the start that they would not all progress equally through the programme. To combat this, if one of the participants were struggling one of the nurses would sit with them and reduce the repetitions of the exercise. As long as the group size is around 6 to 8 this was not considered to be a problem going forward. HF patients need to be aware when they have reached their maximum exercise tolerance and accept their limitations.

The time of the exercise sessions may have alienated some of the younger HF patients as many still have to attend work. All of the participants enrolled in the study were retired and able to attend two afternoons a week. Perhaps if the cohort had been broader with younger participants the higher level of exercise may have been reached.

The participants felt that the female on the DVD was very serious and not particularly motivational. This could have been due to the fact that she had to concentrate on many techniques and aspects whilst filming the DVD.

The participants in the study brought in a CD as they felt the music encouraged them to exercise. Johnson, Otto et al (2001) agree that the playing of music especially in older people exercise sessions encourages the older population to engage in the exercise, they found that playing music lessened the feelings of monotony, discomfort and difficulty.

The incremental shuttle walk test was used to assess which level of the DVD the participants would initiate the exercise, in either the low or high group. The participants commented they felt the ISWT was intimidating and felt pressurised and uncomfortable, as though they were competing against the buzzer rather than performing the walk test to the best of their ability. A similar finding was highlighted in the REACH-HF study as participants felt the walk test was an “unpleasant experience” (Lang, C et al 2018).

Adsett, Mullins et al (2011) acknowledge the debate continues in the literature as to the role of the 6MSWT in comparison to measure VO2peak, but due to low cost and ease of use it is the first choice in the clinical setting.

The ISWT entails participants walking along a 10 metre corridor from end to end at participants own pace, aiming to cover as much ground as possible in six minutes. Participants are able to slow down or stop but they must be certain that they could not have walked any further in that 6 minutes when the test ends (Morales, Martinez et al 1998). Carrying out the test twice is recommended to account for any learning which may take place. Some studies have done this within the same week, others within 30 minutes (Alison, Kenny et al 2012). The American Thoracic Society recommend that baseline functional capacity tests be repeated within the space of a week and if carried out on the same day one hour apart. Alison, Kenny et al (2012), It is likely that both the 6MSWT and ISWT when used in the HF population show no learning as the individuals are physiologically close to their maximum exercise capacity whilst undertaking the test. This was the findings in the feasibility study when the ISWT test was completed participants would have been unable to repeat the test.

The appropriate exercise intensity for patients with HF, was achieved by participants undertaking the ISWT, and using the CBE METS table (See Appendix 8). This ensured participants exercised at a therapeutic intensity of 65 to 70% of their maximum capacity.

Data from NACR (2019) showed that around 25% of patients do not complete the full number of sessions in CR programmes, all participants involved in the feasibility study completed all sessions and undertook a post ISWT. Anecdotally patients reported the exercise programme appeared to enhance their efficacy, as they expressed feeling they had control over their HF condition rather than HF controlling them. By attending the exercise programme, they felt more confident to carry out their daily activities. These outcomes were similar to the findings in the REACH-HF (2018), although on a much smaller scale which found some participants' fitness declined, others improved, while the average number of participants stayed the same and showed no improvement in their fitness levels, but efficiency improved. Sabbag, Mazin et al (2018) state the majority of HF patients have more than one comorbidity, and are unlikely to get fitter they tend to become more efficient in everyday life.

Overall, we need to manage our expectations in people with HF, the study has highlighted that the documented NYHA of participants was not necessarily compatible with their exercise ability neither was their age. Although the numbers in the study were small it showed that age and fitness appeared to have no correlation. The participants all managed to complete the 16 sessions over an 8 week period. There were no adverse events recorded during or after the 8 week exercise programme, or hospital admissions.

The participants in the feasibility study undertook therapeutic exercise in a group setting, at the appropriate level to maintain their fitness. The study has shown that older participants enjoy exercising in a group as they gain friendship, camaraderie and overall become more efficient in everyday tasks. Different menus of approaches of exercise are being offered to patients as the NHS long term plan (2019) states. The mode of delivery at present of CR continues to be dominated (80%) by group based exercise with home based CR being taken up by around 10% of patients (NACR 2018).

The methodology was useful in highlighting that the split in two groups should be made at a lower level, as HF patients have lower levels of exercise capacity. The ISWT showed all participants levels of fitness were lower than 5 METS. The study highlighted very early on that a high and low fitness group would not be feasible for use within the HF population. As all the participants except one could not reach the high level, and would be perhaps more suitable in a healthy cohort without any co morbidities. The DVD used was devised by Prof Doherty and has already been through stringent tests, it was also used on the REACH-HF study and was formulated specifically for HF patients (Taylor et al 2018).

The literature search highlighted that older participants enjoy exercising in groups, it also improves quality and quantity of life (Long, Mordi et al 2019). Although different menus of exercise are needed as one type of exercise does not fit all cohorts.

What does it mean for clinical practice?

Overall the feasibility study has shown that group based CBE exercise using a DVD is feasible for NHS CR services, in a group based exercise. Cardiac Rehabilitation can safely be offered

to HF patients in a hospital setting, offering exercise at 65-75% of their maximum without any adverse events, using the CBE programme.

Feasibility studies have an important role to play in the development of clinical practice, as they can highlight early on if there is a need to complete a larger study, or if the results are unfavourable a main study may not be viable (Arain, Campbell et al 2010).

With an ever increasing number of patients living longer and suffering HF symptoms, it has never been more important to access CR (Taylor, Walker 2019). As stated earlier in the study, CR for HF patients is widely recommended by guidelines, NICE CG108 (2010), DOH (2013) more recently superseded by NICE NG106 (2018). Taylor, Walker et al (2019) add it clearly states in the long term plan the greater need for a greater variation in CR programmes. The gap is still evident in the literature for group based exercise. The study could be used for the basis of a service improvement delivery, offering patients CBE in a group setting for HF patients. Going forward it would be interesting to see if a larger study is undertaken into CBE in a group setting

Conrad et al (2017) state there has been a decline HF incidence particularly in patients aged 60-79 years which suggests HF prevention has improved, perhaps due to environmental, public health measures and improvements in clinical care. The work has shown that the profile of patients with HF is complex and forever changing with a tendency towards older age and multiple co-morbidities demonstrating that both prevention and management are becoming more complex. Increasing patients' ability to complete daily tasks cannot be underestimated, a slight increase in exercise tolerance can have the greatest impact on a patient's life living with HF. Perhaps the onus does not need to be on trying to increase fitness levels, instead and especially for those with more severe heart failure (e.g. NYHA Class III & IV) helping patients to become more efficient and productive with the fitness they possess nay be a more appropriate target. Participant feedback during the exercise sessions, as part of this feasibility study, continued to emphasise that the types of exercises on the DVD were very simple and just like the things they do in normal life. This form of specificity (i.e. exercise training aligned with the intended to performance) was a key part of the CBE DVD design which has been shown to yield significant positive changes in QoL (Dalal et al 2020).

The design, implementation and data collection related to this feasibility study pre-dates the coronavirus pandemic and Covid-19 which has now led to a significant reduction in the number of cardiac patients attending hospital following heart attacks or new onset heart failure. The response to Covid-19 has also resulted in a move away from group based exercise which could impact on the extent to which the NHS will engage with hospital group based rehabilitation.

Conclusion

The main aim of this research was to design a study to "evaluate the feasibility of delivering a group based CBE intervention using NHS CR services at the appropriate intensity for patients with heart failure?"

- The study was designed by the student and approved as an acceptable intervention by an NHS ethics committee
- An NHS heart failure service was able to incorporate the study and recruit patients
- Patients were able to carry out the CBE intervention safely without suffering any harm or adverse events
- Baseline and post intervention tests of physical fitness where conducted safely producing data that was able to show a trend towards improvement
- Limitations were recorded so that any future studies or clinical service could benefit from the lessons learnt as part of this study.

Based on the above I would like to conclude that it is indeed feasible to deliver a CBE in a group setting for patients with heart failure. Although the response to Covid-19 has, for now, resulted in a move away from group based exercise, in hospital settings, CBE is a form of group exercise that can be more easily carried out with adherence to social distancing.

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Appendices

Appendix 1: How the idea was formed

First contact was made with the physiotherapy department in the trust, to gauge if any physiotherapist had an interest in HF exercise, unfortunately due to management and service commitments a physiotherapist was not be able to assist. CR teams around the country tend to either have a physios therapist or a BACPR level 4 qualified instructor working with the team.

A meeting was arranged with the CRIG committee group to discuss the venue to be used. Initially the room allocated by the medical business manager at the trust was on a second floor level, lifts and stairs were available. CRIG highlighted from a patient's perspective how unsuitable and difficult it would be to access the second floor room, for the heart failure cohort as many have restricted mobility and can only walk short distances. CRIG pointed out that due to lack of exercise tolerance volunteers and wheelchairs would be needed to assist participants to the exercise room. A visit to the hospital was arranged with CRIG to view the allocated facilities, which concluded that a different location was needed on a ground floor.

Local community and leisure centres were approached for availability, as appropriate disabled access was needed on ground level. Popular belief at the outset was that patients and the leisure centre would benefit from the exercise being held at the local leisure centre. Patients could move away from the hospital setting for their care, and would hopefully become service users after the feasibility study was completed. The manager of the leisure centre agreed, however was not able to waiver the cost of the room so another venue needed to be sourced.

The committee for the hospital social club was approached and the hall was available to be booked twice weekly on a Tuesday and Thursday for a 6 month period. The building was on the hospital grounds and free for staff use, it had appropriate access and was on ground level with hospital parking or access to the hospital shuttle bus.

CRIG also pointed out that the hospital parking is expensive, and if patients are giving up their time freely twice weekly could there be some concession on parking. It was acknowledged as

a valid point, meetings were arranged with the head of research and development in the trust and it was agreed that they would fund the parking fees for all participants involved in the feasibility study. R&D wanted to support its nurses to carry out research and the participants that were giving up their time freely.

CRIG perused all paperwork to be used in the study to gain feedback from both a patient and service user perspective. Medical jargon was highlighted in the participant questionnaires that the lay person may not understand. This was rectified and the questionnaires became more patient and service user friendly.

The switchboard in the trust was visited and resuscitation team notified of the room and days the exercise sessions were to be undertaken. The local ambulance service station was visited by the principal investigator to inform them of the sessions, the information was stored on the computerised system so that no delay would be met if these services were needed.

As well as the support from CRIG, the principle investigator of the study was approached by the local group of Scunthorpe Lyons society, to see if they could provide any equipment for the study. A flat screen TV with DVD player was required and two blood pressure machines and a trolley to carry all the exercise equipment on this was bought by the Lyons. A presentation was arranged for both CRIG and the Lyons to donate the goods and money to the HF team. A publicity photograph was taken and was included in the trust's newsletter and on the hospital hub.

Appendix 2: Literature Search

MEDLINE via OVID

Search date = 3rd May 2019

Results = 168 records

Database: Ovid MEDLINE(R) ALL <1946 to May 01, 2019>

Search Strategy:

---

1 (chair$ adj6 exercis$).ti,ab,kw. (135)

2 chair-assisted exercis$.ti,ab,kw. (1)

3 chair-based exercis$.ti,ab,kw. (13)

4 chair-rising exerci$.ti,ab. (2)

5 chair-sitting exercis$.ti,ab,kw. (1)

6 chair-stand$ exercis$.ti,ab,kw. (1)

7 ED-chair$.ti,ab. (6)

8 resistance chair$.ti,ab,kw. (3)

9 rocking-chair exercis$.ti,ab,kw. (1)

10 ((seated or sitting) adj4 exercis$).ti,ab,kw. (616)

11 seated classes.ti,ab,kw. (2)

12 (chair adj2 yoga).ti,ab,kw. (16)

13 (chair adj2 "tai chi").ti,ab,kw. (0)

14 ((seated or sitting) adj2 yoga).ti,ab,kw. (10)

15 ((seated or sitting) adj2 "tai chi").ti,ab,kw. (11)

16 chair-yoga.ti,ab,kw. (14)

17 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 (768)

18 "Aged, 80 and over"/ or Aged/ (2935537)

19 Middle Aged/ (4105867)

20 Frail Elderly/ (10173)

21 (old adj1 (adult$ or people or person$)).ti,ab,kw. (8068)

22 (older adj1 (adult$ or people or person$)).ti,ab,kw. (98302)

23 (elderly adj1 (adult$ or people or person$)).ti,ab,kw. (29392)

24 (elderly or elder or elders or senior or seniors or veteran or veterans).ti,ab,kw. (305785)

25 (frail adj1 (adult$ or people or person$)).ti,ab,kw. (294)

26 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 (4895950)

27 17 and 26 (335)

28 limit 27 to (english language and yr="2009 -Current") (168)

……

EMBASE via OVID

Search date = 3rd March 2019

Result s= 200

Database: Embase <1996 to 2019 Week 17>

Search Strategy:

---

1 (chair$ adj6 exercis$).ti,ab,kw. (191)

2 chair-assisted exercis$.ti,ab,kw. (1)

3 chair-based exercis$.ti,ab,kw. (18)

4 chair-rising exerci$.ti,ab. (2)

5 chair-sitting exercis$.ti,ab,kw. (3)

6 chair-stand$ exercis$.ti,ab,kw. (2)

7 ED-chair$.ti,ab. (11)

8 resistance chair$.ti,ab,kw. (2)

9 rocking-chair exercis$.ti,ab,kw. (1)

10 ((seated or sitting) adj4 exercis$).ti,ab,kw. (546)

11 seated classes.ti,ab,kw. (2)

12 (chair adj2 yoga).ti,ab,kw. (31)

13 (chair adj2 "tai chi").ti,ab,kw. (1)

14 ((seated or sitting) adj2 yoga).ti,ab,kw. (11)

15 ((seated or sitting) adj2 "tai chi").ti,ab,kw. (15)

16 chair-yoga.ti,ab,kw. (26)

17 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 (769)

18 "Aged, 80 and over"/ or exp Aged/ (2259577)

19 Middle Aged/ (1018123)

20 Frail Elderly/ (8878)

21 (old adj1 (adult$ or people or person$)).ti,ab,kw. (7655)

22 (older adj1 (adult$ or people or person$)).ti,ab,kw. (118513)

23 (elderly adj1 (adult$ or people or person$)).ti,ab,kw. (31306)

24 (elderly or elder or elders or senior or seniors or veteran or veterans).ti,ab,kw. (356747)

25 (frail adj1 (adult$ or people or person$)).ti,ab,kw. (424)

26 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 (2996124)

27 17 and 26 (266)

28 limit 27 to (english language and yr="2009 -Current") (200)

……

CINAHL via EBSCO

Search date = 3rd May 2019

Results = 136 records

S1 TI (chair* N6 exercis*) OR TI "chair-assisted exercis*" OR TI "chair-based exercis*" OR TI "chair-rising exerci*" OR TI "chair-sitting exercis*" OR TI "chair-stand* exercis*" (42)

S2 AB (chair* N6 exercis*) OR AB "chair-assisted exercis*" OR AB "chair-based exercis*" OR AB "chair-rising exerci*" OR AB "chair-sitting exercis*" OR AB "chair-stand* exercis*" (108)

S3 TI ED-chair* OR TI " resistance chair*" OR TI " rocking-chair exercis*" OR TI (((seated or sitting) N4 exercis*)) OR TI " seated classes*" OR TI (chair N2 yoga) OR TI (chair N2 "tai chi") OR TI (((seated or sitting) N2 yoga)) OR TI (((seated or sitting) N2 "tai chi")) OR TI chair-yoga* (92)

S4 AB ED-chair* OR AB " resistance chair*" OR AB " rocking-chair exercis*" OR AB (((seated or sitting) N4 exercis*)) OR AB " seated classes*" OR AB (chair N2 yoga) OR AB (chair N2 "tai chi") OR AB (((seated or sitting) N2 yoga)) OR AB (((seated or sitting) N2 "tai chi")) OR AB chair-yoga* (301)

S5 S1 OR S2 OR S3 OR S4 (452)

S6 (ZG "aged, 80 & over") or (ZG "aged: 65+ years") or (ZG "middle aged: 45-64 years") (9)

S7 (ZU "aged") or (ZU "aged, 80 and over") (417)

S8 (MH "Aged+") OR (MH "Aged, 80 and Over+") (433)

S9 TI (old N1 (adult* or people or person*)) OR TI (older N1 (adult* or people or person*)) OR TI (elderly N1 (adult* or people or person*)) OR TI (elderly or elder or elders or senior or seniors or veteran or veterans) OR TI (frail N1 (adult* or people or person*)) (107,393)

S10 AB (old N1 (adult* or people or person*)) OR AB (older N1 (adult* or people or person*)) OR AB (elderly N1 (adult* or people or person*)) OR AB (elderly or elder or elders or senior or seniors or veteran or veterans) OR AB (frail N1 (adult* or people or person*)) (131,014)

S11 S6 OR S7 OR S8 OR S9 (1,122,628)

S12 S5 AND S11 (203)

S13 S5 AND S11 Limiters - Published Date: 20090101-20191231 (136)

Appendix 3: Patients Participation

Northern Lincolnshire and Goole NHS
NHS Foundation Trust

Participant Information Sheet

1. Feasibility study of a group chair based exercise using a DVD in patients with left ventricular systolic dysfunction.

2. **You are invited to take part in a research study. Before you decide, it is important for you to understand why the research is being carried out and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.**

What is the purpose of the study?
To see if completing a twice weekly exercise programme will improve fitness levels in patients with left ventricular systolic dysfunction over an eight week period.

Depending on the outcome it is hoped that exercise in the heart failure population will become part of routine care given at Scunthorpe General Hospital

Where is the research being conducted?
The research is being conducted at Scunthorpe General Hospital.

Why have I been chosen?
We are asking any patient who has left ventricular systolic dysfunction (Heart failure). Only patients with left sided heart failure will be asked to participate in this study.

What will I be asked to do?
You will be asked to attend a Pre assessment appointment where your blood pressure and pulse will be checked, and an incremental walk test will be undertaken to gauge your fitness level. An incremental walk test is carried out by walking in between two cones which are positioned 10 meters apart. Whilst you are walking a CD will be playing, you will know when to begin because the CD will play a triple bleep then you will start walking. As the test progresses the time you have to reach the next cone is shortened by the bleeps becoming quicker and you will have to reach the cone before the CD makes a bleeping sound. The test ends when you are unable to reach the cone before the bleep sounds. This will be explained in greater detail at the pre-assessment. Your fitness level will decide whether you will be allocated into group one or group two for the seated exercise programme. The exercise will be delivered using a DVD, a qualified fitness instructor and two nurses will also be present throughout the exercise session. You will need to attend twice a week for eight weeks. Each time you arrive for your session, your blood pressure and pulse will be taken to ensure it is safe for you to carry out the exercise. Comfortable clothing should be worn.

After the twice weekly sessions end you will be asked to repeat the incremental walk test to reassess your fitness levels. You will also be asked to fill out several questionnaires regarding your psychological and emotional state which should take less than five minutes. These are the only additional tasks that are required when you participate.

Do I have to take part?
It is up to you to decide whether to take part or not. If you do decide to take part, you will be asked to sign a consent form. This does not mean that you have to continue to take part in the study and you are free to leave at any time without giving a reason.

If you decide not to participate in the study your routine care will not be affected in any way. If you leave the study at any time, your after-care will remain the same and you will still be seen in the outpatient clinic where you will receive usual care.

Is there any possible benefit to me if I take part?
If you complete the 8 week exercise programme we would anticipate that you would experience a slight increase in your exercise tolerance which may result in an improvement in your breathlessness and fatigue. This in turn may result in a slight improvement in your daily activities.

Are there any risks, disadvantages or costs in taking part?

Not that we can for see as you will be working at 70% of your maximum exercise tolerance. The costs of parking will be funded by the trust.

Will the information about me be kept confidential?
Yes. Any information about you will be stored electronically and entries will be coded so that they do not refer to you directly. It is part of our job to make sure that all the information is safe and will only be seen by the doctors and nurses looking after you.
We will ask for your permission to let your GP (family doctor) know that you are participating in this study, but he or she will not have access to the information from your questionnaires without your agreement.

What will happen to the information about me after the study?
Once the study is completed, the results are likely to be published in a medical journal. However, you will not be identifiable as an individual in any of these publications. It is possible to be provided with a copy of the results of this study upon completion if you wish.
You can see the information that we have about you at any time by contacting me at the address below.

Thank you for taking the time to read this information sheet.

If you would like to know any more please contact
Named nurse lead
Scunthorpe General Hospital

Appendix 4: Consent Form

Northern Lincolnshire and Goole NHS
NHS Foundation Trust

CONSENT FORM

Participant Identification Number for this trial:

Feasibility study of chair based exercise using a DVD in patients with left ventricular systolic dysfunction.

Name of Researcher: GB

Please initial box

1. I confirm that I have read and understand the information sheet dated …… (version1) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered to my satisfaction. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason and without my medical care or legal rights being affected. ☐

3. I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from the research and statistician from regulatory Authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐

4. I agree to my GP being informed of my participation in the study. ☐

5. I agree to take part in the above study. ☐

_____	_____	_____
Name of Patient	Date	Signature

_____	_____
_____	
Name of Person taking consent	Date	Signature

When completed: 1 for participant; 1 for researcher site file; 1 (original) to be kept in medical notes.

Version one

Appendix 5: Hospital and Anxiety Depression Scale

Hospital Anxiety and Depression Scale (HADS)

GL assessment
the measure of potential

Name: _____ Date: _____

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 **underline 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		

HADS copyright © R.P. Snaith and A.S. Zigmond, 1983, 1992, 1994.
Record form items originally published in *Acta Psychiatrica Scandinavica*, 67, 361–70,
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Appendix 6: Dartmouth Quality of life

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

Appendix 7: GP letter

Northern Lincolnshire and Goole NHS
NHS Foundation Trust

Dear Dr ……..

Your patient …….DOB……/……/……..

As you are aware your patient has left ventricular systolic dysfunction (LVSD). Nice (2010) state that we should be offering this patient group, exercise. The heart failure team at SGH are conducting a feasibility study whereby patients are offered exercise in a group based setting watching a DVD (the DVD has 7 levels and participants will have a pre assessment including an incremental walk test to highlight their level of fitness before commencing the exercise). Exercise will be prescribed on an individual basis, working patients at 70% of their maximum. There will be two groups, group one participants with a METS of less than 5, above 5METS will be group two. The sessions will run for 8 weeks on a twice weekly basis.

The patient above has been invited to join the study and he / she has consented to take part in the above study.
I enclose a copy of the Patient Information Sheet that was given to your patient prior to consenting to take part in this study.

If you have any specific questions relating to this study please do not hesitate to contact Gill Bromby Heart Failure nurse at Scunthorpe General Hospital. Tel: 01724 290093 .

Yours sincerely

Appendix 8: ISWT CBE

Incremental Shuttle Walk Test (ISWT) levels & MET values						Chair based exercise (CBE)	
ISWT stage	Metres walked	Shuttles 1-102	Speed (mph)	(kph)	METs average	Proposed CBE level *	CBE mean & (peak) METS **
1	10-30	3	1.12	1.8	1.75	One (half)	1.3 (1.5)
2	40-70	4	1.50	2.4	2.15	One (full)	
3	80-120	5	1.88	3.0	2.4	Two	1.6 (1.9)
4	130-180	6	2.26	3.6	2.75	Two	
5	190-250	7	2.64	4.3	3.05	Three	1.8 (2.2)
6	260-330	8	3.02	4.9	3.35	Three	
7	340-420	9	3.40	5.5	3.8	Four	2.5 (3.0)
8	430-520	10	3.78	6.1	4.1	Four	
9	530-630	11	4.16	6.7	4.3	Five	3.2 (3.8)
10	640-750	12	4.54	7.3	4.4	Five	
11	760-880	13	4.92	7.9	4.7	Six	3.5 (4.1)
12	890-1020	14	5.30	8.5	5.0	Six	
						Seven	3.9 (4.5)

**The proposed CBE level would start patients at around 65 to 70% of their ISWT Metabolic Equivalents (METs) score which is an expression of physical fitness.*

*** MET values in this table were derived from direct measurement (Vo2 analysis) of 30 patients with heart failure. MET values in the higher range () were around 10% higher in fitter participants who were able to carry out the CBE movements with greater intensity.*

Appendix 9: General themes and responses from the R&D lead and research panel.

1. Why had 8 weeks been decided for the length of the study?

This length of time was decided on based on the REACH-HF 2018 protocol.

2. The study protocol initially did not define clearly which cohort of HF patients would be included in the study either systolic or Diastolic.

The service offered at present in the main investigator work load is patients with left sided failure HFrEF these will be the participants enrolled into the study.

3. Throughout the research proposal abbreviations were used but no abbreviation page was included.

An abbreviation page has now been added.

4. It was not clear in this first document who would approach the participants for the study, so they would not feel compelled to take part i.e. a neutral person should approach them.

The participants would be approached by the site investigator, to avoid any bias or cohesion.

5. The researchers' role is not clear in the recruitment of the participants.

This was addressed the main investigator had no part in the enrolment of the participants this was solely undertaken by the site investigator.

6. May be helpful to state the participants will not be cold called and that patients opted in.

The participants were not "cold called" they were approached in the clinic sessions and made aware of the study, it was their choice to opt in.

7. How long will the recruitment period take?

Recruitment period was 4 months.

8. How will you know if the participants MET capability has changed to move between groups?

The participants exercise tolerance will hopefully improve during the sessions, depending on the RPE score and the overall observations a decision will be made to either move or leave the participants at the level they are on by the FI and the nurses. Some participants may be moved to the next level only to find that they need to move back down.

9. Do participants have to meet all the inclusion criteria?

YES the participants will have to meet the whole inclusion criteria.

10. Would any participants be included with implantable devices should this be in the exclusion list?

Patients with devices are now encouraged to exercise and would definitely not be excluded from the study, they would be encouraged. Practice has changed nationally.

11. Will the participants' information sheet be pre checked by a service user group?

A service user group CRIG was used throughout the study to gain a service users perspective on all aspects of the study.

12. Will the participants be compensated for time, parking and travel as they are being asked to attend twice a week for eight weeks plus pre assessments?

Good point, this was also highlighted by CRIG they too felt that patients are giving up their time and they should be compensated. The R&D department in the trust agreed to fund the parking fees for the duration of the study. There was also a shuttle but which ran every 20 minutes which the participants could access as most had blue badges this service was free.

13. Do participants receive usual care? Will they be denied access to normal cardiac rehabilitation this is not explained.

In the study area there is no routine CR for HF patients, this is one of the main reasons for the study to be undertaken. Usual care is access to the HF team.

14. Need to explain that the baseline assessments are standard and part of usual CR care.

The baseline assessments undertaken are part of usual CR monitoring and cardiac care.

15. Where is the 'mobility sensitive' hospital venue? What does mobility sensitive mean?

Mobility sensitive was used to mean that the area in the hospital would have to take into account participants with poor mobility it was not a good use of grammar and was changed.

16. How will the participants' safety during exercise be monitored.

Safety was a main issue which was monitored by participants being prescribed exercise at 65-70% of their maximum ability. The exercise was overseen by a FI and two senior nurses. Participants were asked throughout the exercise to mark their RPE using a Borg scale, so if they were struggling this was highlighted early.

17. Is the DVD designed for participants with HF?

The DVD was devised by Patrick Doherty and has been through stringent measures, it has also been used in the REACH-HF 2017 study. It was devised specifically with HF patents in mind.

18. Why use a DVD why not a taught chair based exercise group.

The DVD is part of the study which is to see if it is feasible to use the DVD in a group rather than one to one as the DVD has previously been used. It is hoped in the future a copy of the DVD will be given for the participants to take home and exercise.

19. Have the cardiac arrest teams been consulted about supporting the research

Yes the cardiac arrest team were aware and on board as was the local ambulance station, in case of any untoward incidents. The room number and location was logged.

20. Is data stored on encrypted NHS computers, and reported data encrypted.

All data was stored in cryptically on computers and memory stick, only the two nurses had access to the passcode. All participants' paper information was kept in a locked cupboard in a room with a pass code on the door.

Appendix 10: Letter from University

THE UNIVERSITY of York

RESEARCH & ENTERPRISE DIRECTORATE
Innovation Centre
York Science Park
Heslington
York, YO10 5DG

Contracts and Sponsorship Manager:
Dr Michael Barber
Telephone +44 1(0)1904 435154
Email [redacted]

14 October 2016

To whom it may concern,

Project title:	**Feasibility of a Chair Based Exercise Approach in Patients with Systolic Heart Failure**
Chief Investigator	**Professor Patrick Doherty**

The University of York confirms that it is the Sponsor of this Project within the meaning of the Research Governance Framework for Health and Social Care (Second edition, April 2005) and that it has fulfilled or will fulfil the following responsibilities:

- Putting and keeping in place arrangements for initiation and management and funding of the Project;
- Satisfying itself that the research protocol respects the dignity, rights, safety and well-being of participants and the relationship with care professionals;
- Satisfying itself that the research protocol has been appropriately peer reviewed and is of satisfactory scientific quality;
- Satisfying itself that the Chief Investigator has the knowledge and experience to lead the research team, and that he/she understands and is able to discharge his/her responsibilities under the Research Governance Framework for Health and Social Care.
- Satisfying itself that the Project will be conducted in an environment with the organisational support required to promote quality research, including data protection arrangements and access to data analysis facilities;
- Satisfying itself that the Project has ethical approval before it begins;
- Satisfying itself that arrangements will be kept in place for monitoring and reporting on the research, including prompt reporting of suspected serious adverse incidents;
- Ensuring the research complies with the law;
- Ensuring that there are in place insurance arrangements that cover negligent harm as appropriate for the Project.

Yours sincerely,

Signed: Dr Michael Barber
Sponsor's Representative

Appendix 11: University letter of insurance

HENDERSON
INSURANCE BROKERS

Henderson Insurance Brokers Limited
Trueman House
Capitol Park
Leeds
LS27 0TS

Tel 0113 393 6300
Fax 0113 393 6363

www.hibl.co.uk

18 July 2016

To Whom it May Concern

Dear Sirs,

EVIDENCE OF INSURANCE – The University of York &/or Subsidiary Companies

We are writing to confirm that we act as Insurance Brokers to the above client and that we have arranged liability insurance on their behalf as detailed below:

EMPLOYERS LIABILITY

Cover in respect of indemnity for claims made for death, injury or disease to any person arising out of and in the course of their employment.

INSURER	:	Allianz Insurance plc
POLICY NUMBER	:	SZ/24961353
PERIOD OF INSURANCE	:	1st August 2016 – 31st July 2017
LIMIT OF INDEMNITY	:	£25,000,000 each occurrence including costs and expenses

PUBLIC/PRODUCTS LIABILITY

Indemnity in respect of claims made for death, injury or disease to persons (other than employees) or loss or damage to third party property arising out of and in the course of the business.

PRIMARY INSURER	:	Allianz Insurance plc
POLICY NUMBER	:	SZ/24961353
PERIOD OF INSURANCE	:	1st August 2016 – 31st July 2017
LIMIT OF INDEMNITY	:	£25,000,000 each occurrence (and in the aggregate in respect of Products Liability) – provided by Primary Policy and Excess Layer cover

PROFESSIONAL INDEMNITY

Indemnity in respect of the Legal Liability to Third Parties for breach of professional duty due to negligent act, error or omission in connection with your business.

INSURER	:	Royal & Sun Alliance
POLICY NUMBER	:	RTT271525
PERIOD OF INSURANCE	:	1st August 2016 – 31st July 2017
LIMIT OF INDEMNITY	:	£10,000,000 each occurrence and in the aggregate £1,000,000 in the aggregate in respect of Pollution

Appendix 12: Chair based exercise DVD questionnaire

Northern Lincolnshire and Goole NHS
NHS Foundation Trust

CHAIR BASED EXERCISE DVD QUESTIONNAIRE

This is a short survey to ask your opinion about the DVD exercise sessions you have undertaken at the hospital. This will help us decide if this is something that other patients may benefit from.

Please place a circle around the Yes or No response in the following questions:

21. Were the DVD exercises clear on your screen? Yes or No

2. Were the exercises easy to follow? Yes or No

3. When you were watching the DVD how useful were the following:

	Please place a circle around the number				
	Not useful				Very useful
Voice over	1	2	3	4	5
Number of repetitions on the screen	1	2	3	4	5
Exercise name on the screen	1	2	3	4	5

4. Were the speed and pace of the exercise: Too slow Just right Too fast

5. Were any exercises uncomfortable or painful? Yes or No

If yes please state which level of the DVD exercise: 1 2 3 4 5 6 or 7

6. What was the most difficult thing for you in performing the exercises?

In your own words: ……..

7. What was the most rewarding thing for you in performing the exercises?

In your own words: ……..

8. Would you recommend this DVD exercise approach to other patients?

Yes or No

Summary Feedback from Questionnaire

1. All the participants felt that the exercise DVD exercises were clear on the screen**.**

2. They felt that the exercises were easy to follow, but that was because they felt supported by the nurses and FI.

3. Overall all participants felt that the voice over was helpful on the DVD. The repetitions in most cases was at the correct level. But participants felt it as helpful to work with alongside the nurse or the FI.

4. The exercise speed was at the right pace.

5. Some of the participants mentioned that they had some soreness to their muscles, but they realised that they had not attempted any formal exercise in their day to day lives

6. Some participants expressed finding it difficult to stand during some of the exercise. They were given the option to sit down but preferred to stand like their group members.

7. Participants expressed feeling -

   ” in control of the heart failure, not the heart failure controlling them”.
   “Part of a group of people who actually understood what living with heart failure is like”
   “Exercise helped with mobility”
   “Comradeship, with others”
   “Relative ease when standing from a seated position”

8. All participants said they would recommend the DVD approach to other patients.

Appendix 13: HRA approval information sheet

Ms Gill Bromby
51 Ogilvy Drive
Scunthorpe
DN17 2PW

Email: hra.approval@nhs.net

25 January 2017

Dear Ms Bromby

Letter of HRA Approval

Study title:	**Feasibility of a chair based exercise approach in patients with systolic heart failure.**
IRAS project ID:	**181067**
REC reference:	**16/LO/2184**
Sponsor	**University of York**

I am pleased to confirm that **HRA Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.
- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

It is critical that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details

and further information about working with the research management function for each organisation can be accessed from www.hra.nhs.uk/hra-approval.

Appendices

The HRA Approval letter contains the following appendices:

- A – List of documents reviewed during HRA assessment
- B – Summary of HRA assessment

After HRA Approval

The document *"After Ethical Review – guidance for sponsors and investigators"*, issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

In addition to the guidance in the above, please note the following:

- HRA Approval applies for the duration of your REC favourable opinion, unless otherwise notified in writing by the HRA.
- Substantial amendments should be submitted directly to the Research Ethics Committee, as detailed in the *After Ethical Review* document. Non-substantial amendments should be submitted for review by the HRA using the form provided on the HRA website, and emailed to hra.amendments@nhs.net.
- The HRA will categorise amendments (substantial and non-substantial) and issue confirmation of continued HRA Approval. Further details can be found on the HRA website.

Scope

HRA Approval provides an approval for research involving patients or staff in NHS organisations in England.

If your study involves NHS organisations in other countries in the UK, please contact the relevant national coordinating functions for support and advice. Further information can be found at http://www.hra.nhs.uk/resources/applying-for-reviews/nhs-hsc-rd-review/.

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please email the HRA at hra.approval@nhs.net. Additionally, one of our staff would be happy to call and discuss your experience of HRA Approval.

HRA Training

We are pleased to welcome researchers and research management staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

Your IRAS project ID is **181067**. Please quote this on all correspondence.

Yours sincerely

Thomas Fairman
HRA Assessor

Email: hra.approval@nhs.net

Copy to: *Professor Patrick Doherty, University of York,*
(Chief Investigator and Sponsor Contact)
Ms Eleanor Parker, Northern Lincolnshire and Goole NHS Foundation Trust
(Lead NHS R&D Contact)

IRAS project ID	181067

Appendix A - List of Documents

The final document set assessed and approved by HRA Approval is listed below.

Document	*Version*	*Date*
GP/consultant information sheets or letters [GP Letter]	1	25 October 2016
IRAS Application Form [IRAS_Form_13122016]		13 December 2016
Letter from sponsor [Sponsor letter]		
Non-validated questionnaire [DVD questionnaire]	1	25 October 2016
Other [Louise Gore CV]		
Other [University Insurance letter]		
Other [Letter from NLaGFT]		26 October 2016
Participant consent form [Consent form]	1	25 October 2016
Participant information sheet (PIS) [P.I.S.]	1	25 October 2016
Research protocol or project proposal [Protocol]	1	28 April 2016
Summary CV for Chief Investigator (CI) [C.I./Uni supervisor CV - Prof Doherty]		
Summary CV for student [Gill Bromby's CV]		
Validated questionnaire [Dartmouth Co-op & HADS questionnaire]	1	

IRAS project ID	181067

Appendix B - Summary of HRA Assessment

This appendix provides assurance to you, the sponsor and the NHS in England that the study, as reviewed for HRA Approval, is compliant with relevant standards. It also provides information and clarification, where appropriate, to participating NHS organisations in England to assist in assessing and arranging capacity and capability.

For information on how the sponsor should be working with participating NHS organisations in England, please refer to the *participating NHS organisations, capacity and capability* and *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* sections in this appendix.

The following person is the sponsor contact for the purpose of addressing participating organisation questions relating to the study:

Name: Professor Patrick Doherty
Tel: 01904321393
Email: patrick.doherty@york.ac.uk

HRA assessment criteria

Section	HRA Assessment Criteria	Compliant with Standards	Comments
1.1	IRAS application completed correctly	Yes	No comments
2.1	Participant information/consent documents and consent process	Yes	No comments
3.1	Protocol assessment	Yes	No comments
4.1	Allocation of responsibilities and rights are agreed and documented	Yes	This is a non-commercial single site study taking place in the NHS where that single participating NHS organisation has confirmed that no study agreements are required. If this study is subsequently extended to other NHS organisation(s) in England, an amendment should be submitted to the HRA, with a Statement of Activities

IRAS project ID	181067

Section	HRA Assessment Criteria	Compliant with Standards	Comments
			and Schedule of Events for the newly participating NHS organisation(s) in England.
4.2	Insurance/indemnity arrangements assessed	Yes	Where applicable, independent contractors (e.g. General Practitioners) should ensure that the professional indemnity provided by their medical defence organisation covers the activities expected of them for this research study
4.3	Financial arrangements assessed	Yes	No application for external funding has been made. No study funding will be provided to sites.
5.1	Compliance with the Data Protection Act and data security issues assessed	Yes	No comments
5.2	CTIMPS – Arrangements for compliance with the Clinical Trials Regulations assessed	Not Applicable	No comments
5.3	Compliance with any applicable laws or regulations	Yes	No comments
6.1	NHS Research Ethics Committee favourable opinion received for applicable studies	Yes	REC Favourable Opinion was issued by the City and East Research Ethics Committee on the 12th January 2017. Amended documents were submitted on by the researchers to comply with HRA Approval standards. These were classified by the sponsor as a non-substantial amendment.
6.2	CTIMPS – Clinical Trials Authorisation (CTA) letter received	Not Applicable	No comments
6.3	Devices – MHRA notice of no objection received	Not Applicable	No comments

IRAS project ID	181067

Section	HRA Assessment Criteria	Compliant with Standards	Comments
6.4	Other regulatory approvals and authorisations received	Not Applicable	No comments

Participating NHS Organisations in England

This provides detail on the types of participating NHS organisations in the study and a statement as to whether the activities at all organisations are the same or different.
All participating NHS organisations will undertake the same study activities. There is therefore only one study site 'type' involved in the research. The Chief Investigator or sponsor should share relevant study documents with participating NHS organisations in England in order to put arrangements in place to deliver the study. The documents should be sent to both the local study team, where applicable, and the office providing the research management function at the participating organisation. For NIHR CRN Portfolio studies, the Local LCRN contact should also be copied into this correspondence. For further guidance on working with participating NHS organisations please see the HRA website. If chief investigators, sponsors or principal investigators are asked to complete site level forms for participating NHS organisations in England which are not provided in IRAS or on the HRA website, the chief investigator, sponsor or principal investigator should notify the HRA immediately at hra.approval@nhs.net. The HRA will work with these organisations to achieve a consistent approach to information provision.

Confirmation of Capacity and Capability

This describes whether formal confirmation of capacity and capability is expected from participating NHS organisations in England.
NHS organisations in England that are participating in the study **will be expected to formally confirm their capacity and capability** to host this research. • Following issue of this letter, participating NHS organisations in England may now confirm to the sponsor their capacity and capability to host this research, when ready to do so. How capacity and capacity will be confirmed is detailed in the Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria) section of this appendix. • The Assessing, Arranging, and Confirming document on the HRA website provides further information for the sponsor and NHS organisations on assessing, arranging and confirming capacity and capability.

Principal Investigator Suitability

This confirms whether the sponsor position on whether a PI, LC or neither should be in place is correct for each type of participating NHS organisation in England and the minimum expectations for education, training and experience that PIs should meet (where applicable).

IRAS project ID	181067

A Principal Investigator should be appointed at study sites.

GCP training is not a generic training expectation, in line with the HRA statement on training expectations.

HR Good Practice Resource Pack Expectations

This confirms the HR Good Practice Resource Pack expectations for the study and the pre-engagement checks that should and should not be undertaken

As a non-commercial study undertaken by local staff, it is unlikely that letters of access or honorary research contracts will be applicable, except where local network staff employed by another Trust (or University) are involved (and then it is likely that arrangements are already in place). Where arrangements are not already in place, network staff (or similar) undertaking any of the research activities listed in A18 or A19 of the IRAS form (except for administration of questionnaires or surveys), would be expected to obtain an honorary research contract from one NHS organisation (if university employed), followed by Letters of Access for subsequent organisations. This would be on the basis of a Research Passport (if university employed) or an NHS to NHS confirmation of pre-engagement checks letter (if NHS employed). These should confirm enhanced DBS checks, including appropriate barred list checks, and occupational health clearance. For research team members only administering questionnaires or surveys, a Letter of Access based on standard DBS checks and occupational health clearance would be appropriate.

Other Information to Aid Study Set-up

This details any other information that may be helpful to sponsors and participating NHS organisations in England to aid study set-up.

The applicant has indicated that they do not intend to apply for inclusion on the NIHR CRN Portfolio.

Appendix 14: NLAG letter

Northern Lincolnshire and Goole NHS
NHS Foundation Trust

Research & Development
Northern Lincolnshire & Goole
NHS Foundation Trust
Tel: 01724 – 290410

NHS RESEARCH APPROVAL LETTER

30th January 2017

Mrs Gill Bromby
Heart Failure Nurse
Northern Lincolnshire & Goole NHS Foundation Trust
Scunthorpe General Hospital

Dear Mrs Bromby

Re: Feasibility of a chair based exercise approach in patients with systolic heart failure

REC reference number: 16/LO/2184
IRAS number: 181067

Further to the Health Research Authority (HRA) approval of which the Trust has been informed, I can confirm that capacity and capability to deliver the study in the Trust have been checked, all necessary preparations have been made and the trial can now begin recruiting participants.

PLEASE ALLOW ME TO REMIND YOU; we are now required to work toward the National Institute of Health Research (NIHR) target of recruiting the first participant into studies within 30 days after Trust approval has been issued. Therefore can you please inform the Research & Development Department once you have recruited the first participant in to this study.

Please also inform the Research & Development department where you have been unable to meet or that you anticipate problems meeting the target as soon as possible.

As a provider of NHS services we need to collect figures on the above timeline and we are expected to submit those figures to the NIHR and in addition need to publish this data on our Trust website.

Failing to meet these requirements (submission and publication) could result in the NIHR withholding funding from the Trust.

Please note that the trial must be conducted in accordance with the approved protocol, the Clinical Trial Regulations and the applicable Standard Operating Procedures. You should have discussed these matters during Site Initiation but if you are in any doubt or need any other information regarding this, please do not hesitate to contact the Trust Research & Development Department.

THE FINAL LIST OF DOCUMENTS APPROVED BY THE TRUST ARE AS FOLLOWS:

DOCUMENT	*VERSION*	*DATE*
Protocol	**1**	**28 April 2016**
GP letter	**1**	**25 October 2016**
Participant Information Sheet	**2**	**9 January 2017**
Consent Form	**1**	**25 October 2016**
DVD questionnaire	**1**	**25 October 2016**
Dartmouth Co-op &amp questionnaire	**1**	
HADS questionnaire	**1**	

May I wish you every success with the trial.

Kind regards

M. Hood

Mrs Marion Hood
Research Management and Governance Manager
Northern Lincolnshire & Goole NHS Foundation Trust

CC: Professor P Doherty

Appendix 15: CRIGs Comments

The first Meeting with CRIG back in January 2016 some of their comments were captured as to what CR means to them. Caught on Dictaphone their thoughts on supporting the CBE. It was very clear speaking to them that they supported any kind of CR whole heartedly.

Comments;

“CR important part of treatment”.

“No amount of medications can make you better but CR can”.

“As a group we would not know each other without CR”.

“CR gave back our confidence”

“Me and thee on borrowed time lets enjoy it”.

“Doctors put us back together CR allow us a reason to live”

Appendix 16: IRAS form

IRAS Form | Reference: 16/Io/2184 | IRAS Version 5.3.2

Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

Please enter a short title for this project (maximum 70 characters)
Chair based exercise in patients with heart failure v1

1. Is your project research?

(●) Yes ( ) No

2. Select one category from the list below:

( ) Clinical trial of an investigational medicinal product
( ) Clinical investigation or other study of a medical device
( ) Combined trial of an investigational medicinal product and an investigational medical device
( ) Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice
( ) Basic science study involving procedures with human participants
(●) Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
( ) Study involving qualitative methods only
( ) Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)
( ) Study limited to working with data (specific project only)
( ) Research tissue bank
( ) Research database

If your work does not fit any of these categories, select the option below:

( ) Other study

2a. Please answer the following question(s):

a) Does the study involve the use of any ionising radiation? ( ) Yes (●) No
b) Will you be taking new human tissue samples (or other human biological samples)? ( ) Yes (●) No
c) Will you be using existing human tissue samples (or other human biological samples)? ( ) Yes (●) No

3. In which countries of the UK will the research sites be located? *(Tick all that apply)*

☑ England
☐ Scotland

☐ Wales
☐ Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

◉ England
◯ Scotland
◯ Wales
◯ Northern Ireland
◯ This study does not involve the NHS

4. Which applications do you require?

IMPORTANT: If your project is taking place in the NHS and is led from England select 'IRAS Form'. If your project is led from Northern Ireland, Scotland or Wales select 'NHS/HSC Research and Development Offices' and/or relevant Research Ethics Committee applications, as appropriate.

☑ IRAS Form
☐ Confidentiality Advisory Group (CAG)
☐ National Offender Management Service (NOMS) (Prisons & Probation)

For NHS/HSC R&D Offices in Northern Ireland, Scotland and Wales the CI must create NHS/HSC Site Specific Information forms, for each site, in addition to the study wide forms, and transfer them to the PIs or local collaborators.

For participating NHS organisations in England different arrangements apply for the provision of site specific information. Refer to IRAS Help for more information.

Most research projects require review by a REC within the UK Health Departments' Research Ethics Service. Is your study exempt from REC review?

◯ Yes ◉ No

5. Will any research sites in this study be NHS organisations?

◉ Yes ◯ No

5a. Are all the research costs and infrastructure costs (funding for the support and facilities needed to carry out research e.g. NHS Support costs) for this study provided by a NIHR Biomedical Research Centre, NIHR Biomedical Research Unit, NIHR Collaboration for Leadership in Health Research and Care (CLAHRC), NIHR Patient Safety Translational Research Centre or a Diagnostic Evidence Co-operative in all study sites?

Please see information button for further details.

◯ Yes ◉ No

Please see information button for further details.

5b. Do you wish to make an application for the study to be considered for NIHR Clinical Research Network (CRN) Support and inclusion in the NIHR Clinical Research Network Portfolio?

Please see information button for further details.

◯ Yes ◉ No

The NIHR Clinical Research Network provides researchers with the practical support they need to make clinical studies happen in the NHS e.g. by providing access to the people and facilities needed to carry out research "on the ground".

If you select yes to this question, you must complete a NIHR Clinical Research Network (CRN) Portfolio Application Form (PAF) immediately after completing this project filter question and before submitting other applications. Failing to complete the PAF ahead of other applications e.g. HRA Approval, may mean that you will be unable to access NIHR CRN Support for your study.

6. Do you plan to include any participants who are children?

○ Yes ◉ No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

○ Yes ◉ No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the Confidentiality Advisory Group to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

○ Yes ◉ No

9. Is the study or any part of it being undertaken as an educational project?

◉ Yes ○ No

Please describe briefly the involvement of the student(s):
Undertaking the study

9a. Is the project being undertaken in part fulfilment of a PhD or other doctorate?

○ Yes ◉ No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

○ Yes ◉ No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

○ Yes ◉ No

Integrated Research Application System
Application Form for Research administering questionnaires/interviews for quantitative analysis or mixed methodology study

IRAS Form (project information)

Please refer to the E-Submission and Checklist tabs for instructions on submitting this application.

The student should complete this form on behalf of the Chief Investigator. Guidance on the questions is available wherever you see this symbol displayed. We recommend reading the guidance first. The complete guidance and a glossary are available by selecting Help.

Please define any terms or acronyms that might not be familar to lay reviewers of the application.

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
Chair based exercise in patients with heart failure v1

Please complete these details after you have booked the REC application for review.

REC Name:
South east coast-Surrey

REC Reference Number:
16/lo/2184

Submission date:
28/11/2016

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:

Feasibility of a chair based exercise approach in patients with systolic heart failure.

A2-1. Educational projects

Name and contact details of student(s):

Student 1

Title	Forename/Initials	Surname
Ms	Gill	Bromby

Address

Post Code
E-mail
Telephone
Fax

Give details of the educational course or degree for which this research is being undertaken:
Name and level of course/ degree:

Masters in philosophy (MHIL) Level 7

Name of educational establishment:
York university

Name and contact details of academic supervisor(s):

Academic supervisor 1

	Title	Forename/Initials	Surname
	Professor	Patrick	Doherty
Address	Department of Health Sciences		
	Seebohn Rowntree Building		
	York University		
Post Code	[redacted]		
E-mail	[redacted]		
Telephone	[redacted]		
Fax			

Please state which academic supervisor(s) has responsibility for which student(s):
Please click "Save now" before completing this table. This will ensure that all of the student and academic supervisor details are shown correctly.

Student(s)	Academic supervisor(s)
Student 1 Ms Gill Bromby	☑ Professor Patrick Doherty

A copy of a current CV for the student and the academic supervisor (maximum 2 pages of A4) must be submitted with the application.

A2-2. Who will act as Chief Investigator for this study?

- ○ Student
- ◉ Academic supervisor
- ○ Other

A3-1. Chief Investigator:

	Title	Forename/Initials	Surname
	Prof	Patrick	Doherty
Post	Chair in Cardiovascular Health, Director of the national audit of cardiac rehabilitation, Deputy head of department(Research)		
Qualifications			
Employer	York University		
Work Address	Department of Health Sciences		
	Seebohn Rowntree Building		
	York University		
Post Code	[redacted]		
Work E-mail			
* Personal E-mail			

Work Telephone [redacted]
* Personal Telephone/Mobile
Fax

** This information is optional. It will not be placed in the public domain or disclosed to any other third party without prior consent.*
A copy of a current CV (maximum 2 pages of A4) for the Chief Investigator must be submitted with the application.

A4. Who is the contact on behalf of the sponsor for all correspondence relating to applications for this project?
This contact will receive copies of all correspondence from REC and HRA/R&D reviewers that is sent to the CI.

	Title	Forename/Initials	Surname
	Prof	Patrick	Doherty
Address	Department of health studies		
	Seebohn rowntree building		
	york university		
Post Code	[redacted]		
E-mail			
Telephone			
Fax			

A5-1. Research reference numbers. *Please give any relevant references for your study:*

Applicant's/organisation's own reference number, e.g. R & D (if available):
Sponsor's/protocol number:
Protocol Version: 1
Protocol Date:
Funder's reference number:
Project website:

Additional reference number(s):

Ref.Number Description	Reference Number

Registration of research studies is encouraged wherever possible. You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you have registered your study please give details in the "Additional reference number(s)" section.

A5-2. Is this application linked to a previous study or another current application?

◯ Yes ◉ No

Please give brief details and reference numbers.

2. OVERVIEW OF THE RESEARCH

To provide all the information required by review bodies and research information systems, we ask a number of specific questions. This section invites you to give an overview using language comprehensible to lay reviewers and members of the public. Please read the guidance notes for advice on this section.

- ☐ Epidemiology
- ☑ Feasibility/ pilot study
- ☐ Laboratory study
- ☐ Metanalysis
- ☐ Qualitative research
- ☐ Questionnaire, interview or observation study
- ☐ Randomised controlled trial
- ☐ Other (please specify)

A10. What is the principal research question/objective? *Please put this in language comprehensible to a lay person.*

Is chair based exercise using a DVD in a group setting feasible for patients with left sided heart failure?

A11. What are the secondary research questions/objectives if applicable? *Please put this in language comprehensible to a lay person.*

Is 8 weeks long enough to see changes in fitness and Quality of Life?

Is there an increase in adverse events (such as hospital readmissions) during the intervention period?

A12. What is the scientific justification for the research? *Please put this in language comprehensible to a lay person.*

With an ageing population, more patients surviving MI and developing HF.
The gap in the literature, highlighted by NICE guidance, recommends group based exercise but this is not being taken up by many heart failure patients as shown through the National Audit of Cardiac Rehabilitation (NACR 2015).

This study seeks to test the feasibility of a chair based exercise programme as a potential alternative that may be attractive to patients with lower fitness levels.

This will be the first study to test the feasibility of group based DVD led exercise in this population.

A13. Please summarise your design and methodology. *It should be clear exactly what will happen to the research participant, how many times and in what order. Please complete this section in language comprehensible to the lay person. Do not simply reproduce or refer to the protocol. Further guidance is available in the guidance notes.*

The feasibility study will be undertaken to determine whether chair based exercise (CBE) using a DVD can benefit patients with heart failure, and help reduce symptoms and improve exercise tolerance levels and unscheduled admissions to hospital.

To determine the patients exercise tolerance an incremental walk test will be completed before the exercise programme begins to check the participants fitness. The ISWT gives a measure of distance walked and an estimate of metabolic equivalents (METs) which is an alternative way of expressing the outcomes as a measure of fitness. One MET is defined as the amount of oxygen a person consumes or the energy expended per unit of body weight during 1 minute of rest.
The study will be undertaken using two groups, group one the participants fitness (METs) will be less than 5, group two will be above 5 METs.
A pre assessment will be undertaken to take into account any contraindications or precautions before the study commences.
Baseline observations of the blood pressure and pulse will be taken pre and post exercise.
The patient will rest for 15 mins before commencing the walk test.
The incremental walk test is carried out by the participant walking between two cones which are placed 10 meters apart.
As the participant walks a CD will issue standard prompts. Each time the bleep sounds the participant will increase their speed. The bleep test quickens at the start of each incremental level.
Using the same prompt if the participant is more than 0.5 meters away from the cone when the bleep sounds they will be told they are not going quick enough and to try to make up their pace.

A6-1. Summary of the study. *Please provide a brief summary of the research (maximum 300 words) using language easily understood by lay reviewers and members of the public. Where the research is reviewed by a REC within the UK Health Departments' Research Ethics Service, this summary will be published on the Health Research Authority (HRA) website following the ethical review. Please refer to the question specific guidance for this question.*

NICE (2010) state exercise should be available to the heart failure patients yet few programmes offer such a service. This study will test the feasibility of prescribing appropriate exercise levels in this population and evaluate the influence of an 8 week chair based exercise training programme. This will involve group exercise using a DVD in participants with heart failure.
Prior to the exercise programme participants will undertake an incremental walk test to determine their physical fitness which will be used to (1) split into two groups low and high physical fitness categories and (2) evaluate their progress following the exercise programme. Blood pressure and pulse checks will be carried out at baseline assessment, prior to and following each exercise training session. Anxiety, depression, DVD questionnaire, and quality of life questionnaires will also be administered.
The study will be carried out in a hospital setting. Participants will follow the exercise by watching a DVD, the sessions will be overseen by senior cardiology nurses and a qualified fitness instructor with expertise in cardiac rehab.
All participants with a documented diagnosis left ventricular systolic dysfunction confirmed by echocardiography will be eligible for consideration. The study will run twice weekly for an 8 week period.
If participants exercise levels alter during the 8 weeks they will be able to change between the two groups.
After the twice weekly sessions for an 8 week if the participants ask they will be given a copy of the DVD. The incremental walk test, anxiety and depression and quality of life measures will be repeated at the end of the exercise period.

A6-2. Summary of main issues. *Please summarise the main ethical, legal, or management issues arising from your study and say how you have addressed them.*

Not all studies raise significant issues. Some studies may have straightforward ethical or other issues that can be identified and managed routinely. Others may present significant issues requiring further consideration by a REC, HRA, or other review body (as appropriate to the issue). Studies that present a minimal risk to participants may raise complex organisational or legal issues. You should try to consider all the types of issues that the different reviewers may need to consider.

Representative population: All patients that use the hospital service will be informed about the study and subject to meeting inclusion criteria and giving consent they will become participants in the study. The main inclusion to entry is the diagnosis of stable left side heart failure. Patients with unstable heart failure would be at too high a risk for exercise interventions. Our NHS service does not accept referrals for patients with right sided heart failure.

Risk of harm through exercise: The exercise will be tailored to the ability of participants and they will not be asked to exercise harder than 70% of their maximum effort based on their walk test values. Contra-indication to exercise based on published guidance will inform participant inclusion. In addition the study will be undertaken in a hospital setting with access to the crash team if a problem should arise, oxygen and a defibrillator will be in the room , both senior nursing and a qualified fitness instructor will be in attendance at each session.

Biased sampling and outcomes: The researcher will not invite participants into the study or be involved in the incremental walk tests or questionnaires, an allocated member of the team will do this. Questions about the study will be addressed by other members of the team.
Meaningfulness of the study: A cardiac patient interest group has been consulted from the start of the study to gain their views and comments on the feasibility study.

3. PURPOSE AND DESIGN OF THE RESEARCH

A7. Select the appropriate methodology description for this research. *Please tick all that apply:*

- ☐ Case series/ case note review
- ☐ Case control
- ☑ Cohort observation
- ☐ Controlled trial without randomisation
- ☐ Cross-sectional study
- ☐ Database analysis

They will be observed for untoward signs and symptoms.
The ISWT ends when the participant is more than 0.5 meters away from the cone when the bleep sounds one lap is allowed for the participant to catch up, or if the participant become symptomatic the test will end.
At the end of the test the participant can sit or if they prefer they can stand.

Patient involvement, through the local cardiology patient interest group,has been included from the inception of the study and will be consulted throughout the study.

A cohort of participants both male and female with left ventricular systolic dysfunction will attend twice weekly over an eight week period.
Blood pressure and pulse recordings will be taken before and after the exercise program.

The walk test will be repeated at the end of the 8 weeks.
If patients request a copy of the DVD at the end of the 8 weeks one will be given, if they do not require one than usual care will continue.

A14-1. In which aspects of the research process have you actively involved, or will you involve, patients, service users, and/or their carers, or members of the public?

- [x] Design of the research
- [ ] Management of the research
- [ ] Undertaking the research
- [ ] Analysis of results
- [x] Dissemination of findings
- [ ] None of the above

Give details of involvement, or if none please justify the absence of involvement.
The patient cardiology support group will be involved early on in the design of the study and their opinions sought.

4. RISKS AND ETHICAL ISSUES

RESEARCH PARTICIPANTS

A15. What is the sample group or cohort to be studied in this research?

Select all that apply:

- [ ] Blood
- [ ] Cancer
- [x] Cardiovascular
- [ ] Congenital Disorders
- [ ] Dementias and Neurodegenerative Diseases
- [ ] Diabetes
- [ ] Ear
- [ ] Eye
- [x] Generic Health Relevance
- [ ] Infection
- [ ] Inflammatory and Immune System
- [ ] Injuries and Accidents
- [ ] Mental Health

- [ ] Metabolic and Endocrine
- [ ] Musculoskeletal
- [ ] Neurological
- [ ] Oral and Gastrointestinal
- [ ] Paediatrics
- [ ] Renal and Urogenital
- [ ] Reproductive Health and Childbirth
- [ ] Respiratory
- [ ] Skin
- [ ] Stroke

Gender:	Male and female participants
Lower age limit: 30	Years
Upper age limit: 85	Years

A17-1. Please list the principal inclusion criteria (list the most important, max 5000 characters).

Patients with documented heart failure.
Evidence of heart failure with a recent echo-cardiogram undertaken in the last year.
Stable on medication.
Both male and female participants
Patients aged 30 and above

A17-2. Please list the principal exclusion criteria (list the most important, max 5000 characters).

The following exclusions are based on national guidance for exercise training in patients with cardiac disease which includes the BACPR and ACPICR
Exclusions included:
Unstable Angina
Cognitive impairment
Myocardial infarction (heart attack) in the previous month
Hypertension at rest more than 180 mm Hg systolic and 100 mm Hg diastolic blood pressure.
Recent cardiac related hospital admission in the past two weeks.
De-compensation of heart failure within the last month before commencing the exercise programme.
Introduction of a new medication within a month of starting the exercise programme (up-titration acceptable)
Weight gain of >2kg over two days which has not resolved in the last week
Recent significant deterioration in exercise tolerance or increase in breathlessness
Recent surgery or on the waiting list for significant surgery.
Resting heart rate above 120 BPM.
Acute myocarditis or Pericarditis
Thrombophlebitis
Recent embolism
Acute systemic illness or fever.
Uncontrolled Diabetes.
Significant ischemia at low work rates <2 METS
Progressive worsening of exercise tolerance over the past 2-3 days.
Decrease in systolic blood pressure with exercise.
Supine resting heart rate of >100 bpm
Pre existing significant co-morbidities

Patient notes and patient and or carer communications will be used to verify the existence of the above criteria.

RESEARCH PROCEDURES, RISKS AND BENEFITS

A18. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol. *These include seeking consent, interviews, non-clinical observations and use of questionnaires.*

Please complete the columns for each intervention/procedure as follows:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
3. Average time taken per intervention/procedure (minutes, hours or days)
4. Details of who will conduct the intervention/procedure, and where it will take place.

Intervention or procedure	1	2	3	4
information sheet	1	0	15 mins	Heart failure specialist nurse in the hospital
patient consent	1	0	15mins	Heart failure specialist nurse in the hospital
Shuttle walk test pre/post assessment	3	0	30mins	Heart failure specialist nurse in the hospital
HAD Scale score	2	0	15min	Heart failure specialist nurse in the hospital
Dartmouth CO-OP Score	2	0	15 mins	Heart failure specialist nurse in the hospital
16 Exercise Sessions	16	0	30mins	Heart failure specialist nurse in the hospital
DVD questionnaire	2	0	5 mins	Heart failure specialist nurse in the hospital

A21. How long do you expect each participant to be in the study in total?

12 weeks which will include assessment pre and post the intervention.

A22. What are the potential risks and burdens for research participants and how will you minimise them?

For all studies, describe any potential adverse effects, pain, discomfort, distress, intrusion, inconvenience or changes to lifestyle. Only describe risks or burdens that could occur as a result of participation in the research. Say what steps would be taken to minimise risks and burdens as far as possible.

Inclusion risk

Flare up of condition or adverse reaction due to exercise being too hard. This is minimised by doing the baseline fitness test on all participants and prescribing the exercise intensity based on their ability. If any participants were to experience an exercise related event we have a defibrillator, and oxygen will be available delivered by trained staff. All staff have resuscitation skills. Before the study takes place a meeting will be arranged with the resusitation staff to

inform them of the programme taking place and the room to be used.The crash team will be notified the room and times of exercise so that if there are any eventualities there will be no delays in attending. The team will be contacted by ringing 222 through the operator using a phone in the room.

There could be a perception that inclusion of participants with restricted mobility could lead to discomfort and distress. This will be minimised by the mode of delivery of the exercise (chair based) in a location that is easily accessible for patients with restricted mobility.
Unable to speak English. The Big word will be available or a family or friend may translate. Staff will also grade their language.

Unable to read All participants who need support to get to the room will be met by a meet and greet

Hospital transport will be available, spouses or significant others will be able to accompany participants if they are the designated driver.

Research indicates not all Heart failure patients are very active in a morning.
Sessions will be held in an afternoon so all participants will be able to attend.

A23. Will interviews/ questionnaires or group discussions include topics that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could occur during the study?

◯ Yes ◉ No

A24. What is the potential for benefit to research participants?

Increase fitness, quality of life and physical activity status.
Increased confidence.
Ability to exercise safely and rate their own levels of exertion and help recognise their own limitations.
Improve activities of daily living.

A26. What are the potential risks for the researchers themselves? *(if any)*

Setting up the exercise space with chairs with arm rests. This will be accounted for by following the Trust moving and handling procedures.

RECRUITMENT AND INFORMED CONSENT

In this section we ask you to describe the recruitment procedures for the study. Please give separate details for different study groups where appropriate.

A27-1. How will potential participants, records or samples be identified? Who will carry this out and what resources will be used?*For example, identification may involve a disease register, computerised search of GP records, or review of medical records. Indicate whether this will be done by the direct healthcare team or by researchers acting under arrangements with the responsible care organisation(s).*

The patients who will be approached will be patients already on the Heart Failure nurses caseload by another nurse so they do not feel compelled to take part in the study. As part of routine service delivery when patients attend clinics and consultations they will be made aware of the study at the end of the clinic consultation. They will be given the opportunity to take away an information sheet explaining the study in full, after having the sheet for several days they will also have a contact number which they should ring if they wish to participate. They will be made aware that if they do not want to participate their usual; care will not be affected.
As part of clinic preparation the team check past medical history and reports which will allow them to identify suitable participants based on inclusion and exclusion criteria.

A27-2. Will the identification of potential participants involve reviewing or screening the identifiable personal information of patients, service users or any other person?

◉ Yes ◯ No

Please give details below:
A member of the patient's existing clinical care team will have access to personal data as part of the process of identifying participants.

A27-3. Describe what measures will be taken to ensure there is no breach of any duty of confidentiality owed to patients, service users or any other person in the process of identifying potential participants. *Indicate what steps have been or will be taken to inform patients and service users of the potential use of their records for this purpose. Describe the arrangements to ensure that the wishes of patients and service users regarding access to their records are respected. Please consult the guidance notes on this topic.*

Pseudonyms will be included on the patient questionnaires (Dartmouth and HAD scores).
GP letters only sent to GP with the patients consent.
Fitness instructor will not have access to the patients hospital notes.

A27-4. Will researchers or individuals other than the direct care team have access to identifiable personal information of any potential participants?

○ Yes ◉ No

A28. Will any participants be recruited by publicity through posters, leaflets, adverts or websites?

○ Yes ◉ No

A29. How and by whom will potential participants first be approached?

Potential participants will be approached by an independent team member working within the heart failure service. To reduce subjectivity the above person will be tasked with inviting potential participants into the study,and carry out the incremental walk tests. If the participants have any questions regarding the study a clinical colleague contact name and number will be given available on the information sheet.

A30-1. Will you obtain informed consent from or on behalf of research participants?

◉ Yes ○ No

If you will be obtaining consent from adult participants, please give details of who will take consent and how it will be done, with details of any steps to provide information (a written information sheet, videos, or interactive material). Arrangements for adults unable to consent for themselves should be described separately in Part B Section 6, and for children in Part B Section 7.

If you plan to seek informed consent from vulnerable groups, say how you will ensure that consent is voluntary and fully informed.

Written information sheet.
Consent form
Consent will be gained by another member of the study team.

If you are not obtaining consent, please explain why not.

Please enclose a copy of the information sheet(s) and consent form(s).

A30-2. Will you record informed consent (or advice from consultees) in writing?

◉ Yes ○ No

A31. How long will you allow potential participants to decide whether or not to take part?

- ☐ Social Care Service computers
- ☐ Home or other personal computers
- ☑ University computers
- ☐ Private company computers
- ☐ Laptop computers

Further details:
As the researcher is using this study as part of an MPHIL qualification, some of the data may be shared with The University of York. Data will be handled and analysed by the researcher and strict confidentiality will apply. The Data Protection Act 1998 will be observed throughout this project.

A37. Please describe the physical security arrangements for storage of personal data during the study?

An encrypted memory stick with a password known only to the research team will be used and all paper documents will be stored in a locked filing cupboard at all times. The filing cabinet is in a room with a pin code access.

A38. How will you ensure the confidentiality of personal data? *Please provide a general statement of the policy and procedures for ensuring confidentiality, e.g. anonymisation or pseudonymisation of data.*

Names and addresses will only be used by the clinical care team. The exercise instructor will have access to patient names as part of the delivery of the programme.

A40. Who will have access to participants' personal data during the study? *Where access is by individuals outside the direct care team, please justify and say whether consent will be sought.*

The clinical care team and the investigator will have access to the participants data.

Storage and use of data after the end of the study

A41. Where will the data generated by the study be analysed and by whom?

At York university by Professor Patrick Doherty.

A42. Who will have control of and act as the custodian for the data generated by the study?

	Title	Forename/Initials	Surname
	Ms	Gill	Bromby
Post	Heart Failure Nurse		
Qualifications			
Work Address	Northern Lincolnshire and Goole NHS foundation Trust Cliff Gardens Scunthorpe		
Post Code	[redacted]		
Work Email			
Work Telephone			
Fax			

A43. How long will personal data be stored or accessed after the study has ended?

- ◉ Less than 3 months

A minimum of 48 hours

A33-1. What arrangements have been made for persons who might not adequately understand verbal explanations or written information given in English, or who have special communication needs?*(e.g. translation, use of interpreters)*

Patients whose first language is not English will have the opportunity to have a translator, this will be done by using the Big Word translator on the telephone,
Or a friend or family member may translate for them.

A35. What steps would you take if a participant, who has given informed consent, loses capacity to consent during the study? *Tick one option only.*

- ○ The participant and all identifiable data or tissue collected would be withdrawn from the study. Data or tissue which is not identifiable to the research team may be retained.
- ◉ The participant would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected or any other research procedures carried out on or in relation to the participant.
- ○ The participant would continue to be included in the study.
- ○ Not applicable – informed consent will not be sought from any participants in this research.
- ○ Not applicable – it is not practicable for the research team to monitor capacity and continued capacity will be assumed.

Further details:

The researcher will withdraw any patient, who has given consent, who loses capacity during the study, and any data collected until the patient is withdrawn will be destroyed.

If you plan to retain and make further use of identifiable data/tissue following loss of capacity, you should inform participants about this when seeking their consent initially.

CONFIDENTIALITY

In this section, personal data means any data relating to a participant who could potentially be identified. It includes pseudonymised data capable of being linked to a participant through a unique code number.

Storage and use of personal data during the study

A36. Will you be undertaking any of the following activities at any stage (including in the identification of potential participants)?*(Tick as appropriate)*

- ☐ Access to medical records by those outside the direct healthcare team
- ☐ Access to social care records by those outside the direct social care team
- ☑ Electronic transfer by magnetic or optical media, email or computer networks
- ☐ Sharing of personal data with other organisations
- ☐ Export of personal data outside the EEA
- ☐ Use of personal addresses, postcodes, faxes, emails or telephone numbers
- ☐ Publication of direct quotations from respondents
- ☐ Publication of data that might allow identification of individuals
- ☐ Use of audio/visual recording devices
- ☐ Storage of personal data on any of the following:
  - ☑ Manual files (includes paper or film)
  - ☑ NHS computers

- ◯ 3 – 6 months
- ◯ 6 – 12 months
- ◯ 12 months – 3 years
- ◯ Over 3 years

A44. For how long will you store research data generated by the study?

Years: 5
Months: 0

A45. Please give details of the long term arrangements for storage of research data after the study has ended. *Say where data will be stored, who will have access and the arrangements to ensure security.*

The research data will be kept in a locked cupboard only the investigator will have access. The information will be stored in such a way so that all information will be kept safe and confidentual, and disposed off as per Trust Policy.

INCENTIVES AND PAYMENTS

A46. Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in this research?

◯ Yes ◉ No

A47. Will individual researchers receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research?

◯ Yes ◉ No

A48. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share holding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?

◯ Yes ◉ No

NOTIFICATION OF OTHER PROFESSIONALS

A49-1. Will you inform the participants' General Practitioners (and/or any other health or care professional responsible for their care) that they are taking part in the study?

◉ Yes ◯ No

If Yes, please enclose a copy of the information sheet/letter for the GP/health professional with a version number and date.

A49-2. Will you seek permission from the research participants to inform their GP or other health/ care professional?

◉ Yes ◯ No

It should be made clear in the participant's information sheet if the GP/health professional will be informed.

PUBLICATION AND DISSEMINATION

A50. Will the research be registered on a public database?

◯ Yes ◉ No

Please give details, or justify if not registering the research.
This is a feasibility study in a local trust which is part of an MPhil qualification.

Registration of research studies is encouraged wherever possible.
You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you are aware of a suitable register or other method of publication, please give details. If not, you may indicate that no suitable register exists. Please ensure that you have entered registry reference number(s) in question A5-1.

A51. How do you intend to report and disseminate the results of the study? *Tick as appropriate:*

☑ Peer reviewed scientific journals
☐ Internal report
☑ Conference presentation
☐ Publication on website
☐ Other publication
☐ Submission to regulatory authorities
☐ Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators
☐ No plans to report or disseminate the results
☐ Other (please specify)

A52. If you will be using identifiable personal data, how will you ensure that anonymity will be maintained when publishing the results?

There will be no identifiable data used in any form of publication

A53. Will you inform participants of the results?

◉ Yes ◯ No

Please give details of how you will inform participants or justify if not doing so.
Each participant will be written to individually after the feasibility study has ended. This will relate to the feasibility of the intervention (chair based exercise) within a the heart failure service rather than individual patient performance.

5. Scientific and Statistical Review

A54. How has the scientific quality of the research been assessed? *Tick as appropriate:*

☐ Independent external review
☐ Review within a company
☐ Review within a multi−centre research group
☐ Review within the Chief Investigator's institution or host organisation
☐ Review within the research team
☑ Review by educational supervisor

☐ Other

Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:
The research proposal has been reviewed by the university supervisor and the Trust local research panel.
Also submitted to the Health Sciences Research Governance Committee at the University of York in August 2016.

For all studies except non-doctoral student research, please enclose a copy of any available scientific critique reports, together with any related correspondence.

For non-doctoral student research, please enclose a copy of the assessment from your educational supervisor/ institution.

A56. How have the statistical aspects of the research been reviewed? *Tick as appropriate:*

☐ Review by independent statistician commissioned by funder or sponsor
☐ Other review by independent statistician
☐ Review by company statistician
☐ Review by a statistician within the Chief Investigator's institution
☑ Review by a statistician within the research team or multi−centre group
☑ Review by educational supervisor
☐ Other review by individual with relevant statistical expertise
☐ No review necessary as only frequencies and associations will be assessed – details of statistical input not required

In all cases please give details below of the individual responsible for reviewing the statistical aspects. If advice has been provided in confidence, give details of the department and institution concerned.

	Title Forename/Initials Surname
	Prof Patrick Doherty
Department	Department of Health Sciences
Institution	York University
Work Address	York University
	Department of Health Sciences
	Seebohm Rowntree Building
Post Code	[redacted]
Telephone	
Fax	
Mobile	
E-mail	

Please enclose a copy of any available comments or reports from a statistician.

A57. What is the primary outcome measure for the study?

Is chair based exercise using a DVD, delivered in a group setting, safe and deliverable in patients with heart failure.

A58. What are the secondary outcome measures? *(if any)*

Does completing chair based exercise improve a patient's exercise tolerance as measured through the ISWT.

The number of adverse events such as hospital readmissions HADS and Dartmouth QoL.

A59. What is the sample size for the research? *How many participants/samples/data records do you plan to study in total? If there is more than one group, please give further details below.*

Total UK sample size: 24

Total international sample size (including UK):

Total in European Economic Area:

Further details:
The National Audit of Cardiac Rehab (NACR) 2015 report showed that 3,744 patients with a primary diagnosis of heart failure accessed exercise based rehab. The NACR data shows that average uptake for the cardiac rehabilitation equated to 47% uptake, however the heart failure population is unlikely to achieve this level hence a lower expectation of recruitment for this study is anticipated. For this feasibility study we will recruit patients with a range of exercise capacity (fitness) to cover the two categories of exercise (high and low) in the chair based exercise DVD. We reviewed local service up take to assess the number of potential participants.

A60. How was the sample size decided upon? *If a formal sample size calculation was used, indicate how this was done, giving sufficient information to justify and reproduce the calculation.*

The national audit of cardiac rehabilitation (NACR) 2015 report showed that 3,744 patients with a primary diagnosis of heart failure accessed exercise based rehabilitation nationally. The NACR data shows that average take up for cardiac rehabilitation equated to a 47% uptake, however the heart failure population is unlikely to achieve this level hence a lower expectation of recruitment for this study is anticipated.

Based on local service data for 2014-15 220 patients with left sided heart failure accessed the heart failure service that year. Given a recruitment period of 4 months a 33% recruitment success over 4 months would give us a total of 24 participants (mix of both male and female) would be recruited through the service during the time scale of the study. This assumes a 33% take up from those patients offered exercise, which will give us 12 participants in each of the two exercise categories of low and high fitness. The estimated uptake figure comes from the NHS CVD Outcomes Strategy (2013) which sets an ambition to increase uptake from 4% to 33% minimum patients with heart failure.

A61. Will participants be allocated to groups at random?

◯ Yes ◉ No

A62. Please describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.

Pre and post assessment data using anxiety and depression measures (HADS), walk test (ISWT) and quality of life (Dartmouth Coop tool) will be collected and described using means or median values as appropriate. The sample size derived from this feasibility study is too small to carryout a thorough analysis of pre and post differences but the data will help define future expectations in terms of the differences between pre and post intervention outcome measures and help inform future sample size estimations in this population.

6. MANAGEMENT OF THE RESEARCH

A63. Other key investigators/collaborators. *Please include all grant co−applicants, protocol co−authors and other key members of the Chief Investigator's team, including non-doctoral student researchers.*

	Title	Forename/Initials	Surname
	Ms	Gillian	Bromby
Post	Cardiac Specialist Nurse		
Qualifications			

Employer	Northern Lincolnshire and Goole NHS Foundation Trust
Work Address	Cliff Gardens Scunthorpe North Licolnshire
Post Code	
Telephone	
Fax	
Mobile	
Work Email	

Title	Forename/Initials	Surname
Ms	Louise	Gore

Post	Heart Failure Nurse
Qualifications	
Employer	Northern Lincolnshire and Goole NHS Foundation Trust
Work Address	Cliff Gardens Scunthorpe North Lincolnshire
Post Code	
Telephone	
Fax	
Mobile	
Work Email	

A64. Details of research sponsor(s)

A64-1. Sponsor

Lead Sponsor

Status:
- ○ NHS or HSC care organisation
- ◉ Academic
- ○ Pharmaceutical industry
- ○ Medical device industry
- ○ Local Authority
- ○ Other social care provider (including voluntary sector or private organisation)
- ○ Other

Commercial status: Non-Commercial

If Other, please specify:

Contact person

Name of organisation	University of York
Given name	Karl

Family name	Atkin
Address	Department of Health Sciences
Town/city	Seebohm Rowntree Building
Post code	YO10 5DD
Country	UNITED KINGDOM
Telephone	
Fax	
E-mail	

Is the sponsor based outside the UK?

◯ Yes ◉ No

Under the Research Governance Framework for Health and Social Care, a sponsor outside the UK must appoint a legal representative established in the UK. Please consult the guidance notes.

A65. Has external funding for the research been secured?

☐ Funding secured from one or more funders

☐ External funding application to one or more funders in progress

☑ No application for external funding will be made

What type of research project is this?

◉ Standalone project

◯ Project that is part of a programme grant

◯ Project that is part of a Centre grant

◯ Project that is part of a fellowship/ personal award/ research training award

◯ Other

Other – please state:

A66. Has responsibility for any specific research activities or procedures been delegated to a subcontractor (other than a co-sponsor listed in A64-1) ? *Please give details of subcontractors if applicable.*

◯ Yes ◉ No

A67. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK or another country?

◯ Yes ◉ No

Please provide a copy of the unfavourable opinion letter(s). You should explain in your answer to question A6-2 how the reasons for the unfavourable opinion have been addressed in this application.

A68-1. Give details of the lead NHS R&D contact for this research:

Title	Forename/Initials	Surname
Ms	Eleanor	Parker

Organisation: Northern Lincolnshire and Goole NHS Foundation Trust
Address: R&D Department HYMS Building Flemyng House
Scunthorpe General Hospital
Cliff Gardens, Scunthorpe
Post Code
Work Email
Telephone
Fax
Mobile

Details can be obtained from the NHS R&D Forum website: http://www.rdforum.nhs.uk

A69-1. How long do you expect the study to last in the UK?

Planned start date: 04/01/2017
Planned end date: 04/07/2017
Total duration:
Years: 0 Months: 6 Days: 1

A71-1. Is this study?

- (•) Single centre
- ( ) Multicentre

A71-2. Where will the research take place? *(Tick as appropriate)*

- [x] England
- [ ] Scotland
- [ ] Wales
- [ ] Northern Ireland
- [ ] Other countries in European Economic Area

Total UK sites in study 1

Does this trial involve countries outside the EU?
( ) Yes (•) No

A72. Which organisations in the UK will host the research? *Please indicate the type of organisation by ticking the box and give approximate numbers if known:*

[x] NHS organisations in England	1
[ ] NHS organisations in Wales	
[ ] NHS organisations in Scotland	
[ ] HSC organisations in Northern Ireland	
[ ] GP practices in England	
[ ] GP practices in Wales	
[ ] GP practices in Scotland	

☐ GP practices in Northern Ireland
☐ Joint health and social care agencies (eg community mental health teams)
☐ Local authorities
☐ Phase 1 trial units
☐ Prison establishments
☐ Probation areas
☐ Independent (private or voluntary sector) organisations
☐ Educational establishments
☐ Independent research units
☐ Other (give details)

Total UK sites in study: 1

A73-1. Will potential participants be identified through any organisations other than the research sites listed above?

◯ Yes ◉ No

A74. What arrangements are in place for monitoring and auditing the conduct of the research?

Routine monitoring in line with the Trust requirements for Research Governance. Oversight from the University of York supervisor.

A76. Insurance/ indemnity to meet potential legal liabilities

Note: in this question to NHS indemnity schemes include equivalent schemes provided by Health and Social Care (HSC) in Northern Ireland

A76-1. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research? *Please tick box(es) as applicable.*

Note: Where a NHS organisation has agreed to act as sponsor or co-sponsor, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For all other sponsors, please describe the arrangements and provide evidence.

☐ NHS indemnity scheme will apply (NHS sponsors only)
☑ Other insurance or indemnity arrangements will apply (give details below)

The University of York will be the sponsor for this research study.

Please enclose a copy of relevant documents.

A76-2. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research? *Please tick box(es) as applicable.*

Note: Where researchers with substantive NHS employment contracts have designed the research, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For other protocol authors (e.g. company employees, university members), please describe the arrangements and provide evidence.

☐ NHS indemnity scheme will apply (protocol authors with NHS contracts only)

☑ Other insurance or indemnity arrangements will apply (give details below)

The University of York will be the sponsor for this research study.

Please enclose a copy of relevant documents.

A76-3. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research?

Note: Where the participants are NHS patients, indemnity is provided through the NHS schemes or through professional indemnity. Indicate if this applies to the whole study (there is no need to provide documentary evidence). Where non-NHS sites are to be included in the research, including private practices, please describe the arrangements which will be made at these sites and provide evidence.

☑ NHS indemnity scheme or professional indemnity will apply (participants recruited at NHS sites only)

☐ Research includes non-NHS sites (give details of insurance/ indemnity arrangements for these sites below)

Please enclose a copy of relevant documents.

A78. Could the research lead to the development of a new product/process or the generation of intellectual property?

○ Yes ◉ No ○ Not sure

PART C: Overview of research sites

Please enter details of the host organisations (Local Authority, NHS or other) in the UK that will be responsible for the research sites. *For NHS sites, the host organisation is the Trust or Health Board. Where the research site is a primary care site, e.g. GP practice, please insert the host organisation (PCT or Health Board) in the Institution row and insert the research site (e.g. GP practice) in the Department row.*

Investigator identifier	Research site	Investigator Name
IN2	(●) NHS site ( ) Non-NHS site Country: England Organisation name Address Post Code	Forename Gill Middle name Family name Bromby Email Qualification (MD...) Country

PART D: Declarations

D1. Declaration by Chief Investigator

1. The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.
2. I undertake to abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.
3. If the research is approved I undertake to adhere to the study protocol, the terms of the full application as approved and any conditions set out by review bodies in giving approval.
4. I undertake to notify review bodies of substantial amendments to the protocol or the terms of the approved application, and to seek a favourable opinion from the main REC before implementing the amendment.
5. I undertake to submit annual progress reports setting out the progress of the research, as required by review bodies.
6. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Officer. I understand that I am not permitted to disclose identifiable data to third parties unless the disclosure has the consent of the data subject or, in the case of patient data in England and Wales, the disclosure is covered by the terms of an approval under Section 251 of the NHS Act 2006.
7. I understand that research records/data may be subject to inspection by review bodies for audit purposes if required.
8. I understand that any personal data in this application will be held by review bodies and their operational managers and that this will be managed according to the principles established in the Data Protection Act 1998.
9. I understand that the information contained in this application, any supporting documentation and all correspondence with review bodies or their operational managers relating to the application:
    - Will be held by the REC (where applicable) until at least 3 years after the end of the study; and by NHS R&D offices (where the research requires NHS management permission) in accordance with the NHS Code of Practice on Records Management.
    - May be disclosed to the operational managers of review bodies, or the appointing authority for the REC (where applicable), in order to check that the application has been processed correctly or to investigate any complaint.
    - May be seen by auditors appointed to undertake accreditation of RECs (where applicable).
    - Will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.
    - May be sent by email to REC members.
10. I understand that information relating to this research, including the contact details on this application, may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 1998.
11. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named below. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

Contact point for publication*(Not applicable for R&D Forms)*

NRES would like to include a contact point with the published summary of the study for those wishing to seek further information. We would be grateful if you would indicate one of the contact points below.

◉ Chief Investigator

- ◯ Sponsor
- ◯ Study co-ordinator
- ◯ Student
- ◯ Other – please give details
- ◯ None

Access to application for training purposes *(Not applicable for R&D Forms)*

Optional – please tick as appropriate:

☑ I would be content for members of other RECs to have access to the information in the application in confidence for training purposes. All personal identifiers and references to sponsors, funders and research units would be removed.

Signature: .....

Print Name: Professor P Doherty

Date: *(dd/mm/yyyy)*

D2. Declaration by the sponsor's representative

If there is more than one sponsor, this declaration should be signed on behalf of the co-sponsors by a representative of the lead sponsor named at A64-1.

I confirm that:

1. This research proposal has been discussed with the Chief Investigator and agreement in principle to sponsor the research is in place.

2. Any necessary indemnity or insurance arrangements, as described in question A76, will be in place before this research starts. Insurance or indemnity policies will be renewed for the duration of the study where necessary.

3. Arrangements will be in place before the study starts for the research team to access resources and support to deliver the research as proposed.

4. Arrangements to allocate responsibilities for the management, monitoring and reporting of the research will be in place before the research starts.

5. The duties of sponsors set out in the Research Governance Framework for Health and Social Care will be undertaken in relation to this research.

   Please note: *The declarations below do not form part of the application for approval above. They will not be considered by the Research Ethics Committee.*

6. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named in this application. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

7. Specifically, for submissions to the Research Ethics Committees (RECs) I declare that any and all clinical trials approved by the HRA since 30th September 2013 (as defined on IRAS categories as clinical trials of medicines, devices, combination of medicines and devices or other clinical trials) have been registered on a publically accessible register in compliance with the HRA registration requirements for the UK, or that any deferral granted by the HRA still applies.

Signature: .....

Print Name: Mr K Atkin

D3. Declaration for student projects by academic supervisor(s)

1. I have read and approved both the research proposal and this application. I am satisfied that the scientific content of the research is satisfactory for an educational qualification at this level.

2. I undertake to fulfil the responsibilities of the supervisor for this study as set out in the Research Governance Framework for Health and Social Care.

3. I take responsibility for ensuring that this study is conducted in accordance with the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research, in conjunction with clinical supervisors as appropriate.

4. I take responsibility for ensuring that the applicant is up to date and complies with the requirements of the law and relevant guidelines relating to security and confidentiality of patient and other personal data, in conjunction with clinical supervisors as appropriate.

Academic supervisor 1

This section was signed electronically by Professor Patrick Doherty on 12/12/2016 14:19.

Job Title/Post:	Chair in Cardiovascular Health
Organisation:	University of York
Email:	[redacted]

17: Abbreviations

ACPICR Association of chartered physiotherapists in cardiac rehabilitation

AF Atrial Fibrillation

BACPR British Association of Cardiac Rehabilitation and Prevention

BHF British Heart Failure

CABG Coronary Artery Bypass Graft

CBE Chair Based Exercise

CCBE Consensus chair based exercise

CHD Coronary Heart Disease

COPD Chronic Obstructive Pulmonary Disease

CR Cardiac Rehabilitation

CRIG Cardiac Rehabilitation Interest Group

CVD Cardiovascular Disease

DCM Dilated Cardio Myopathy

DT Dual Therapy

DVD Digital Video Disc

EC Exercise Capacity

FI Fitness Instructor

GCP Good Clinical Practice

HADs Anxiety and Depression Score

HF Heart Failure

HFpEF Heart Failure with Preserved Ejection Fraction

HFrEF Heart Failure with Reduced Ejection Fraction

HRQoL Health Related Quality of Life

HTN Hypertension

IHD Ischemic Heart Disease

ISWT Incremental shuttle Walk Test

LVSD Left Ventricular Systolic Dysfunction

MET Metabolic Equivalent

MI Myocardial Infarction

6MSWT 6 Minute shuttle walk test

NACR National Audit for Cardiac Rehabilitation

NHS National Health Service

NICE National Institute for Health and Clinical Excellence

NICOR National Institute Cardiology Outcomes Research

NIHR National Institute of Health Research

NYHA New York Heart Association

QoL Quality of Life

REACH-HF Rehabilitation Enablement in Chronic Heart failure

WHO World Health Organisation