A Feasibility and Exploratory Study of Cardiac Rehabilitation in Acute Coronary Syndrome

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Declaration

I declare the work in this thesis to be my own, except where stated

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Dedication

To my husband Gordon, my daughter Fiona, my son David and the two mums Jean and Florrie for all their support and to Aunt Joyce, who believed a promise made was a debt unpaid

'Debt paid'

Acknowledgements

I would like to express my gratitude to the men and women who were willing to share their experiences with me and take part in the studies. I would also like to thank my work colleagues within Cardiac Rehabilitation and Heart Failure who have supported me in so many ways. My thanks go to NHS Ayrshire & Arran, who funded my course and to my colleagues within the CHD Managed Clinical Network who supported me through the process. A huge thank you to my supervisors: Professor Kate Niven and Dr Ashley Shepherd, for their time, patience, support and guidance. Lastly, I would like to thank all those closest to me, without whom I would never have made it this far, especially my husband Gordon and my mum Jean, without whose help, I could not have managed over the last ten years.

Abbreviations

ACS	Acute Coronary Syndrome
ACSLT	Acute Coronary Syndrome with Low Troponin
ACC	American College of Cardiology
BACR	British Association of Cardiac Rehabilitation (until 2010)
BACPR	British Association of Cardiac Rehabilitation and Prevention (from 2010)
BBB	Bundle Branch Block
BCS	British Cardiovascular Society
BDI	Becks Depression Inventory
BHF	British Heart Foundation
BMI	Body Mass Index
BP	Blood Pressure
CABG	Coronary Artery Bypass Graft
CHD	Coronary Heart Disease
CKMB	Serum Creatine Kinase MB
CLASP	Cardiac Limitations and Symptoms Profile
CMS	Cardiac Misconception Scale
CR	Cardiac Rehabilitation
CSM	Common Sense Model of Self Regulation
CVD	Cardiovascular Disease
DOH	Department of Health
ECG	Electrocardiograph
ESC	European Society of Cardiology
FT	Fibrinolytic Therapy,

GRACE	Global Registry of Acute Coronary Events
HADS	Hospital Anxiety and Depression Scale
HDL	High Density Lipoprotein
HF	Heart Failure
HRQoL	Health Related Quality of Life
ISD	Information Services Department
JBS	Joint British Societies
LDL	Low Density Lipoprotein
MI	Myocardial Infarction
MRC	Medical Research Council
NICE	National Institute for Health and Clinical Excellence
NSTEMI	Non ST Elevation MI
PCI	Percutaneous Coronary Intervention
PPCI	Primary Percutaneous Coronary Intervention
QLMI	Quality of Life after Myocardial Infarction questionnaire
QoL	Quality of Life
RCT	Randomised Controlled Trial
RUIT	Reconceptualisation of Uncertainty in Illness Theory
SAQ	Seattle Angina Questionnaire
SEHD	Scottish Executive Health Department (until 2007)
SEIQoL-DW	Schedule for the Evaluation of Individual Quality of Life-Direct Weighting
SF36v2	Short Form 36 version 2
SIGN	Scottish Intercollegiate Guideline Network
SGHD	Scottish Government Health Department (from 2007)

STAI	State-Trait Anxiety Inventory
STEMI	ST Elevation MI
UA	Unstable Angina
UK	United Kingdom
WHO	World Health Organisation

Glossary

Acute Coronary Syndrome	A sudden onset of chest pain due to a narrowing or blockage in one of the coronary arteries
Acute Coronary Syndrome with Low Troponin	As above, but with small amounts of damage below the cut off point for MI
Bundle Branch Block	A defect of the heart's electrical system
Cardiovascular disease	This includes Coronary Heart Disease (about 50%), stroke (25%), and all other diseases of the circulatory system
Coronary Artery Bypass Graft	An operation to bypass a section or sections of coronary arteries and improve blood supply to the heart
Coronary Heart Disease	Coronary Heart Disease occurs when the walls of the coronary arteries become narrowed by a gradual build-up of atheroma
Co-morbidity	A state where an individual has two or more diseases

Dyspnoea	Laboured or difficult breathing, otherwise known as breathlessness
Fibrinolytic Therapy	Patients are given a clot dissolving drug which reduces the damage that is caused by a Myocardial Infarction
Heart Failure	This occurs if the heart becomes less efficient at pumping blood around the body due to damage to heart muscle
Hypertension	High blood pressure, systolic blood pressure >140mmHg, diastolic blood pressure > 90mmHg
Incidence	A measure of morbidity based on the number of new episodes of an illness in a population over a period
Myocardial Infarction	Death of heart muscle (myocardium) which follows sudden reduction in or cessation of the flow of blood down the coronary arteries, can be either Non ST Elevation Myocardial Infarction or ST Elevation Myocardial Infarction

Morbidity	A state of being diseased
Mortality	The incidence of death in a population in a given period
Myocardial Ischaemia	Myocardial ischaemia occurs when blood flow to the heart muscle is decreased by a partial or complete blockage of your heart's arteries
Myocardial Necrosis	Death of tissue due to general or local inadequacy of blood supply to the heart muscle
Non ST Elevation Myocardial Infarction	Myocardial Infarction, where all other indicators with the exception of ST elevation are present.
Prevalence	A measure of morbidity based on current sickness in the population at a particular time
Percutaneous Coronary Intervention	Normally includes coronary angioplasty and stenting as an arranged admission

Primary Percutaneous Coronary Intervention	Normally includes coronary angioplasty and stenting as an emergency in the hour following diagnosis of MI
Primary Prevention	The prevention of the development of a condition e.g. CHD, by avoidance of factors known to contribute to its development
Secondary Prevention	In CHD, interventions such as lifestyle changes or drugs aimed at prevention slowing or reversing the progression of the disease
Stable Angina	Term used for angina, which is relatively predictable and the intensity and frequency of which remains similar over long periods
ST Elevation Myocardial Infarction	Myocardial Infarction, where >1mm ST elevation is present on at least two limb leads or >2mm ST elevation is present in chest leads
Troponin T	An enzyme in the blood that can detect amounts of damage to the heart muscle

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Abstract

Background: Cardiac Rehabilitation (CR) has been shown to be effective in reducing mortality and morbidity in Coronary Heart Disease (CHD). There is a limited amount of research that evaluates the impact of menu-based CR, in patients with Acute Coronary Syndrome with Low Troponin levels (ACSLT).

Aim: This thesis contains a feasibility study and an exploratory study. The feasibility study aimed to examine the feasibility of a Randomised Controlled Trial (RCT) which would test the impact of a menu-based CR programme, on individuals diagnosed with ACSLT, against standard care. This feasibility study included staff views. The exploratory study aimed to explore the impact that ACSLT and CR can have on this client group.

Method: The feasibility study was a repeated measures case-control trial of menu-based CR based on the theoretical framework of the Common Sense Model of Self-Regulation (CSM), using a range of health assessments. The areas assessed included misconceptions, symptoms, anxiety, depression and Health Related Quality of Life (HRQoL). In addition, focus groups were held with both ward and specialist CR staff to seek their views on the feasibility of a RCT of menu-based CR for ACSLT.

The exploratory study consisted of description and analysis of the data that had been collected from the participants over the two year period as above. In addition it included qualitative data that had been collected during interviews with the participants.

Findings: Participants (n=33) were recruited from cardiology wards following an admission with ACSLT. They were assessed at baseline (T1), nine months (T3) and 24 months (T4). Twenty-five participants completed the studies. The

feasibility study was successful in its aim of testing the CR intervention and protocols for a further RCT. The intervention was acceptable to the participants and to the specialist staff, although the ward staff did not see the need for a RCT. The measures used, with the exception of the self-reporting measures, were suitable and provided a wide range of data that could be utilised in a RCT. However the changes to diagnostic categories meant that a RCT would no longer be feasible.

The exploratory study found that both groups were similar on a range of baseline demographic and clinical factors. There was a tendency to benefit within the exploratory study which favoured the intervention. An additional finding from the exploratory study was the degree of uncertainty experienced by the participants, within the context of a changing political and clinical landscape.

Discussion and conclusions: The studies presented in this thesis add to our knowledge by highlighting some of the difficulties in designing a RCT of menu-based CR in a specific subgroup of CHD and by presenting outcome data for a small group of participants that have not previously been studied within the literature. This data suggests that there was a tendency to benefit for the intervention that requires further study.

Implications for practice: Patients with ACSLT are now being included in CR programmes due to the changes within the diagnostic criteria. Clinicians have little understanding of the impact of CR on this group of patients, or what type of interventions would work best. Large RCT's will however be problematic and this thesis has highlighted that further work is required to explore how CR can best improve the well-being of individuals with ACSLT.

Chapter One Introduction & overview of thesis

1.1 Introduction

This chapter briefly outlines the rationale for the focus on this area of clinical practice and the organisation of this thesis, which contains: a feasibility study and an exploratory study. The feasibility study aimed to examine the feasibility of a Randomised Controlled Trial (RCT) which would test the impact of a menu-based Cardiac Rehabilitation (CR) programme, on individuals diagnosed with Acute Coronary Syndrome with Low Troponin levels (ACSLT), against standard care. This feasibility study included staff views. The exploratory study aimed to explore the impact that ACSLT and CR can have on this client group.

The research base for ACSLT relates mainly to medical treatment and there has been little attention paid to the impact that CR could have on this group of individuals. This thesis aims to contribute to the body of knowledge regarding CR and ACSLT and to inform future research design and service provision.

1.2 Personal statement

When I applied to start this clinical doctorate, I was asked a question about the gap between research and practice and how did I think it could be altered. The original answer I gave is lost in the mist of years of study. However this concept of a gap between research and practice remained crucial to the formulation and design of this thesis. Not only the gap in time between research being undertaken and its implementation in practice, or not, but also the fact that research is often not carried out in the areas that clinical practice currently requires.

From the time that I decided to enter nursing, I had no doubt that I wanted to work within cardiology. I came from a family where the impact of Coronary Heart Disease (CHD) is well recognised. Following my training, I have spent 26 years within the speciality, as a staff nurse, specialist nurse and latterly as a consultant nurse. I have progressed from someone who provides care for this group of patients, to someone who influences policy and service development through my participation in local, regional, and national forums. I have been involved in standard setting and benchmarking exercises in cardiology throughout the National Health Service (NHS) in Scotland. But, despite this progression and slight change of focus in my career, I have remained committed to ensuring that the best possible care is provided for the individuals within my caseload and that this care is based on the emerging evidence base. However, I have also been aware that much of what we do in CR has a limited evidence base, and often we advise individuals based on clinical expertise alone.

Clinical practice changes rapidly and is based on a pragmatic approach to the situation that clinical teams find themselves in. Choices are made, about what works well and what doesn't, using feedback systems from individuals and clinical staff. In addition, clinical teams have to respond to policy changes and this does not always closely follow the research base. This is very apparent in CR, where the research base focuses primarily on Myocardial Infarction (MI) and Coronary Artery Bypass Grafts (CABG) with a smaller research base for other cardiac diagnoses. Yet clinical teams committed to the specialty, voluntary organisations and individuals who have undergone CR and have felt the benefit, have managed to influence opinion and alter policy. This is reflected in both the

National Service Framework for CHD (DOH 2000) and the CHD and Stroke Strategy for Scotland (SGHD 2009a). These strategies go beyond the evidence base and health professionals must now look to develop services for groups not previously offered CR. At the time these strategies were developed, there had been limited research on the impact comprehensive CR can have on groups, such as the elderly, ethnic minority groups, women and particularly on clients with other cardiac diagnoses. I had been involved in, and supportive of, the strategies and was clearly aware that they posed significant challenges to CR clinicians in providing evidenced based care. In summary, this conflict between my role in policy and my role as an evidenced based practitioner is key to the way in which I developed this thesis.

1.3 Background

Cardiovascular disease (CVD) refers to any disease that affects the cardiovascular system, principally CHD, vascular diseases of the brain and kidney, and peripheral arterial disease. Cardiovascular diseases remain the biggest cause of deaths worldwide. An estimated 17.3 million people died from CVD in 2008 yet 80% of these deaths were preventable (WHO 2012).

The most common form of CVD is CHD. An estimated 7.3 million people died of CHD worldwide in 2008 (WHO 2012). In Europe, CHD accounts for an estimated 1.95 million deaths each year and is the most common cause of death in the UK, with a total of 88,000 deaths attributed to CHD in 2008 (British Heart Foundation (BHF) 2012b). Scottish CHD mortality is amongst the highest in Western Europe (Tunstall-Pedoe et al 1999). Significant attention has been paid over recent decades to reducing mortality and morbidity from CHD. There

have been a wide range of treatments developed to minimise the damage and impact of the disease process. These include the introduction of thrombolysis in the 1980's, the development of a range of secondary prevention drugs such as aspirin, beta-blockers, statins and ace-inhibitors, and the more recent development of primary angioplasty (PPCI) across most of Scotland (SGHD 2009a). New diagnostic techniques have allowed clinicians to pick up a wider range of damage to heart muscle and this has led to changes in diagnostic categories over the last ten years. This improved ability to detect disease has allowed clinicians to introduce preventative strategies at a far earlier stage in the development of CHD. Increasingly, methods of risk assessment such as Framingham (D'Agostino et al 2001) or ASSIGN (Woodward et al 2007) are being used to guide prevention strategies. These have focused on the modifiable risk factors of smoking, hypertension, lack of physical activity, diet and blood cholesterol, with more recent focus on psychosocial risks such as depression and deprivation. All of these improvements have led to a reduction in deaths from CHD in Scotland of 60% over the last ten years (ISD 2011).

The research suggests that modification of currently known risk factors has the potential to prevent most premature cases of MI worldwide (Yusuf et al 2004). Deaths and rates of morbidity, from all forms of CHD, fell by at least 50% in most countries from about 1980 to 2000 (Capewell and O'Flaherty 2009**).** It has been argued that two-thirds of this decline can be attributed to a decrease in adverse events and reflects reductions in the prevalence of major risk factors. The remaining third is attributable to reduced case-fatality rates, owing mainly to treatments (Tunstall-Pedoe et al 1999). However it is clear, from the evidence

above that any intervention designed to reduce the highlighted risk factors can have a significant impact on the health of the individual ith CHD.

Cardiac Rehabilitation is one of the interventions designed to utilise this evidence base and to improve the life of individuals following a cardiac event. It aims to return them to as normal a lifestyle as possible through exercise, education, support for behaviour modification, and attention to psychosocial factors (Bethell et al 2008). The evidence base for CR shows that there are large differences in the quality of evidence for the various components of such a complex intervention. The evidence base for the exercise component of CR is comprehensive and compelling. Although focusing in the main on MI, CABG and PCI, there is evidence that CR can have an impact on the physical health of participants with a variety of diagnoses through exercise. There is also some suggestion of benefit from psychological interventions within CR. However this evidence base is currently ambiguous and there is a need for further research into misconceptions, anxiety, depression, and Health Related Quality of Life (HRQoL). The research base on the impact of educational interventions in CR is varied. There are some difficulties in differentiating the impact of education and psychological interventions within CR. There is a need therefore for further exploration of the role that menu-based CR can play in the care of individuals.

1.4 Cardiac Rehabilitation as a complex intervention

Cardiac Rehabilitation is now a cornerstone in the recovery process for individuals with CHD. There are many definitions of CR around, however the Scottish Intercollegiate Guideline Network (SIGN) defined the key elements as:

' the process by which individuals with cardiac disease, in partnership with a multidisciplinary team of health professionals, are encouraged and supported to achieve and maintain optimal physical and psychosocial health' (SIGN 2002 p1)

Increasingly, CR has been accepted by the United Kingdom (UK) and devolved governments as an essential component of care (DOH 2000, SIGN 2002, NICE 2007).

The evidence base for CR has gradually evolved over the last thirty years, with the first meta-analysis being completed in 1988 and latest meta-analysis being completed in 2011. This evidence base will be explored in greater detail in chapter 3. However, much of the evidence to date has been collected in the MI and CABG populations. Current healthcare policy in the UK argues that CR should be provided to a wider range of cardiac diagnoses, despite the limited evidence base (SIGN 2002). This is a challenging situation for clinicians and further research is needed to support clinical practice.

Originally, CR services in the UK focused on exercise programmes alone. Standard CR had historically taken the form of a structured exercise programme in a hospital setting with educational and psychological support and advice on risk factors. During the 1990's this meant that programmes often had strict exclusion criteria, based on fitness to exercise. Patients such as the elderly, those with complex co-morbidities and those with ongoing symptoms were often

excluded (Tod et al 2002).The move towards a more inclusive process saw the introduction of firstly the term comprehensive and then menu-based CR. Comprehensive CR describes the addition of a variety of services to the exercise based component of CR. Menu-based in contrast makes exercise only one part of the menu and focuses on a wider range of treatment options.

In standard or comprehensive CR, the exercise component consisted of an exercise programme, based mainly in hospital, working at moderate intensity, usually twice a week and in a group setting. The other components of the programme were delivered within this context. If a patient was unable to access the exercise component, they often did not receive the other elements of CR. Clinicians recognised that this type of intervention did not suit a lot of patients and clinical practice in CR developed into a menu-based approach for the provision of care (SIGN 2002).

A menu-based approach recognises the need to tailor the delivery of services to an individual's goals and circumstances. A menu-based programme could include specific education to reduce cardiac misconceptions and encourage smoking cessation and weight management. It could include vocational rehabilitation to assist return to work or retirement; or referral to a psychologist, cardiologist, or exercise physiologist. Exercise is no longer the primary focus, but only one of the services that could be provided as part of the menu. In addition exercise could be provided in a variety of ways from the traditional moderate intensity hospital class, to a low intensity class, a class in the community, or a home exercise programme, depending on the needs of the patient.

The choice of interventions, within a menu-based programme, is individualised according to need and can vary considerably from individual to individual. These diverse components act, and interact, with one another to achieve a range of outcomes. However the evidence base on menu-based CR is limited.

This increasing focus on individualised care within CR has highlighted that CR programmes need to become more effective in addressing the psychological needs of the individual as well as their physical needs (Linden et al 1996, Mayou 1996, Taylor et al 2004). Surveys have highlighted that psychosocial factors are still poorly assessed (Lewin et al 1998) and that the measurement of psychological and quality of life (QoL) criteria within programmes is not universally carried out (Bethell et al 2000). Healthcare professionals within CR do not use psychological interventions systematically due to limited identification of the patient's illness beliefs and expectations. Programmes do not ground interventions in a specific theory or framework. The need to pursue the establishment of a well-grounded theoretical framework to develop models of care that deliver effective CR interventions, has been clearly recognised (DOH 2000), and highlighted, in guidelines issued by the British Association of Cardiac Rehabilitation (BACR) (Coats et al 1995).

Menu-based CR is a complex intervention with varied pathways according to individual need. There is a need for further research on menu-based CR that addresses the needs of individuals with cardiac diagnoses other than MI and CABG.

1.5 Acute Coronary Syndrome Low Troponin

The need for further research within CR has been highlighted in section 1.4, but a diagnosis that requires further exploration is ACSLT. This is a term that has appeared in the last decade within the CHD medical terminology (SIGN 2007a). However the term of ACSLT is relatively new and poorly understood across many healthcare organisations and communities. This group would previously been classified as unstable angina (UA) as the biomarkers in use, prior to the discovery of the troponins, would have been unable to detect this low level of damage to cardiac muscle. Research has shown that the morbidity and mortality of patients with ACSLT is similar in severity to those diagnosed with MI (SIGN 2007a).

In 2004, individuals with ACSLT would not have met the referral criteria in force in the majority of CR programmes (Lewin et al 2004). The evidence base for this cardiac diagnosis focused mainly on medical treatment and there were limited data on other forms of treatment including CR. Audit data in NHS Ayrshire and Arran showed that the numbers likely to be affected by this diagnosis were similar to the numbers of individuals diagnosed with MI; approximately 400 a year. This group of individuals were discharged, with a diagnosis that was poorly understood, and received care that did not reflect the standards of those diagnosed with MI, but they faced similar challenges in terms of mortality and morbidity. This therefore made ACSLT and CR a priority area for further research. This thesis will therefore focus on individuals with ACSLT and will contribute to the evidence base on CR for this diagnosis.

1.6 Theoretical framework for Cardiac Rehabilitation

The need for further research within menu-based CR that utilises a theoretical framework has been highlighted in section 1.3. The Common Sense Model of Self-Regulation (CSM) is particularly suited to understanding and improving an individual's management of their chronic illness (Leventhal et al 1980, Leventhal et al 2003). The theory involves individuals monitoring their efforts and outcomes in managing tasks and using this information to regulate the process towards achieving desired goals. As a theoretical model, it describes patients as active problem solvers who make sense of a threat to their health such as physical symptoms or an illness, by developing their own cognitive representations of the threat, which in turn, determine how they respond. (Leventhal et al 1980, Leventhal et al 2003). As has been stated previously, many CR programmes do not utilise a theoretical framework when designing a programme. The impact of using a framework such as the CSM model to underpin a complex intervention such as CR is one that requires further study.

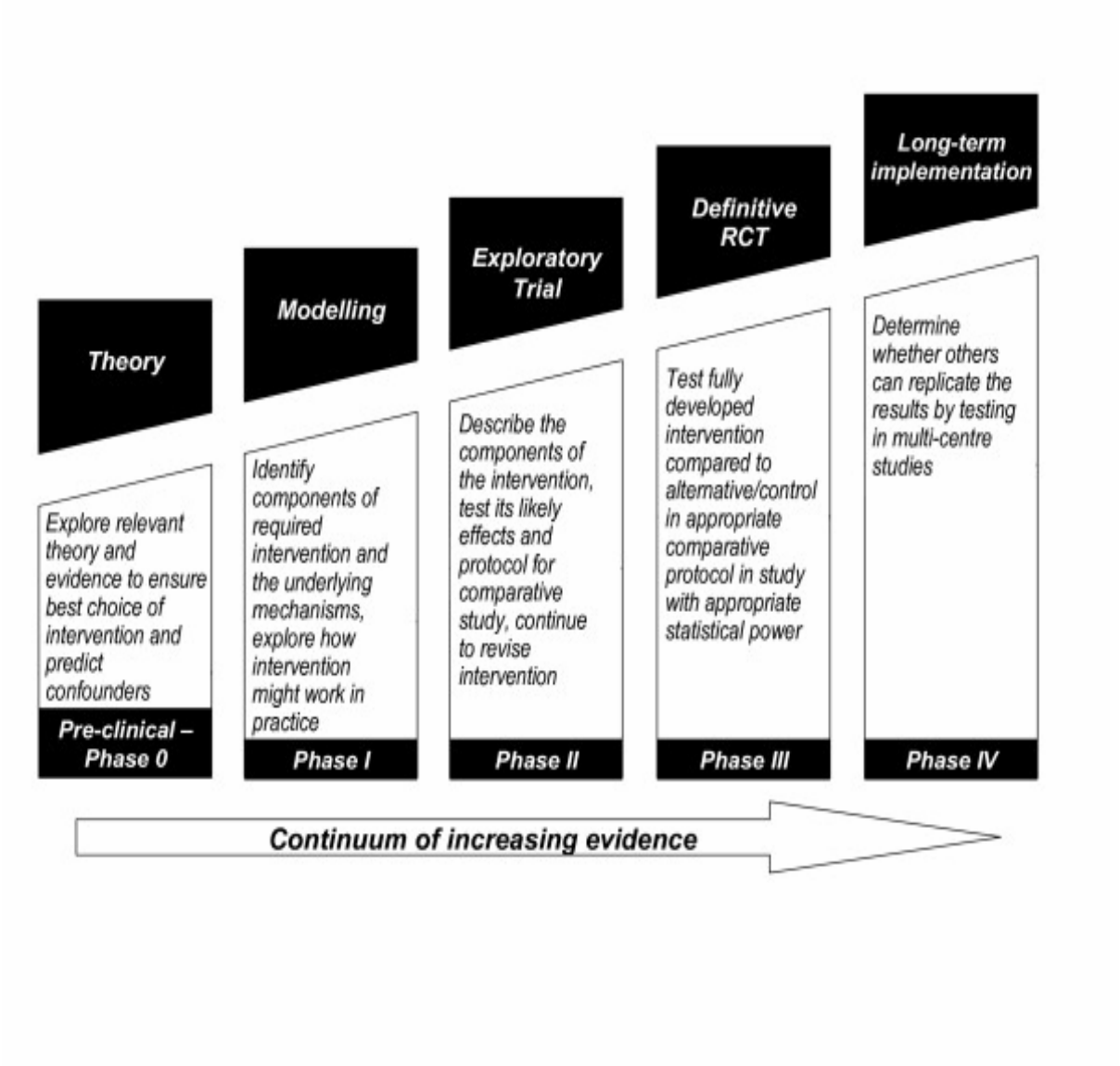
1.7 A framework for research

The need for further research within menu-based CR has been highlighted in chapter 1.3-1.6. Healthcare is moving toward the goal of implementing evidence-based interventions that have been rigorously evaluated and found to be both efficacious and effective (Bowen et al 2009). However the design and evaluation of complex interventions, such as CR, is problematic. There are a large number of diverse components within a CR programme, including the theoretical framework, which, act and interact with one another to achieve a range of outcomes for the individual.

The Medical Research Council (MRC) provides a framework for researching complex interventions, setting out four phases in the development and evaluation of such interventions (Campbell et al 2000, Medical Research Council 2000). Since its publication in 2000, this framework has been used in research concerning a wide variety of treatments, services and interventions (Robinson et al 2005, Byrne et al 2006, Blackwood 2006, Redfern et al 2006).

This thesis will focus on the first three phases of the MRC framework, by examining the underpinning evidence for CR (pre-clinical Phase) and by modelling what the CR intervention should look like (Phase I). The research studies carried out in this thesis encompasses Phase II, where mechanisms are identified and outcomes are predicted. It is intended that the feasibility study will test the feasibility of carrying out a large study in this population group. It will describe the components of the intervention, test their likely effects on the population and revise the intervention on the basis of the results. This would allow for the development of a RCT to test the intervention further, with an appropriate level of power (Phase III). The exploratory study will provide further data on the impact that ACSLT and CR can have on this client group. It is hoped these studies will contribute to the body of knowledge regarding CR in order to inform future service provision (Phase IV).

Figure 1:1: The MRC framework for the evaluation of complex interventions



MRC 2000

1.8 Aim of the thesis

This thesis contains a feasibility study and an exploratory study. The feasibility study aimed to examine the feasibility of a RCT which would test the impact of a menu-based CR programme, on individuals diagnosed with ACSLT, against standard care. This feasibility study included staff views. The exploratory study aimed to explore the impact that ACSLT and CR can have on this client group.

1.9 Research questions

In attempting to meet the aim of the thesis, specific research questions were devised:

Feasibility Study

- Would a RCT of a menu-based CR programme for individuals with a diagnosis of ACSLT be feasible?
- How do staff caring for individuals with ACSLT view the study and the feasibility of a RCT of CR

Exploratory Study

- What impact did a menu-based CR programme for individuals with a diagnosis of ACSLT have on four areas
    - Cardiac misconceptions
    - Cardiac symptoms
    - Anxiety and depression.
    - HRQoL
- How do individuals with ACSLT view their illness?

This thesis includes a feasibility study and an exploratory study. However, these studies used the same group of participants, who were recruited while in-patients within the wards, and data were collected from the participants throughout the timescale of the studies. The data relating to feasibility are reported in the feasibility study and the data gathered from both quantitative and qualitative measures are reported in the exploratory study. The term participant will be used for the patients who took part in the studies.

Nursing and physiotherapy staff took part in the focus groups as part of the feasibility study and they will be referred to as staff. The terms; feasibility study, exploratory study, studies, and thesis will be used throughout. In order to avoid confusion, the term “feasibility study” will be used when it relates to issues of feasibility. The term “exploratory study” will be used when it relates to the data collected from participants. The term “studies” will be used when information from both studies is being discussed and the term “thesis” will be used to describe the work overall.

1.10 Timeline of the thesis

This thesis was carried out in a time of change within cardiology and this had a substantial impact on the outcome of the studies. Figure 1:2 highlights some of the events that have influenced this thesis.

Figure 1:2 Timeline for thesis

Oct 2004-Oct 2005	• First review of relevant literature
October 2005	• Research proposal completed
March 2005	• Ethics application submitted to NHS Ayrshire and Arran and Stirling University Ethics Committees*****
Jan 2006	• Ethics approval granted
November 2006	• Start of recruitment at site 1 and 2
February 2007	• Recruitment now difficult at site 1 due to changes in clinical diagnosis
June 2007	• Two additional nurses tasked with recruitment
October 2007	• Recruitment now difficult at site 2 due to changes in clinical diagnosis, making recruitment difficult at both sites
November 2007	• Scottish Government release guidance on definition of MI*****
November 2007	• Recruitment Stopped
July 2008	• Data Collection completed
2008-2012	• Data analysis, and write up *****
2011-2012	• Second review of literature
Oct 2013	• Submission

* Leave of absence

1.11 Organisation of the thesis

In this first chapter, the context for this thesis has been described. This includes a discussion on CR as a complex intervention and areas where further study would be beneficial. The MRC framework for complex interventions has been discussed (MRC 2000) and will form the underlying framework for the rest of the thesis.

In the second chapter, a review of the literature in relation to CHD describes the impact of this disease on the health of the Scottish population, and the factors contributing to its development. This chapter then continues by describing the many improvements in the management of CHD that have occurred in recent decades, and how the risk and impact can be mitigated by modern developments in cardiac care. This encompasses the Pre-clinical Phase of the MRC framework.

In the third chapter, the development of one of these improvements, that of CR will be discussed. The historical background and evidence base for this treatment will be considered and suggestions for further research highlighted. There will be an exploration of the theories which can underpin CR practice, in particular, the CSM (Leventhal et al 1980, Leventhal et al 2003). This chapter relates to Phase I of the MRC framework where components of the intervention and underlying mechanisms are identified.

The fourth, fifth and sixth chapters relate to Phase II of the MRC framework. The fourth chapter will describe and discuss the methodology employed to meet the aims of the thesis, taking into account the clinical context and information from the literature. The design of the studies and coordination will be discussed

first, followed by ethical considerations and recruitment. The measures and process for data collection will then be addressed, and finally, timescales.

The fifth chapter will present the issues explored in the feasibility study. These issues include: recruitment and retention, the acceptability of a CR intervention to participants and staff, and the appropriateness of the outcome measures chosen to measure cardiac misconceptions, symptom severity, anxiety, depression, and HRQoL.

In the sixth chapter, the results obtained using these outcome measures and participant interviews will be presented.

In the seventh chapter, the findings of the thesis which illustrate new knowledge are discussed along with, the limitations of the studies, implications for clinical practice, and recommendations for future research.

1.12 Conclusion

This chapter has outlined the rationale for the focus on this area of clinical practice. There is a need for further research that examines menu-based CR grounded in a theoretical framework. This is particularly important in the context of ACSLT. This group of individuals were discharged, with a diagnosis that was poorly understood, and received care that did not reflect the standards of those diagnosed with MI, but they faced similar challenges in terms of mortality and morbidity. This therefore made ACSLT and CR a priority area for further research. The overall aim of this thesis is to contribute to the body of knowledge regarding CR and ACSLT and to inform future research design and service provision. This will be achieved by both feasibility and exploratory studies.

Chapter Two Coronary Heart Disease

2:1 Introduction

This chapter will follow the MRC framework (MRC 2000) for researching complex interventions, by highlighting the evidence base for CHD. Studies appearing in MEDLINE, and CINAHL databases were initially accessed between 2003 and 2005, and reviewed regarding objectives, methodological issues, results and clinical relevance. The literature review was then ongoing from 2005 until 2012. Both electronic and manual searches were conducted, using the key words 'patients', 'Coronary Heart Disease' 'Acute Coronary Syndrome". These words were coupled with 'CHD risk factors' and 'treatment', in searches of the literature undertaken to review the current research base on interventions for CHD. Meta-analysis, systematic reviews, randomised controlled trials and observational studies were reviewed with respect to the aforementioned areas.

This chapter will describe the incidence of CHD and changes in clinical practice within cardiology that have led to the development of the diagnostic category of Acute Coronary Syndrome (ACS) and the sub-category of ACSLT. This chapter then continues by discussing the risk factors for CHD and the many improvements in the management of CHD that have occurred in recent decades.

2.2 Background

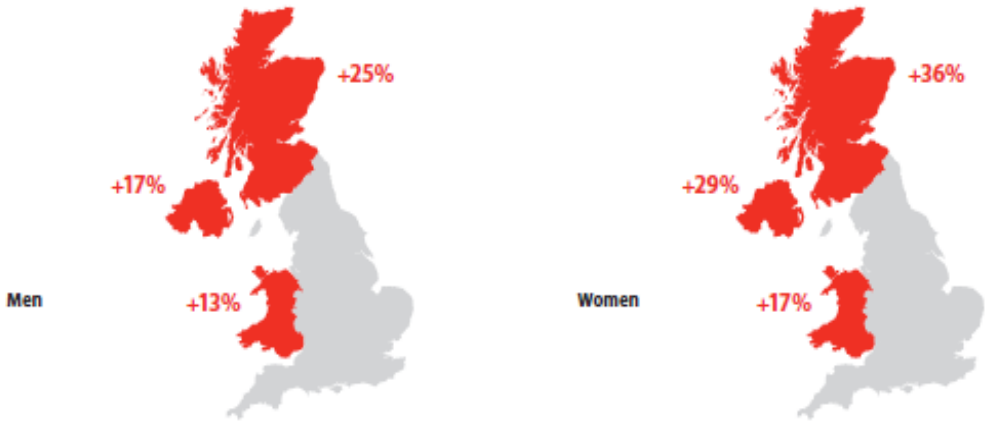
Cardiovascular disease (CVD) refers to any disease that affects the cardiovascular system, principally CHD, vascular diseases of the brain and kidney, and peripheral arterial disease. This group of diseases remain the

biggest cause of deaths worldwide. An estimated 17.3 million people died from CVD in 2008, yet 80% of these deaths were preventable (WHO 2012). Over the last two decades, CVD has increased, at an astonishingly fast rate, in low and middle-income countries. At the same time, mortality rates have declined in many high-income countries (Mendis et al 2011). Rates of mortality and morbidity from CVD fell, by at least 50%, in many high-income countries from 1980 to 2000 (Unal et al 2005, Capewell and O'Flaherty 2009). Some two-thirds of this decline can be attributed to a decrease in adverse events and reflects reductions in the prevalence of major risk factors. The remaining third is attributable to reduced case-fatality rates, owing mainly to treatments (Tunstall-Pedoe et al 1999). However flattening rates of death from CVD in younger age groups have also now been reported in the United States (US), the UK, Australia and elsewhere (Capewell and O'Flaherty 2009). Worsening trends in CVD may be even greater among people in socially deprived groups (O'Flaherty et al 2009). The main cause of death in the UK remains CVD, with 191,000 deaths each year, one in three of all deaths (BHF 2010).

The most common form of CVD is CHD. An estimated 7.3 million people died of CHD worldwide in 2008 (WHO 2012). In Europe, CHD accounts for an estimated 1.95 million deaths each year and is the most common cause of death in the UK, with a total of 88,000 deaths attributed to CHD in 2008 (BHF 2012b). Death rates have fallen in the UK over the last fifty years, but the prevalence continues to increase, due to improvements in treatments and the rising age of the population (Unal et al 2005, BHF 2012a). Currently there are 2.7 million people in the UK living with CHD (BHF 2012a). Rising life

expectancy and improvements in prognosis can only have a further impact on prevalence in the coming decades (Unal et al 2005).

Figure 2:1 Differences in Age-standardised CHD mortality rates by sex and country 2009 United Kingdom



BHF trends in CHD 1961-2011(BHF 2012)

Note: Percentages refer to the difference in age-standardised mortality for men or women compared to the male or female rate in England

2.3 Coronary Heart Disease in Scotland

This worldwide challenge of tackling CHD is reflected in the health of the Scottish population. As seen from Figure 2:1, the CHD mortality rate for men living in Scotland is 25% higher than England and 36% higher for women. CHD will directly affect the majority of the Scottish population, at some point in their life, either individually or through their family or friends. The incidence of CHD is higher amongst men, the elderly and in deprived areas of Scotland (SIGN 2007b).

Significant attention has been paid in Scotland over recent decades to reducing mortality and morbidity from CHD. Within Scotland a target was set of

a 60% reduction between 1995 and 2010. The age-standardised mortality rate (for under 75's) for CHD has fallen from 124.6 per 100,000 population in 1995, to 49.0 per 100,000 population in 2010, a reduction of 60.7%. The target has therefore been achieved (ISD 2011).

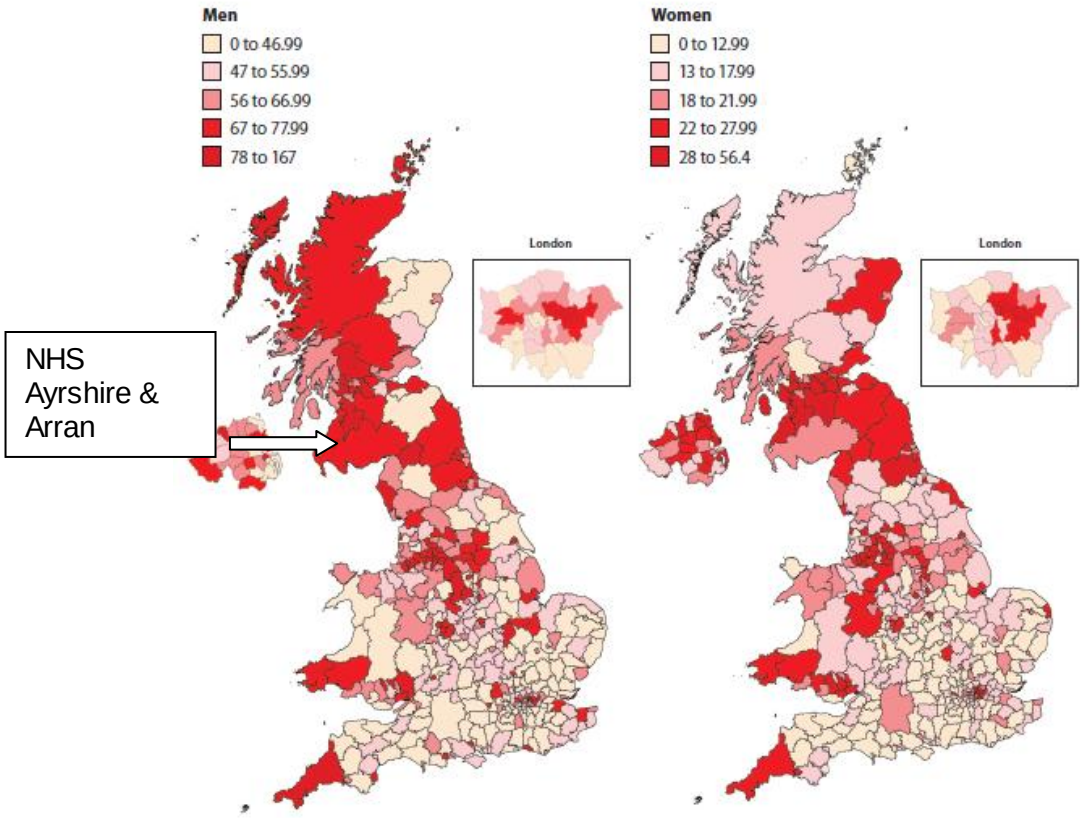
However, although mortality from CHD has fallen, it is a matter of concern that rates of decline in CHD mortality for men and women aged 35-54 years show recent, significant flattening. Specifically, the annual percentage change in men was – 6.28% between 1986 and 2003, but only – 0.55% between 2003 and 2006. Between 2003 and 2006 the two most deprived quintiles of the Scottish population showed an increase of CHD mortality of 16.8% and 10% respectively (SGHD 2009a).

In the Scottish health survey of 2008, the prevalence rates for CHD were 6.9% for men and 5.6% for women (SGHD 2009a) with the prevalence rate increasing dramatically across the age groups, peaking in the 75+ age group at 26.8% and 20.2% respectively. This has implications for the healthcare sector as the population of the UK is ageing. Over the last 25 years, the percentage of the population aged 65 and over increased from 15 per cent in 1984 to 16 per cent in 2009, an increase of 1.7 million people. By 2034, 23 per cent of the UK population is projected to be aged 65 and over (Office of National Statistics 2012). This will mean increasing numbers of individuals with CHD, who require healthcare from the NHS in Scotland. It is therefore not a surprise that the Scottish government in its strategy 'Better Health, Better Care' confirmed that CHD remains a clinical priority (SGHD 2007).

2.4 Coronary Heart Disease in NHS Ayrshire and Arran

This thesis was based in NHS Ayrshire and Arran on the west coast of Scotland. Even within Scotland, a variation in CHD mortality between health boards can be seen, with NHS Ayrshire and Arran having one of the highest mortality and prevalence rates in Scotland (SGHD 2011, BHF 2012b). As can be seen in Figure 2:2, CHD is therefore an area of huge challenge for NHS Ayrshire and Arran.

Figure 2:2 CHD Premature Mortality rates per 100,000, by sex and local authority, 2008-2010



CHD statistics in Scotland 2012 (BHF 2012b)

2.5 Manifestations of Coronary Heart Disease

Chapter 2:1-2:4 has demonstrated that CHD is a major challenge for healthcare systems both internationally, nationally and locally. This section will focus on the manifestations of CHD and specifically on ACS and ACSLT. The development of CHD happens over a number of years and a number of diagnoses are associated with it. These are:

- ACS where one of the coronary arteries become narrowed or blocked and causes damage to the muscle of the heart. This leads to symptoms of chest pain and admission to hospital. This diagnosis can be divided into several categories which will be described below.
- Stable Angina where the artery may become so narrow that it cannot deliver enough oxygen-containing blood to the heart muscle, when its' demands are high, resulting in pain or discomfort. This does not lead to blockage and damage to heart muscle, but can restrict life choices.
- Heart Failure (HF), which occurs if the heart becomes less efficient at pumping blood around the body, due to damage to the heart muscle.

The term ACS is one that is not well understood by a large portion of the population. It is an umbrella term for MI and UA (Fox et al 2004). Both have a common aetiology in the formation of thrombus on an inflamed and complicated atheromatous plaque. Patients with erosion or rupture of an atheromatous coronary plaque may or may not go on to develop MI. This confers particular risks, as a result of impairment of left ventricular function, and mechanical and

arrhythmic complications (Fox et al 2004). An accurate and consistent diagnosis of MI is therefore important to guide patient management.

The World Health Organization (WHO) classification of MI states that the term MI is generally used when myocardial necrosis due to myocardial ischemia is evidenced in a clinical setting (WHO 1979). Their criteria for the identification of MI recommended that the condition can be diagnosed if any two of the following three features were present:

- Symptoms of myocardial ischemia (continuous chest pain for 20 minutes)
- Electrocardiograph(ECG) changes with ST segment elevation or Q wave development
- Elevation of sensitive and specific cardiac enzymes in the circulation

The third of these criteria has led to debate among cardiologists over the last decade. With the development of more sensitive assays of cardio-specific enzymes such as Troponin T, there has been confusion around the terminology describing patients with MI. Particularly those who have an elevation of cardio-specific enzymes, but do not meet the second criteria of ST elevation or Q wave development (Fox et al 2004). This led to the development of the current classification system for MI, which is described as either:

- ST elevation MI (STEMI), where >1mm ST elevation is present on at least two limb leads or >2mm ST elevation is present in chest leads.
- Non ST elevation MI (NSTEMI), where all other indicators with the exception of ST elevation are present. (Fox et al 2004)

An additional area of debate has been the level of cardio-specific enzyme rise that would be considered positive for MI. In 2000, a joint working group from the European Society of Cardiology (ESC) and the American College of Cardiology (ACC) published a redefinition of MI which stated that any elevation, however small, of troponin levels is evidence of a MI (ESC/ACC 2000). However, within the UK, the British Cardiovascular Society (BCS) Working Group recommended that in the context of a typical ACS, MI should be diagnosed when the maximum Troponin T increase is >1.0ng/ml (Fox et al 2004). This recommendation was made on the basis that the risk of death at this level of rise in Troponin T is similar to that seen with the WHO definition (WHO 1979).

Table 2:1 Worldwide definitions of Acute Coronary Syndrome

12 hour serum Troponin T concentration (ng/l)			
	<0.01	**>0.01 and <1.0**	**>1.0**
BCS definition	ACS with UA	ACS with myocyte necrosis	ACS with clinical MI
ESC/ACC	UA	MI	MI
WHO definition	UA	UA	MI
30 day mortality	4.5%	10.4%	12.9%
6 month mortality	8.6%	18.7%	19.2%

SIGN (2007a)

As can be seen from Table 2:1, the disparity amongst the definitions, relates to the middle group (Troponin T >0.01 and <1.0) or ACSLT as defined within this thesis. Before the identification of the troponins, patients with ACSLT would have been classified as UA, as the cardio-specific markers in use at that time would have been unable to detect any damage to cardiac muscle. Yet the current definitions from BCS/ACC/ESC recognise that patients with ACSLT are different from those with UA. They have an adverse prognosis, including increased risk of death, compared with patients with UA without an increased marker. The data used to calculate this risk of death comes from the Global Registry of Acute Coronary Events (GRACE). This is a widely accepted method of determining risk, developed from a international observational database of outcomes for patients who are hospitalized with ACS. The database includes; over 200 hospitals, in 28 countries, that enrol a total of more than 10,000 patients per year (GRACE investigators 2001). From this data, the researchers have been able to establish factors that influence survival. These include: age, heart rate, systolic blood pressure (BP), creatinine levels, presence of HF, ECG changes, cardiac arrhythmias, and raised cardiac enzymes. The data is entered into a table and the probability of death or MI in the next six months can be calculated. From Table 2:1 it can be seen that individuals with ACSLT are at similar risk to those with MI and research is required into what interventions would benefit these individuals.

2.6 Risk factors for Coronary Heart Disease

There is a large amount of evidence about the reasons why some individuals develop CHD and also consensus that there are key contributory risk factors. Large studies have shown that multiple risk factors, rather than a single

risk factor, significantly increases the risk of CHD (Tunstall-Pedoe et al 1999). The risk increases with age and men are more likely to suffer from CHD prematurely than women. Family history also appears to play a part in the development of this disease (BHF 2012a).

The INTERHEART study assessed the importance of risk factors for CHD worldwide (Yusuf et al 2004). Nine measured and potentially modifiable risk factors accounted for more than 90% of the proportion of the risk for acute MI. These risk factors included smoking, elevated blood cholesterol, lack of physical activity, psychosocial factors, history of hypertension or diabetes, poor dietary pattern, obesity, and alcohol consumption. The effect of these risk factors was consistent in men and women, across different geographic regions, and by ethnic group. Worldwide, the two most important risk factors were smoking and abnormal lipids. Hypertension, diabetes, psychosocial factors and abdominal obesity were the next most important, but their relative effects varied in different regions of the world (Yusuf et al 2004). The British Regional Heart Study found that smoking, BP and abnormal lipids accounted for 90% of attributable risk of CHD (Emberson et al 2003).

If we consider the risk factors individually, we can see that smoking is closely related to premature mortality. Men under 65 who smoke are three times more likely to die of CHD than non-smokers of a comparable age and men between 65 and 84 who smoke are twice as likely to die as non-smokers (Doll el al 2004). Yusuf et al (2004) showed that there was a strong relationship between the number of cigarettes smoked and the risk of MI, while individuals, who smoke more than 40 a day, had ten times the risk of non-smokers. It has

been argued that in developed countries around 12% of all disease burden and over 20% of CVD was due to smoking (WHO 2002). Yusuf et al (2004) estimated that 29% of heart attacks in Western Europe were due to smoking, and that smokers and former smokers were at almost twice the risk of a heart attack, compared to those who never smoked.

The link between CVD risk and variation in blood lipid concentration was shown in a study of over 356,000 men aged 35-57 years who were followed up for six years (Stamler et al 1986). The study demonstrated a continuous, graded, strong relationship between serum cholesterol and six year age adjusted CHD mortality. A meta-analysis of data from 90,056 participants in 14 randomised trials of statin therapy showed that a 1.0 mmol/l reduction in Low Density Lipoprotein (LDL) cholesterol lowered the five year relative risk of a major vascular event by 21%, irrespective of sex, age, BP, pre-existing diabetes or history of a previous vascular event (Baigent et al 2005).

Light to moderate physical activity in healthy adults has been recommended to reduce the risk of mortality and morbidity from any disease. Observational studies show that those with higher physical activity levels are less likely to develop CHD than those who are more sedentary. The research also shows that those who increase their physical activity decrease their chances of developing CHD irrespective of their starting level (Lee et al 2000, Manson et al 2002, Lee et al 2003). These studies confirmed an inverse relationship between physical activity and the risk of a cardiac event after controlling for other key risk factors.

Psychological distress, particularly depression, has been recognised as a risk factor for CHD (Anda et al 1993, Barefoot et al 1996, Hemingway and Marmot 1999). The INTERHEART study found that subjective stress and self-reported depression appeared to be associated with increased risk of developing an acute MI across gender, nationality, ethnic groups, and to be independent of smoking and socio-economic status (Rosengren et al 2004).

Depression is highly prevalent in cardiac patients. Carney et al (1988) followed up 52 patients who had angiography for suspected CHD. At 12 months, 78% of the depressed patients had sustained at least one major cardiac event. Depression symptoms in the cardiac population have been associated with an increased risk of recurrent cardiac events (Frasure-Smith et al 1995), mortality (Barefoot et al 1996) as well as poorer prognosis (Vaccarino et al 2001). Depression is also associated with increased risk following a MI, and it has been shown that persistent psychological distress and poor social support are powerful predictors of outcome independent of the degree of physical impairment (Hemingway and Marmot 1999).

The high prevalence of psychological symptoms and disorders in patients with CHD has been documented by Rugulies (2002). Many people with CHD experience anxiety, depression, emotional and social disturbance, reduced HRQoL and failure to return to work (Petrie and Weinman 1997). Anxiety while in the coronary care unit is associated with an increased risk of ACS and arrhythmic events over the following 12 months (Frasure-Smith et al 1995). A number of studies demonstrate the link between negative perceptions and poor outcome in people with CHD (Maeland and Havik 1987, Petrie et al 1996, Furze et al 2005). Psychological distress is also an important predictor of

hospitalisation costs following a cardiac event, with distressed patients accruing four times the cost of non-distressed patients (Levin 1991).

Blood pressure has been found to be directly related to mortality from CHD (Selmer 1992, Stamler et al 1993). Results from the Seven Countries Study have suggested that the relative increase in mortality from CHD, for a given increase in BP, is similar among different populations and cardiovascular risks (Menottie et al 1996).

Diabetes is recognised as an independent risk factor for CHD in both men and women (Wilson et al 1998, Lotufo et al 2001). Women with diabetes seem to lose most of their inherent protection against developing CHD (Brezinka and Padmos 1994). Lotufo et al (2001), in their study of male US physicians, found that diabetes is associated with a substantial increase in all-cause and CHD mortality. For all-cause mortality, the magnitude of excess risk conferred by diabetes is similar to that conferred by a history of CHD, for mortality from CHD a history of CHD is a more potent predictor of death. The presence of both diabetes and CHD, however, identified a particularly high-risk group.

Manson et al (1990), in a prospective cohort study of over 100,000 female nurses, demonstrated a strong positive association between obesity and the risk of CHD in women. Adjustment for cigarette smoking increased the magnitude of the association. After adjustment for age and smoking, the risk of both non-fatal MI and fatal CHD among women in the heaviest weight category was more than three times higher than that in the leanest weight category. In the Framingham Heart Study, Hubert et al (1983) followed 2,818 women, 28 to 62 years of age, for a 26-year period and found a strong positive association

between relative weight and the incidence of CHD. This association was also found amongst men. Yet in the Seven Countries Study (Keys 1980), no significant association between body mass index in most regions and CHD incidence over 10 years was found. It could be argued that these two studies had different levels of baseline obesity and therefore are not comparable. However, it highlights the difficulty in assessing the impact of obesity itself, versus the impact of obesity on other risk factors such as hypertension, and the resulting increase in CHD risk.

The impact of dietary patterns on CHD has been studied in several areas, with varying results. These areas are dietary fats, salt, fruit and vegetables. The evidence would appear to be variable across these areas of dietary intake. The evidence would appear to be the strongest for a reduction in dietary fats. A Cochrane review examined the effect of reduction or modification of dietary fats, for at least six months, on reducing serum cholesterol levels and on total and CVD mortality and morbidity (Hooper et al 2004). There was no significant effect on total mortality, but a trend was identified towards protection from CVD mortality and significant protection from CVD events. Trials, with at least two years' of follow up, provided stronger evidence of protection against CVD events. The reviewers concluded that there was a small, but potentially important, reduction in CVD risk with a reduction or modification of dietary fat intake, seen particularly in trials of longer duration.

A meta-analysis of 28 trials, on the effect of moderate salt reduction on BP, demonstrated that a modest reduction in salt intake, for four or more weeks, had a significant effect on BP in both hypertensive and normotensive individuals

(He and MacGregor 2002). However a Cochrane review found that it was difficult to link this with a reduction in CVD events (Jürgens and NA 2004).

The evidence for the benefits of a diet high in fruit and vegetables is limited. The recommendation to eat fruit and vegetables to prevent CHD is mainly based on non-randomised studies. Several cohort studies have examined the relationship between fruit and vegetable intake and CHD. Law and Morris (1998) found a decrease in cardiac event rates and Shekelle et al (2004) found a reduction of 15% of CHD linked to consumption of fruit and vegetables. Pereira et al (2004) in their review of cohort studies argue that fruit and vegetables may reduce CHD by means of their protective constituents such as potassium, folate, vitamins, fibre, and other phenolic compounds. They reported an inverse association between intake of fibre from fruit and vegetables and CHD risk. In general, studies in this area report a favourable relationship between fruit and vegetable consumption and CHD occurrence, however no causal link has been shown.

Alcohol is known to have both beneficial and harmful effects on the biochemical basis for CHD and the psychological consequences of the disease (Foppa et al 2002). Two cohort studies, on the effects of alcohol consumption in secondary prevention sub-groups, confirmed the protective effect of moderate drinking (Aguilar et al 2004, Reims et al 2004). In a prospective cohort study, Ajani et al (2000) followed up 87, 938 US male physicians for 5.5 years, 2,790 of these had diabetes. Their results also suggest that light to moderate alcohol consumption is associated with risk reductions in CHD among diabetic and non-diabetic men. Conversely, binge drinking is harmful and associated with: a

poorer lipid profile, an adverse effect on systolic BP, and increased risk of thrombosis (McKee and Britton 1998, Britton and McKee 2000).

Since 1948, The Framingham Heart Study has been committed to identifying the common factors or characteristics that contribute to CVD (D'Agostino et al 2001). Over the years, careful monitoring of the Framingham Heart Study population has led to the identification of the major CVD risk factors as above, as well as valuable information on the effects of these risk factors. The Framingham Heart Study has informed the development of a risk calculator for CHD. The Framingham equation has the advantage of allowing calculations over various time periods (4 to 12 years) and for different outcomes: stroke, CHD, MI and death from either CHD or CVD. Until recently, the majority of people used the Framingham equation for calculating CVD risk.

A further two risk scoring formulas have been developed within the UK. The first is the Joint British Societies (JBS) scoring charts version 2, which are published in the British National Formulary (BNF) (JBS 2005). The JBS2 scoring charts calculate CVD risk, based on the sum of the CHD and stroke risks given by Framingham. The Left Ventricular Hypertrophy and Diabetes risk factors, originally incorporated in the Framingham equation, are not included in the JBS2 charts, as these patients are automatically considered high risk.

The latest risk calculator is the ASSIGN score which was developed in conjunction with SIGN (Woodward et al 2007), to address the issue that the Framingham equation may not accurately calculate risk in populations other than the US. ASSIGN is tailored to the Scottish population and is based on the Scottish Heart Health Extended Cohort, a series of population studies from the

1980s and 1990s, followed up until the end of 2005 (Woodward et al 2007). ASSIGN calculates risk of CVD, but also includes additional risk factors not used by the Framingham equation (family history and social deprivation), which are important in a Scottish context. Death rates from CHD are socially patterned in Scotland, with people in lower social classes more likely to suffer from CHD than those in higher social classes. From 2005-2009 death rates from CHD in Scotland were 84% higher in the most deprived decile compared to the least deprived decile (BHF 2012b).

When the health behaviours associated with CHD risk factors are modified through activities such as smoking cessation, weight management, lipid management, increased physical activity and BP control, CHD can regress and progression can be delayed (SIGN 2000). All three risk calculators are used in clinical practice, both as a way to highlight the need for behaviour change to an individual, and as a tool to decide on treatment options. This has been the underpinning framework, for the last twenty years, for much of the prevention work in CHD within the UK.

Yusuf et al (2004) have argued that the modification of currently known risk factors has the potential to prevent most premature cases of MI worldwide. Deaths and rates of morbidity from CVD fell by at least 50% in most countries from about 1980 to 2000 (Capewell and O'Flaherty, 2009**)** and it has been argued that two-thirds of this decline can be attributed to a decrease in adverse events and reflects reductions in the prevalence of major risk factors The remaining third is attributable to reduced case-fatality rates, owing mainly to treatments (Tunstall-Pedoe et al 1999). The changes in medical treatment will be discussed further in chapter 2:7. However it is clear, from the evidence

above, that any intervention designed to reduce the highlighted risk factors can have a significant impact on the health of the individual with CHD.

2.7 Improved treatment of Coronary Heart Disease

In chapter 2:6, the risk factors for CHD were highlighted and the impact that changes in the risk profile could bring was discussed. This section will focus on changes in treatments within cardiac care that have also contributed to the reduction in mortality from CHD since 1980. These are reperfusion therapy, secondary prevention and CR. Reperfusion therapy applies mainly to individuals who have had a STEMI, or in a small number of cases, those with NSTEMI, while secondary prevention and CR can apply to the wider population with CHD.

Reperfusion therapy consists of two distinct treatments: Fibrinolytic Therapy (FT) and Primary Percutaneous Coronary Intervention (PPCI). Both treatments are designed to clear the coronary arteries following a blockage and reduce mortality and morbidity from MI. This is done using either a drug as in FT, or a metal stent in PPCI. During the 1980's and 90's FT was the only option for treatment, but during the last decade the use of PPCI has increased dramatically (SGHD 2009a).

Nine randomised controlled trials of FT were reviewed by the Fibrinolytic Therapy Trialists Collaborative Group (1994). They looked at deaths during the first 5 weeks after a MI and major adverse events occurring during hospitalisation. This review included 58,600 patients, among whom, 6,177 (10.5%) deaths, 584 (1.0%) strokes, and 436 (0.7%) major non-cerebral bleeds were reported. This treatment was associated with an excess of deaths during

days 0-1, but this was outweighed by a much larger benefit during days 2-35. Despite the early hazard, there was a very clear overall survival advantage produced by FT. Benefit was observed among individuals presenting with STEMI or bundle branch block (BBB), irrespective of age, sex, BP, heart rate, previous history of MI, or diabetes. Among the 45,000 individuals presenting with STEMI or BBB, the relationship between benefit and delay from symptom onset, indicated highly significant absolute mortality reductions of about 30 per 1000 for those presenting within 0-6 hours (Fibrinolytic Therapy Trialists Collaborative Group 1994). The earlier the drug was given, the higher the benefit. The administration of this therapy became commonplace within all cardiology units and formed part of the expected standard of care (SIGN 2000).

Over the last ten years, the concept of opening the artery to improve outcome has been expanded to include PPCI. This treatment aims to make the blood vessels wider; by the use of a balloon to open the vessel, and a metal stent to keep them open. A comprehensive systematic review (Hartwell et al 2005) and meta-analysis (Keeley et al 2003) of RCT data showed that PPCI is superior to FT for the treatment of patients with STEMI. The benefit of PPCI over FT was seen in reduced short and long term mortality, stroke, re-infarction, recurrent ischaemia and the need for CABG, as well as the combined end point of death or non-fatal re-infarction (SIGN 2007a). These benefits were consistent across all patient sub-groups and were independent of the drug used. The greatest benefit was seen in those patients treated within 12 hours of symptom onset (Keeley et al 2003, Hartwell et al 2005). This treatment has replaced FT as the treatment of choice for individuals with STEMI, who live within a 90 minute radius of the nearest cardiac centre providing this service

(SIGN 2007a). Those who can't access PPCI in this time frame still receive FT. An increase in angioplasty and stenting out-with PPCI, known as Percutaneous Coronary Intervention (PCI) has also evolved during the last decade. Often individuals with NSTEMI receive this treatment as a planned intervention following the index admission. Reperfusion therapy has therefore played an important role, over the last three decades, in reducing mortality and morbidity from CHD.

The second area in which improvements have been made in the treatment of CHD is that of secondary prevention. Since the publication of SIGN 41 (2000) on the secondary prevention of CHD, the use of four groups of medications that can reduce mortality and morbidity in individuals with CHD has been recommended. These medications include: platelet inhibitors, beta-blockers, ace-inhibitors and statins. Meta-analyses of platelet inhibitor therapy (Antithrombotic Trialists Collaboration 2002), long term beta-blocker therapy after MI (Freemantle et al 1999) and ace-inhibitor therapy (ACE inhibitor MI Collaborative Group 1998) have confirmed that these drugs reduce mortality following a MI. Several trials have also suggested that the use of statins such as simvastatin and pravastatin can reduce mortality by between 20-30%. In the Scandinavian Simvastatin Survival Study (1994), total mortality was reduced by 30% in the intervention group, due to a 42% decrease in CHD deaths. The need for CABG or PCI was also reduced by 37%. These benefits applied to older as well as younger patients. In the LIPID study (1998), overall mortality was 22% lower in the pravastatin group, with a 24% reduction in deaths from CHD and 25% reduction in deaths from other CVD causes. It is now common

practice to prescribe all four groups of drugs to individuals with CHD where possible.

The third area where improvements in the treatment of CHD since 1980 can be seen is in CR. This intervention was aimed at individuals primarily with MI, CABG and PCI and its provision spread rapidly throughout the UK during the 1990's. The number of centres providing CR grew from 99 services in 1989 to 302 services in 2000 (Bethell et al 2007). The evidence base for this intervention will be explored in more depth in chapter 3. However it is important to note that CR has developed from an exercise only model into a complex multi-factorial and multi-disciplinary intervention. The package of care provided within CR still has a focus on exercise, but also focuses on the reduction of individual risk factors, and the provision of psychosocial support and education.

2.8 Conclusion

Although some important progress has been made in reducing CHD mortality in Scotland, and elsewhere, the expected aging population will lead to a higher prevalence of CHD across the country, so the goal of disease prevention remains. This is dependent, not only on the ability to prevent it occurring, but also on the ability to detect disease early, and treat it appropriately. Recent changes in diagnostic techniques such as the use of "Troponin T" have changed the way in which the clinical cardiology community works. The classification of MI has changed to reflect these developments, identifying more people at risk. However, a great deal of debate exists around the changed definition of MI. Data from the GRACE registry would suggest that individuals with any level of raised troponin have a mortality risk more than

twice those with normal levels. Within the UK, only those with levels above one are treated as an MI, yet within Europe and the USA any rise would lead to this outcome. Despite these differences in diagnosis, the evidence base would suggest that it is important to identify those with ACSLT and put in place management plans that reduce risk.

There is a substantial body of evidence from large longitudinal multi-centre trials that show what the key contributory risk factors to CHD are: smoking, raised blood cholesterol, lack of physical activity, psychosocial factors, hypertension, diabetes, poor dietary pattern, obesity and alcohol consumption. The effect of these key risk factors on CHD has been shown to be consistent in men and women and across different geographic regions. However, the importance attached to each risk factor would appear to vary considerably, with smoking and high blood cholesterol being viewed as closely linked to the development of CHD, and other risk factors varying in importance across the world. The evidence base for treatment of risk factors also varies in strength. There is a considerable amount of evidence supporting the effectiveness of smoking cessation and the lowering of blood cholesterol through medication. However the evidence for treating dietary risk factors such as fat, salt or fruit and vegetables is limited and trials in this area have shown little impact on total mortality.

Despite the variation in the evidence base, the multi-factorial nature of CHD has led to the development of several risk scoring calculators which take the level of risk for each factor into consideration when calculating total risk. The evidence base would suggest that, within Scotland, death rates are socially patterned and that the impact of deprivation on CHD has to be taken in account

in any form of risk stratification. ASSIGN is the only risk calculator to do so (Woodward et al 2007). There is a substantial body of evidence that altering the risk profile of individuals has had an impact on mortality, with two thirds of the decrease in worldwide mortality being attributed to reductions in the prevalence of major risk factors. The remaining reduction is attributed to changes in medical treatment, such as reperfusion therapy and secondary prevention (Tunstall-Pedoe et al 1999). The evidence base for these treatments is overwhelming and the provision of these services has spread across the world. However there is a third element of treatment that has developed and is now worldwide and that is CR. This intervention is embedded in the risk reduction model and the evidence base for it will be explored in greater depth in chapter 3.

In conclusion this chapter has provided an overview of the evidence base that underpins modern cardiac care. This chapter has discussed the incidence of CHD worldwide and within the UK and highlighted changes in clinical practice within cardiac care that have led to the development of the new diagnostic category of ACS and the subcategory of ACSLT. This chapter has also identified the risk factors for CHD and has highlighted the impact on mortality from CHD that improvements in the incidence of risk factors and developments in treatment have made. These developments include CR, which is a multi-factorial, multi-professional intervention and is one of a number of interventions used to improve outcomes for CHD.

Chapter Three Cardiac Rehabilitation

3.1 Introduction

Cardiac Rehabilitation, as it is carried out in the modern NHS, is a complex intervention. The MRC framework for researching complex interventions and its importance for this thesis has been explained in chapter 1:7. This has been followed in chapter 2, by a description of the background and research base on CHD, which demonstrates that CR is one of a number of interventions used to improve outcomes for CHD. Chapter 2 has also shown us that CHD is a major challenge for the NHS, both nationally and locally. Significant changes in the modern management of CHD, as described in chapter 2:7, have highlighted that clinical practice can make a substantial impact on mortality and morbidity. Current policy would suggest that CR is a complex intervention that could improve outcome in a variety of cardiac diagnoses. This chapter will follow the MRC framework for researching complex interventions; by highlighting the evidence base for CR and by describing the relative strength of the evidence on the exercise, psychological and educational domains (Pre-clinical Phase) and by modelling what the intervention should look like (Phase I). This chapter will also examine the strength of the evidence on the components that a CR intervention includes, modes of delivery, attendance and adherence, and will also consider the gaps in the evidence base. It will identify areas of CR practice that require further testing and modelling. This chapter will discuss a new client group for CR, those with ACSLT, about whom there is little research within the CR evidence base, and will describe the theoretical frameworks on which a CR intervention could be based.

In extensive searches of the literature undertaken to review the current research base on CR, studies appearing in MEDLINE, PsycLIT, Embase, CINAHL, and PsycLIT databases were initially accessed between 2003 and 2005, and reviewed regarding objectives, methodological issues, results and clinical relevance. The literature review was then ongoing from 2005 until 2012. Both electronic and manual searches were conducted, using the key words 'patients', 'Coronary Heart Disease' 'Acute Coronary Syndrome" "Cardiac Rehabilitation" These words were coupled with 'CHD risk factors' 'treatment', "emotional health', "anxiety", "depression", "misconceptions", 'quality of life', 'perceived health status', 'treatment beliefs', 'recovery', and 'rehabilitation'' "self regulation" and "uncertainty theory". Meta-analysis, systematic reviews, RCT's and observational studies were reviewed with respect to the aforementioned areas.

3.2 Background

CR programmes evolved during the 1980s and 90s from the recognition that individuals suffered from physical deconditioning as a result of prolonged bed rest, which had been a part of the traditional treatment for MI, and the developing evidence that regular exercise was protective against CVD. There has been a steady increase in the centres providing CR over the last thirty years. The numbers of programmes in the UK grew from 9 centres in 1969 to 99 centres in 1989 and to 302 in 2000. The first Scottish programmes started in the late 1980's. By 2000, all NHS hospitals with coronary care units had access to CR programmes (Bethell et al 2007). Within the UK, CR programmes have often been developed by enthusiastic nursing staff and physiotherapists with limited funding for input from medical staff, clinical psychologists, pharmacists,

dieticians, other therapists or exercise physiologists. Programmes of CR vary considerably; in content, in client groups offered the service, length of intervention, the type of health professionals involved in their delivery, and the setting for that delivery (SNAP 2001). As time has progressed, CR has developed into a multi-dimensional package of care that encompasses a holistic approach looking at physical, social, and psychological needs to improve the individual's recovery from a cardiac event. The goal of CR is therefore, not only to prolong life, but also to improve physical and psychological functioning, symptoms, well-being, and HRQoL (SIGN 2002).

However the research base has not kept up with the developments within CR. There are large differences in the quality of the evidence for the various components of such a complex intervention. These differences were highlighted by the development of the SIGN guideline in 2002 which specifies that individuals should be offered an individualised multi-disciplinary comprehensive package of care. Within this document, there were several areas where the evidence did not reach the level set within SIGN as a gold standard, and recommendations were based on expert opinion. In the following sections the strength of the evidence in three components of this complex intervention will be considered. These areas are the physical, psychological and educational domains.

3.3 Physical domain

The evidence base for CR spans more than fifty years, with many of the initial studies focusing solely on the impact of exercise. This was at a time when many of the current treatment strategies for CHD had not been formulated. There have been three published and widely cited meta-analyses of the

effectiveness of exercise based CR compared to usual care. The first two, by Oldridge et al (1988) and O'Connor et al (1989), demonstrated that individuals randomised to exercise-based CR after MI had a statistically significant reduction in all-cause and cardiac mortality of about 20% to 25%, compared to individuals receiving conventional care. No significant effect on non-fatal re-infarctions was found. The trials within these meta-analyses were carried out, in the main, during the 1970s and 80s, before the development of CR as it is now and before the many changes in medical management that have been discussed. The trials included were small and often of poor methodological quality. The RCTs used in the reviews focussed almost exclusively on low-risk, middle-aged males post MI, thereby excluding women, elderly people and other cardiac patient groups, such as individuals with CABG or HF who may also benefit from CR.

The third meta-analysis was the largest review of exercise-based CR and included 8940 individuals in 48 RCTs (Taylor et al 2004). This review included patients with angina, post MI, CABG or PCI. A total of 19 RCTs assessed exercise training only, 30 RCTs combined exercise with other interventions and one RCT assessed both exercise only and comprehensive CR. Compared to usual care, exercise based CR significantly reduced total mortality by 20% and cardiac mortality by 26%. This is in line with the previous reviews.

Several RCT's, in individuals with chronic stable angina, have consistently shown a significant improvement in exercise tolerance in those in the exercise group (Froelicher et al 1984, Sebrechts et al 1986, Todd and Ballantyne 1992). Both the study by Froelicher et al (1984) and the study by Todd and Ballantyne

(1992) showed a reduction in cardiac symptoms and a reduction in the objective measurements of ischaemia. A RCT of exercise training in HF reported improvements in exercise capacity, myocardial perfusion, QoL, total mortality and hospital admissions (Belardinelli et al 1999). An overview of RCT'S of CR in HF in Europe (European HF training group 1998), that included 134 individuals concluded that: exercise training improved exercise capacity and autonomic indices, training could be conducted either in hospital or at home, 16 weeks was better than six, and a combination of cycle ergometry and callisthenics was better than cycle ergometry alone. Women did as well as men, and elderly individuals were able to train free from complications and with benefit to symptoms, although less effectively than younger patients.

The evidence base for the exercise component of CR, as it is delivered in the RCT's, is therefore comprehensive and compelling. It is this evidence base that has ensured the widespread development of CR across the UK. Within this evidence base, although focusing in the main on MI and CABG and PCI, there is evidence that CR can have an impact on the physical health of participants, with a variety of diagnoses, through exercise.

3.4 Psychological domain

The impact of CR on the psychological domain is an area that has interested many researchers. The impact that CHD can have on psychological functioning has been discussed in chapter 2:7. It has been shown that persistent psychological distress and poor social support are powerful predictors of outcome following MI, independent of the degree of physical impairment (Hemingway and Marmot, 1999). The link between negative perceptions and

poor outcome in people with CHD has been studied by several authors (Maeland and Havik 1987, Petrie et al 1996, Furze et al 2005). Yet there is little attention paid to cardiac misconceptions in the CR evidence base.

However, the evidence that psychological treatments within CR will reduce psychological distress is ambivalent. Comprehensive CR, based predominantly on a cognitive behavioural approach, was evaluated in one randomised trial involving 80 patients with angina, and showed improvements in exercise capacity, emotional distress, symptoms and disability (Lewin et al 1995). Lewin et al (1992) also showed that significant reductions in anxiety and depression can be achieved by a psychological intervention. In his study looking at the effect of counselling on anxiety and depression amongst first time MI patients, Thompson (1989) found that patients who received in-hospital counselling reported statistically significantly less anxiety and depression than those who received routine care alone. This effect was sustained for six months after leaving hospital.

A Cochrane review of psychological interventions in CHD (Rees et al 2004a) found that, where anxiety was measured (9 trials-2756 patients), there was a small, but significant reduction, in anxiety with a psychological intervention. Depression was measured in 11 trials and across all the trials there was a significant reduction in depression following a behavioural intervention. A meta-analysis of 8,988 patients in 37 trials, found that CR programmes including psychological and/or educational interventions resulted in a 34% reduction in cardiac mortality and a 29% reduction in recurrent MI at 1-10 years follow up (Dusseldorp et al 1999). Two meta-analyses support the use of such

therapy (Mullen et al 1992, Linden et al 1996). However two large trials found negative results for psychological outcomes (Jones and West 1996, Frasure-Smith et al 1997). It could be argued that there are several possible explanations for the negative outcome in these trials. These include the inclusion of subjects with low levels of psychological symptoms, outcome measures which were insufficiently sensitive to detect change, provision of a uniform treatment for a heterogeneous range of complaints, and a lack of appropriate training in cardiac psychological interventions among staff. However, it is important that this ambiguity in outcome following a trial of a psychological intervention is explored further.

Modern treatments for CHD need to be considered not only for their impact on mortality or morbidity, but also for their impact on the broader aspects of a patient's life. There has therefore been a rapid and significant growth in the measurement of HRQoL as an indicator of health outcomes in patients with CHD (Thompson and Cheuk-Man 2003). Reaching consensus on a definition of HRQoL is problematic because there are so many diverse views. However, there is consensus that it is a multi-faceted construct that has physiological, psychological, emotional and social components (Roebuck et al 2001). The literature suggests that HRQoL and its measurement is poorly understood and applied inappropriately (Jenkinson and McGee, 1998) and represents the effect of an illness and its treatment as perceived by the patient. Assessing the evidence base with regard to HRQoL and CR can be difficult. Hawkes and Mortenson (2003) found that a third of patients have a decline in SF-36 scores from baseline to 6 months following CR. However, other studies have suggested that CR does improve the HRQoL of patients with CHD

(Lavie and Milani 1995, Belardinelli et al 2001, Pasquali et al 2003). The difficulty for CR in measuring HRQoL is that a generic instrument may not be sensitive enough to detect change over time in the CHD population, yet a disease specific instrument may not apply to all the patients within the CR programme, who suffer from a wide range of cardiac disorders. Many disease specific instruments are designed for a specific subcategory of CHD such as MI or HF. The use of individualised instruments for the measurement of HRQoL has not been widely utilised within CR. Yet these instruments could bring an additional dimension to our understanding of the priorities of individuals with CHD.

In summary, although there is some evidence of benefit from psychological interventions, this evidence base is currently ambiguous and there is a need for further research into misconceptions, anxiety, depression, and HRQoL.

3.5 Educational domain

One of the key components of CR is education on the risk factors for CHD and a focus on behaviour change to improve physical well-being. As with the evidence base for the psychological domain, the data on the impact of CR on these factors is varied. Jolliffe et al (2001) argued that, with a programme of comprehensive CR, there were significant reductions in both total blood cholesterol and LDL cholesterol. Significant reductions in triglycerides also occurred in the comprehensive CR group. Yet they were unable, due to the lack of reporting on medication use, to rule out the possibility that this was due, in part, to the effects of the widespread use of cholesterol-lowering drugs.

Very little data have been collected on the effects of CR on BP measurement. Two large trials showed favourable effects of comprehensive CR, with reductions in systolic BP of -9mmHg and -6.4mmHg respectively (Kallio et al 1979, Haskell et al 1994). Diastolic BP was significantly reduced in the comprehensive CR programme. However there is limited data to confirm this finding.

In a study of patients waiting for CABG, McHugh et al (2001) found that after a programme of health education and motivational interviewing, according to need, patients in the intervention group were more likely to stop smoking, reduce obesity, and improve BP. These positive benefits were also found in anxiety, depression and physical activity.

Dusseldorp et al (1999) in a meta-analysis of 37 studies, argued that health education programmes such as CR yielded significant positive effects on BP, cholesterol, body weight, smoking behaviour, physical exercise and eating habits. A randomised trial of health education for individuals with angina in primary care, found that it improved exercise, diet and QoL, but did not affect smoking rates, lipids or BP levels (O'Neill et al 1996).

A meta-analysis of education in patients with CHD by Mullen et al (1992) demonstrated a significant mortality reduction of 19%, but found no impact on re-infarction or hospitalisation. Another meta-analysis by Dusseldorp et al (1999) concluded that a health education and stress management programme yielded a 34% reduction in cardiac mortality and a 29% reduction in re-infarction. However, this meta-analysis included a mix of psycho-social interventions and therefore cannot be seen as a review of education alone.

Both these reviews included both randomised and non-randomised evidence and enrolled white, middle class males. In addition, they were carried out at a time prior to the rapid developments within cardiac care previously discussed and therefore their applicability to current practice is limited.

In summary, it would appear that educational interventions as part of CR can provide health gain, but that further exploration of the role that education can play in a modern individualised programme of CR and the different benefits that could bring are required.

3.6 Impact on under-represented groups

One of the criticisms of the previously discussed research is that it has concentrated mainly on young male MI and cardiac surgery patients. There is however some research on the impact comprehensive CR can have on other groups such as the elderly, ethnic groups, and women.

As has been stated earlier, the incidence of CHD rises with age and older patients have more modifiable risk factors than younger adults (Fair 2003). There is some evidence that CR can have benefits no matter the age. Effective rehabilitation services have been shown to reduce cardiac death and improve exercise tolerance, functional capacity and QoL in older people (Lavie and Milani 2000, Jolliffe et al 2001, Ades et al 2002, Hage et al 2003, Marchionni et al 2003). In a study looking at patients, older than eighty, who attended at least one session of CR, Muhll et al (2002) demonstrated a 20% increase in functional capacity with exercise based CR in this very elderly cohort, without any adverse events. Exercise based CR appears to be safe in the elderly and studies demonstrate that improvement is similar to younger patients.

A study of patients after MI (Witt et al 2004) found that, although individuals older than 70 years old were less likely to participate in CR, overall survival benefit was better in CR participants compared with non-participants, along with a decrease (28%) in recurrent MI.

Women are generally older when they develop CHD and this has implications for their ability to access and benefit from CR. Issues around attendance will be dealt with in chapter 3:7, however the evidence for benefit in women is also limited. Most of the meta-analyses mentioned in chapter 3:3 included mainly men and did not focus on the benefits to women.

CHD is a major contributor to both morbidity and mortality in ethnic minority populations (Mosca et al 1997, Sheth 1999). The prevalence and degree of the associated risk factors varies across different cultural, ethnic and racial groups. (Yusuf et al 2004, Mosca et al 2004). Yet the evidence base for CR in ethnic groups is limited.

As stated before, it has been recognised that much of the previous CR research has been conducted on white middle class males and the focus needs to shift to identifying how CR can improve impact across diverse populations.

3.7 Uptake and adherence

One of the challenges that has faced CR programmes is the implementation of the research. A recent study looking at uptake and adherence in a RCT found that 73% of all patients admitted to hospital with MI were eligible for CR. Those excluded tended to be older, were more likely to have suffered from previous MI and had a more severe presentation of CHD (Beswick et al 2004).

However, at least an additional 22% did not attend CR. This was due to further selection by CR staff. There was a clear trend for non-invitation in older age groups. Uptake rates amongst older patients can be as low as 14% for women and 20% for men over 62 (Ades et al 1992a, 1992b). It has been argued that older people desire CR programmes that they perceive as being more conducive to their needs (Davidson et al 2003). This could mean communicating the benefits of CR in a way that is meaningful to older people, such as promoting independence, improving their ability to perform household chores and to pursue leisure activities.

In a trial carried out in the West Midlands of England, Jolly et al (2005) found that one reason for the exclusion of ethnic groups in clinical trials was the inability to support the range of minority languages required. They found that significantly more patients of South Asian ethnicity were excluded and that there were large differences between Indian, Pakistani and Bangladeshi patients, with Bangladeshi patients being far more likely to be excluded. However, those who met the language criteria were then recruited to the trial in equal numbers. Studies that have assessed CR uptake in patients from ethnic backgrounds have found that uptake and adherence are especially low in those populations with the highest rates of CHD and who would have a lot to gain from CR (Tod et al 2001). Webster et al (2003) determined that the needs and experiences of the Gujarati Hindu patients, after a cardiac event, were different from those of non-asian patients. They suggested that a lack of accessible culturally appropriate information about CHD, its management and prognosis, may influence South Asian patients post MI behaviour and therefore their adherence to CR recommendations.

Pell et al (1996) in a study of CR in the West of Scotland found that deprivation was associated with an increased risk of MI. Deprived patients were no less likely to be invited to attend CR, but they were significantly less likely to start. In addition, deprived patients who did start the programme were less likely to complete it. There is a dearth of literature reporting the evaluation of simple interventions aimed at improving adherence to CR for all patients or specific groups of patients (Beswick et al 2004).

3.8 Modes of delivery

The literature on the impact of CR in the physical domains shows definite benefits, and in the psychosocial domain, there is some evidence of benefit. However, as has been stated earlier, the components of CR, are both multi-factorial and multi-disciplinary and need to target a wide range of individuals from different backgrounds. There are a number of ways in which CR can be delivered. These include: different intensity of exercise, different venues, and different start dates following a cardiac event. This makes the gathering of evidence of what combination works well and brings the best outcomes difficult. The relative importance of each of the components has not been analysed. There have been few RCT's which compare varying types of programmes or analyse which components have more impact. Taylor et al (2004) found no significant difference in the impact of CR on total mortality when comparing trials of exercise only or comprehensive CR or when comparing trials of different doses of exercise. Jolly et al (2005) reviewed the evidence relating to different modes of delivery, more particularly with regard to home based CR provision. In this review they identified 18 RCT's that compared home based CR to usual care and 6 RCT's that compared home based CR to

centre based CR. In their review they found significant improvements in systolic BP and smoking cessation in home CR when compared to usual care, but when directly compared to centre based CR, they found the effects on exercise tolerance and risk factors to be similar. Although the research tells us that a CR programme can have benefits for a range of people, there is difficulty in implementing these trials in clinical practice. Programmes are constrained by local resources, access issues and poor referral, take-up and attendance rates (Lewin et al 2004). However, none of these trials addressed menu-based programmes where the individual's needs are identified and treated.

In summary, clinical programmes do not have the ability to restrict the participants to specific client groups or specific types of provision, and this has led to a gap between research and clinical practice where menu-based CR has become the recommended mode of delivery (SIGN 2002). This will be explored in greater detail in chapter 3:9.

3.9 Menu-based Cardiac Rehabilitation

Current CR provision within the UK has been examined by several researchers (Bethell et al 2000, Lewin et al 2004) and there has been some progress on developing a benchmark for service provision. In the past, MI was seen as an acute event, something that happens and that you recover from and don't allow to interfere with the future. However in recent years, as secondary prevention strategies have developed, there has been a move away from this to viewing MI as part of a chronic illness (SGHD 2007). As has been shown previously, there are many drugs now that can slow the progression of CHD, in addition, there are strategies involving behavioural change that can impact on

risk reduction. But, in order for these to work, there needs to be compliance on the part of the individual and an understanding by them that this condition will be with them for life. This focus on self-management has been encouraged by government with the development of a focus on long term conditions throughout the healthcare system (SGHD 2008). There has been a move within CR to recommending a menu based approach and standards issued by the BACR support this development (BACR 1999). However the menu-based approach is, for the most part, based on expert guidance and not on research. There is little research that evaluates the impact of menu-based CR as it is currently provided within the UK.

The framework for CR provision in the UK (BACR 1999) is divided into four phases and each represents a different section of the pathway (see Table 3:1). The initial phase covers the stay in hospital and it consists of a full assessment of the individual's needs and the provision of both information and support to the individual and their family, with the focus on explaining the diagnosis and the context of the recovery. This is often undertaken by either a nurse or a physiotherapist in the ward area and is the introduction to the CR programme.

The second phase, or as it is also known as the 'post discharge phase', relates to the period of time between discharge and commencing an outpatient CR programme of some description. The length of this phase can be anywhere from one or two weeks to several months in some programmes, but usually lasts about four to six weeks. During this time, a range of activities can take place according to local circumstances. These could include telephone follow up, home visits from specialist staff, follow up by community nursing teams or

practice nurses or the provision of specialist resources such as the Heart Manual (Lewin et al 1992). The focus during this period is on returning to normal activities and on reducing risk behaviours such as smoking or poor eating habits.

Phase three, or more commonly the 'outpatient phase', relates to the provision of a programme of exercise which commences when the individual is deemed fit to exercise, usually around four to six weeks post cardiac event. The exercise prescription can include home programmes, low or moderate intensity exercise, and either hospital or community provision. It can often include education and support sessions and on-going assessment of individual needs.

Phase four, or the 'maintenance phase', refers to the time following discharge from a CR programme for the rest of the individual's life. It comprises activities designed to reduce risk and help to prevent a further cardiac event. These could include exercise classes, smoking cessation, support groups, secondary prevention clinics in the community and other supports available within the local community. It is not often within the remit of CR programmes, but often falls to local authorities, community services or voluntary groups. Across the UK there are a lot of differences in the resources and component parts of a local CR programme. Not all phases are provided or supported by all programmes. However both phase one and phase three are components of most CR programmes in the UK.

Table 3:1 Phases of Cardiac Rehabilitation

Phase one: Inpatient care	Medical assessment, reassurance and education, correction of cardiac misconceptions, risk factor assessment, mobilisation and discharge planning are the key elements. It is customary to involve family and partners from this early stage.
Phase two: Early post discharge period,	Support can be provided by home visiting, telephone contact and some programmes use the Heart Manual.
Phase three: Outpatient exercise training	A structured exercise programme in a hospital or community setting. A menu-based approach recognises the need to tailor the delivery of services to the individual and is likely to include specific education to reduce cardiac misconceptions and encourage smoking cessation and weight management.
Phase four: Long term maintenance	Involves the maintenance of physical activity and lifestyle change. Membership of a local cardiac support group, a gym or leisure centre, may help maintain physical activity and behavioural change.

Source: SIGN 2002

In summary, the menu-based approach is based on expert guidance and not on research. There is little research that evaluates the impact of menu-based CR as it is currently provided within the UK.

3.10 Acute Coronary Syndrome Low Troponin

As has been discussed in chapter 2:5, the development of new diagnostic tests, which identify small amounts of damage to the heart, have led to changes in the treatment of MI. New diagnostic categories have been created (see Table 2:1), which classify all admissions to hospital with chest pain according to the level of troponin in the bloodstream. There is a large body of evidence on the medical management required for individuals with all categories of ACS including ACSLT (SIGN 2007a). However, although there is evidence for the effectiveness of CR in MI and stable angina, there is little published evidence that looks at the impact of CR on patients with ACSLT. These patients have traditionally not received CR in the UK and little is known of the impact that CR could have on this group.

3.11 Theoretical framework for Cardiac Rehabilitation

The increasing focus on individualised care within CR has highlighted that CR programmes need to become more effective in addressing the psychological needs of the patients as well as their physical needs (Linden et al 1996, Mayou 1996, Jolliffe et al 2001). Surveys have highlighted that psychosocial factors are still poorly assessed (Lewin et al 1998) and that the measurement of psychological and QoL criteria within programmes is not universally carried out (Bethell et al 2000).

Professionals, within CR, do not use psychological interventions systematically due to limited identification of patient's illness beliefs and expectations. Programmes do not ground interventions in a specific theory or framework. The need to pursue the establishment of a well-grounded theoretical framework, to develop models of care that deliver effective CR interventions, has been clearly recognised (DOH 2000), and highlighted in guidelines issued by the BACR (Coats et al 1995).

Over the last twenty years, CR has developed from the initial exercise and risk factor management model to a broader holistic model of multi-disciplinary care. As discussed previously, there are difficulties in implementing evidenced based practice in CR, and improving individual compliance with treatment is therefore an important element of the design of any CR intervention. Therefore, the theoretical framework underpinning the intervention for this thesis needs to have a similar focus. Without accommodating patient's individual psychological perspectives, when developing and delivering care strategies, research indicates that there is a potential for ineffective communication and ultimately a failure to provide appropriate rehabilitation strategies that sustain long term health behaviour change (NHS CRD 1998).

The two theories which have been used to underpin individualised care in CR are the CSM (Leventhal et al 1980, Leventhal et al 2003) and Self-Efficacy (SE) (Bandura 1977). Both theories try to explain why patients with similar conditions differ in their response to that condition and how carers can best manage these differences. Each theoretical framework argues that it is through

the individuals experience, rather than their personality, that patient's actions and perceptions are informed (Lau-Walker, 2004).

The CSM (Leventhal et al 1980, Leventhal et al 2003) is a commonly used model to explain how people interpret current and potential health events or threats. The CSM is organized in five dimensions which together make up common sense perceptions of an illness episode or health threat.

The five key elements of this theory are *identity, timeline, cause, consequences, and control/cure.* Identity refers to the label a person uses or to the symptoms that they view as being part of their illness. Timeline refers to an individual's beliefs about how long the illness will last. Cause describes an individual's personal ideas about the cause of the health problem. Consequences relate to an individual's beliefs about the likely impact of the illness on QoL or functional ability. Control/cure relates to the individuals beliefs about whether the condition can be cured or kept under control and the degree in which the individual plays a part in achieving this.

The CSM is particularly suited to understanding and improving patients' management of chronic illness. The theory involves individuals monitoring their efforts and outcomes in managing tasks and using this information to regulate the process towards achieving desired goals. As a theoretical model it describes patients as active problem solvers, who make sense of a threat to their health such as physical symptoms or an illness, by developing their own cognitive representations of the threat, which in turn, determine how they respond (Leventhal et al 1980, Leventhal et al 2003). The model can be conceptualised as operating in three stages. The first involves the creation of

cognitive and emotional representations and thus goals for coping. The second stage refers to the development and execution of plans for coping directed towards those goals. The third stage of appraisal involves evaluating whether the coping response has moved the individual closer to, or further from, the goals specified by the representation (Lau-Walker 2004). An individual's illness representation involves both concrete (e.g. chest pains) and abstract features (the idea that one is having a heart attack).

The CSM has been used in a number of studies amongst different populations including diabetes (Griva et al 2000), psoriasis (Fortune et al 2002) and multiple sclerosis (Vaughan et al 2003). In CHD, one study by Ades et al (1992a) found that patients who were judged by staff to view their illness less seriously, were less likely to attend CR. Petrie et al (1996) argue that the assessment of illness perceptions may have a valuable role in identifying which patients are likely to benefit from CR programmes. Patients who perceived that, their heart disease has little hope of being controlled, may benefit from another intervention, specifically targeted at changing this perception, before attending CR. Whitmarsh et al (2003) argue that people who attend CR differed from poor/non-attenders in that they perceived a greater number of symptoms and consequences of their illness, greater distress, less strong beliefs that their illness had been caused by a germ or virus, and used problem-focused and emotion-focused coping more frequently. The best predictors of poor or non-attendance were: lower perceptions of symptoms and controllability or curability of the illness, and less frequent use of problem-focused, and more frequent use of maladaptive coping strategies. In a further study, Petrie et al (2002) showed that a brief intervention, based on the CSM, carried

out in hospital, prior to discharge after a MI, caused significant positive changes in patients' views of their MI. Patients in the intervention group also reported they were better prepared for leaving hospital and subsequently returned to work at a significantly faster rate than the control group. Before leaving hospital, patients in the intervention group had significantly modified their perceptions about how long their illness would last and the personal consequences of the MI on their life compared with the control group. The group reported a significantly lower rate of angina symptoms than control subjects, although there were no significant differences in CR attendance between the two groups.

The second theoretical framework that could be used is SE. The leading proponent of SE theory is Albert Bandura (1977), who asserts that behaviour is the outcome of an interaction between cognitive processes and environmental events. People process and synthesise feedback, from sequences of events over long intervals, about the situational circumstances and the patterns and rates of action that are necessary to produce given outcomes. Perceived SE is not a measure of the skills one has, but a belief about what one can do under a different set of conditions, with whatever skills one possesses. A patient may believe that exercise will improve future health, but may still not engage with exercise because they do not see themselves as able to start regular exercise and sustain it.

Bandura (1977) argues that there are four sources of SE with a hierarchy of significance for informing behaviour:

1. Enactive mastery experience which is based on personal mastery experiences
2. Vicarious experience: seeing others perform activities without adverse consequences may generate expectations that they too will improve if they persist in their efforts
3. Verbal persuasion: people are led through suggestion into believing they can cope successfully with what has overwhelmed them in the past
4. Physiological and affective states: an individual's physiological state provides information that can influence efficacy expectation.

Self-Efficacy makes a difference in how people feel, think and act. Levels of SE can enhance or impede the motivation to act. A key element of CR is the need to sustain change over long periods of time and it is here that SE could be seen as a suitable theoretical framework.

Jackson et al (2005) in their review of attendance and adherence in CR found that an important factor in attendance was a high level of SE. Improvements in SE with a CR intervention have also been found by a number of authors (Gardener et al 2003, Lau-Walker, 2004). Gardener et al (2003) also found that SE improved regardless of gender and diagnoses.

Lau-Walker (2004) in a study on the relationship between CSM and SE found that there was a significant relationship between CSM and SE. The greater patients' perceived consequences of the heart condition, the lower was

the general SE available to cope with the condition. Further, the longer the perceived time the condition will affect the patient, the higher the specific SE to maintain a change of diet or exercise regime. Her findings identify that, in the initial phase of recovery, nursing practice needs to focus on the key variables of the CSM of 'consequence' and 'timeline' in order to increase patients' confidence in their ability to cope (SE).

Research on the CSM tends to be associated with health outcome intentions, whereas SE research tends to be associated with predicting long term behaviour changes (Petrie and Weinman 1997, Lau-Walker 2004). Both have merits in the field of CR, however this thesis focuses on health outcomes, rather than long term behaviour change, so the theoretical framework that will be used is the CSM.

3.12 Need for further research

The evidence base for the exercise component of CR, as it is delivered in RCTs, is compelling. But this is not the case for the psychological and educational domains. Although there is some evidence of benefit in psychological interventions within CR, there is also a degree of ambiguity in the CR literature. Areas such as misconceptions, anxiety, depression and HRQoL need further research. Educational interventions in CR can bring health gain, but there is a need for further exploration of the role that education can bring to a menu-based programme of CR. The difficulties within the literature regarding the psychological and education domains are partly due to the difficulty in separating out the key components of CR to allow evaluation. Much of the early CR research has been conducted on white middle class males, yet clinicians working within CR programmes do not have the ability to restrict participants to

specific client groups or specific types of provision. The focus needs to shift to identifying how CR can improve impact across diverse populations and diagnoses.

There is also a limited evidence base reporting the evaluation of simple interventions aimed at improving adherence to CR for all patients or specific groups of patients. Professionals within CR do not use psychological interventions systematically due to limited identification of patient's illness beliefs and expectations. Programmes do not ground interventions in a specific theory or framework which would support better compliance and treatment outcomes.

The research base for menu-based approaches and for some groups such as those with ACSLT is very limited. This has led to a gap between research and clinical practice, where menu-based CR has become the recommended mode of delivery, and CR programmes are being asked to take patients with a wider range of cardiac diagnoses. Clinicians need further research to support them in the development of menu-based services, based on a theoretical framework, particularly in the psychological and educational domain. Despite the gaps in the research, CR has become an accepted part of the recovery of all patients with MI and CABG. Government strategies (DOH 2000, SIGN 2002) have recommended that CR should be available for all patients and this makes the need for further research on these issues essential.

3.13 Conclusion

In the previous chapter, it was noted that CHD is a major challenge for the NHS, both nationally and locally. Significant changes in the modern management of CHD have highlighted that clinical practice can make a substantial impact on mortality and morbidity. The evidence base would suggest that it is important to identify those with a diagnosis of ACSLT and put in place management plans that reduce risk and improve outcome. A treatment that is not currently provided, to individuals with this diagnosis, is CR, which is a multi-factorial, multi-professional intervention and is one of a number of interventions used to improve outcomes for CHD.

The goal of CR is not only to prolong life, but also to improve physical and psychological functioning, symptoms, well-being, and HRQoL (SIGN 2002). In this chapter the evidence base for CR has been reviewed across three domains: exercise, psychological and educational and it has been shown that there are large differences in the quality of evidence for the various components of such a complex intervention. The evidence base for the exercise component of CR is comprehensive and compelling. Although focusing in the main on MI, CABG, and PCI, there is evidence that CR can have an impact on the physical health of participants with a variety of diagnoses through exercise. This is confirmed in several meta-analyses, systematic reviews and RCT's.

If the psychological domain is considered, it can be seen that there is some suggestion of benefit from psychological interventions within CR. However, the findings from this evidence base are currently ambiguous and there is a

need for further research into the role of misconceptions, anxiety, depression, and HRQoL.

The final domain is the educational domain and the research base on the impact of CR on this area is varied. Several meta-analyses would suggest that educational interventions as part of CR can provide health gain. However, there are some difficulties in differentiating the impact of education and of psychological interventions. There is a need for further exploration of the role that education can play in a modern individualised programme of CR.

This chapter has examined a range of issues that have been highlighted in the evidence base for CR, that need to be considered when modelling a CR intervention. These include: the selection of appropriate target groups, uptake, adherence, and modes of delivery. In addition the choice of the theoretical framework on which to base a CR intervention has been discussed. One of the criticisms of the evidence base is that it has concentrated mainly on young male MI and cardiac surgery patients, however there is some research on the impact comprehensive CR can have on other groups such as the elderly, ethnic groups, and women. This evidence base is limited in scope and size and further research in this area is needed. There is a large body of evidence on the medical management required for individuals with all categories of ACS including ACSLT (SIGN 2007a). However, although there is evidence for the effectiveness of CR in MI and stable angina, there is little published evidence that looks at the impact of CR on patients with ACSLT.

There is also a dearth of literature reporting the evaluation of simple interventions aimed at improving adherence to CR for all patients or specific

groups of patients. There have been few RCT's which compare varying types of programmes or analyse which components of CR programmes have more impact. Programmes such as menu-based CR have become the recommended mode of delivery, yet there is a dearth of evidence of the benefits of this type of service delivery. This increasing focus on individualised care within CR has highlighted that CR programmes need to have a theoretical framework on which to base care. In this chapter, two frameworks have been reviewed, both of which have merits in the field of CR. These are CSM and SE. Both theories try to explain why patients with similar conditions differ in their response to that condition. Research on the CSM tends to be associated with health outcome intentions, whereas SE research tends to be associated with the prediction of long term behaviour change (Petrie and Weinman 1997, Lau-Walker 2004). Both have merits in the field of CR, however the theoretical framework that will be used in this thesis is the CSM.

Despite the gaps in the research, CR has become an accepted part of the recovery of all patients with MI and cardiac surgery. Government strategies (DOH 2000, SIGN 2002) have recommended that CR should be available for all patients with CHD and this makes the need for further research on CR and those with ACSLT essential.

In summary, this chapter has followed the MRC framework for researching complex interventions, by highlighting the evidence base for CR and the relative strength of the evidence on the exercise, psychological and educational domains (Pre-clinical Phase) and by modelling what the intervention should look like (Phase I). This chapter has examined the strength of the evidence on

the components that a CR intervention would normally include, modes of delivery, attendance and adherence, and has described the theoretical framework on which the CR intervention will be based. This chapter has also identified areas of CR practice that require further testing and modelling and has identified a client group for CR (ACSLT) about which little is known

Chapter Four Research aims and design

4.1 Introduction

In the previous chapters, following the MRC framework for complex interventions, the research base and the underpinning theory have been highlighted and the components that could make up the intervention modelled. The next step in the framework is that of Phase two; the exploratory trial. The thesis contains a feasibility study and an exploratory study. The feasibility study aimed to examine the feasibility of a RCT which would test the impact of a menu-based CR programme, on individuals diagnosed with ACSLT, against standard care. This feasibility study also included staff views. The exploratory study aimed to explore the impact that ACSLT and CR can have on this client group. The findings of this thesis would inform the design of a RCT (phase three) and the progression thereafter to phase four; implementation into practice.

This chapter will describe and discuss the methodology employed to meet the aims of this thesis, taking into account the clinical context and information from the literature. The design and coordination of the studies will be discussed first, followed by ethical considerations and recruitment. The measures and process for data collection will then be addressed, and finally, timescales and funding.

4.2 Background

As has been previously stated, CR is a complex intervention and the design and evaluation of complex interventions is problematic. There are a large number of diverse components within CR, which act and interact with one

another to achieve a range of outcomes for the participant. The evidence base for CR has been discussed in chapter 3:2-3:9, however, this evidence base is predominantly focused on the post-MI and CABG populations. There is a need to examine the impact within a new client group, those with ACSLT.

4.3 Choice of research methods

As stated the choice of research methods has been determined by the MRC framework, which suggests that a RCT is the gold standard for researching complex interventions. However, before developing a RCT, it is important to determine whether an intervention is appropriate for further testing, in other words, to assess whether or not the ideas and findings can be shaped to be relevant and sustainable (Bowen et al 2009). A feasibility study for a RCT is necessary therefore, to test the study design, instruments used, and the intervention itself in terms of its acceptability to the participants and staff. There are few previously published studies or existing data on CR in ACSLT. It is therefore also important that an exploratory study is carried out to examine the experience of participants with ACSLT. For this reason this thesis uses both quantitative and qualitative methods in collecting data. This is the first step in evaluating the impact that CR can have on this new and novel population.

4.4 Aim of thesis

This thesis contains a feasibility study and an exploratory study. The feasibility study aimed to examine the feasibility of a RCT which would test the impact of a menu-based CR programme, on individuals diagnosed with ACSLT, against standard care. This feasibility study also included staff views. The

exploratory study aimed to explore the impact that ACSLT and CR can have on this client group.

4.5 Research questions

In attempting to meet the aim of the thesis, specific research questions were devised:

Feasibility Study

- Would a RCT of a menu-based CR programme for individuals with a diagnosis of ACSLT be feasible ?
- How do staff caring for individuals with ACSLT view the study and the feasibility of a RCT of CR

Exploratory Study

- What impact did a menu-based CR programme for individuals with a diagnosis of ACSLT have on four areas
    - Cardiac misconceptions
    - Cardiac symptoms
    - Anxiety and depression.
    - HRQoL
- How do individuals with ACSLT view their illness?

This thesis includes two studies: a feasibility study and an exploratory study. However, these studies used the same group of participants, who were recruited while in-patients within the wards, and data were collected from the participants throughout the timescale of the studies. The data relating to feasibility are reported in the feasibility study and the data gathered from both

quantitative and qualitative measures are reported in the exploratory study. The term “participant” will be used for the patients who took part in the studies. Nursing staff took part in the focus groups as part of the feasibility study and they will be referred to as “staff”. The terms; feasibility study, exploratory study, studies, and thesis will be used throughout. In order to avoid confusion, the term “feasibility study” will be used when it relates to issues of feasibility. The term “exploratory study” will be used when it relates to the data collected from participants. The term “studies” will be used when information from both studies is being discussed and the term “thesis” will be used to describe the work overall.

4.6 Feasibility study design

The feasibility study was a exploratory repeated measures longitudinal case-control study, that examined the feasibility of a RCT, which would test the impact of a menu-based CR programme, on individuals diagnosed with ACSLT, against standard care. This feasibility study included staff views on issues of feasibility and CR through the use of focus groups.

4.7 Exploratory study design

The exploratory study was a repeated measures longitudinal case-control study that aimed to explore the impact that CR can have on this client group, through the use of both standardised questionnaires and qualitative data collected at interviews with the participants. This two group study aimed to compare patients who received CR (intervention) with patients who did not (control). Although it would have been beneficial to randomise participants into the two groups, this design was not possible, due to the anticipated impact on

the workload for the CR team. The practicalities of organising and delivering an intervention meant that a case control design was the better choice, as it concentrated the professional resource that was needed into a short time span and this allowed the staff to develop and practice the skills required for this population.

4.8 Ethical considerations

Prior to initiation of the studies, the protocol was submitted to the Ethics committee of NHS Ayrshire and Arran and the Research Ethics Committee of the School of Nursing and Midwifery at the University of Stirling. The studies were conducted within the Research Governance Framework of NHS Ayrshire and Arran and run according to internationally agreed Good Clinical Practice Guidelines (ICH 1996). A summary of the ethical considerations in these studies are considered in the following discussion.

Admission to hospital with an acute cardiac event is a stressful time for any individual and this makes them vulnerable to undue pressure. It was important to remind participants that their participation was entirely voluntary and that they could decline participation or withdraw at any stage of the study. The researcher ensured that all participants were given a full description of what the studies entailed. The researcher is a well-known figure within cardiology and has worked in this area for 18 years. Often, the influence that the person recruiting the individual has, can be crucial. If the researcher is perceived as part of the clinical team, then the individual may be more willing to agree, as they may feel dependent on the care given during their stay in hospital. The individual may also worry over the care they will receive, if they do not take part in the trial, or

they may think that they will get better care if they do. This could have been difficult for the researcher, as in her previous role she would be perceived as part of the clinical team. During the period of these studies however, her only role for this group of participants was as a researcher, and this was made clear to all patients. As the researcher has moved into a managerial role in the last two years, she has withdrawn from the in-patient clinical area. Patients are very vulnerable during a hospital stay and it could have been that, by completing the questionnaires, additional concerns were raised. Clear guidance was available both in the written information from the researcher and from clinical staff who had been updated on the process of the studies and were vigilant in looking for signs of distress. In addition, both the cardiologist and general practitioner were informed of the patient's participation in the studies. There were no instances of distress caused to participants during these studies.

The guidelines (ICH 1996) state that 48 hours minimum should be given to patients to allow them to consider their participation in the studies. As many of these patients only spend four or five days in hospital this was quite difficult to achieve. It was felt that 24 hours to consider participation was achievable and this was agreed to by both ethics committees. The researcher ensured that information was available from admission if the patient met the criteria. Patients were told that they may be approached or not depending on the diagnosis reached and that they should consider if they wished to be involved in the research. This allowed the patient time to consider their opinion on participation before they were approached. The criteria for entry to the studies were clear and concise, so that those not selected, due to a different diagnosis, would be aware that this was the reason. All patients, selected for the research, were

approached by the researcher and given full written and verbal information. They were then given 24 hours to discuss their participation with their families.

Another possible area of difficulty is the fact that participants received usual care or were part of the intervention arm. As the studies were not randomised, the researcher and the ward staff knew beforehand which group the participant would be allocated to and this could have influenced the recruitment process. It may be that, the staff would not see any benefit for their patient in participating in the study, if they were to be in the 'usual care' arm. This could lead to difficulty in recruitment. In this trial it was agreed therefore to use a delayed intervention, in that those in the control arm, who wished to do so, would be offered the chance to take part in the intervention following the completion of the research.

All participants in the studies were assessed following the same protocols. This includes risk stratification using exercise tolerance testing, which they require regardless of participation or not, and assessment by the physiotherapist regarding other health problems, which might influence their ability to exercise. Where the health of the participant deteriorated, and it was felt they were no longer able to cope with the studies, they were withdrawn and usual care continued.

As some participants took part in exercise classes during the intervention there was a potential increased risk of a cardiac event. This is calculated as one event in six years (SIGN 2002). Exercise classes are standard for CR programmes, and protocols were in place to identify the risk for individual participants and to place them in the appropriate class. Consultant cardiologists

were involved in the assessment of risk, prior to the individual's attendance at class, to ensure safety. Classes were supervised by a specialist nurse and emergency arrangements were in place. Should a participant take unwell in class or be unable to complete the required number of sessions, plans were in place for them to be assessed and treated according to local protocols. This did not in fact happen and there were no withdrawals for this reason.

As has been stated previously, the researcher was a clinical expert in the field and there are clear difficulties in stepping out of this clinical role into that of a researcher, particularly if the participant develops health or other problems that should be dealt with immediately. The participant may become unwell or be suffering from a life threatening deterioration in their illness. The researcher was aware that she should not break the confidentiality of the interview without the express permission of the participant. In the event that information became available to the team, about the health of the participant, that suggested continuing would cause them harm, they would have been immediately withdrawn. If a participant had received a terminal diagnosis during the period of the research, or their cardiac condition had deteriorated quickly, completing the studies may have caused them emotional distress. This did not in fact happen, but the researcher was aware of the possibility.

Confidentiality was respected at all times throughout the studies, with adherence to the Data Protection Act (DOH 1998) and compliance with the NHS Scotland Code of Practice on Protecting Patient Confidentiality (SEHD 2003, SGHD 2010). The following measures were taken to protect participants' confidentiality: all participants were assigned identification numbers, all data

was anonymised as soon as possible. The only information that contained demographic data were the registration sheets as this was necessary to facilitate the home visits. This was kept in a locked drawer in the consultant nurse's locked office. All other study material was stored in a locked filling cabinet in the same office. Participants were informed that demographic data would be collected and were assured of anonymity in the material written up for the studies. Any electronic data relating to the studies was only accessible on the Principal Investigators password protected PC, and this was kept in a locked office. The Caldicott Guardian was informed of the existence of the data and it was agreed that the data will be destroyed 15 years after the completion of the research.

4.9 Access to clinical sites

These studies were carried out in NHS Ayrshire and Arran, serving a local population of 375,000. NHS Ayrshire and Arran has a high incidence of CHD, with 22,000 people currently living with CHD. In addition, there are approximately 5,000 admissions a year for a CHD related illness and 2500 new referrals for outpatient cardiology assessment (ISD 2011). The researcher was based within this area and had easy access to the clinical community. The CHD Managed Clinical Network (MCN) funded the research and was keen that both local hospital sites be included, so that information that would guide future service development for individuals with this diagnosis was gathered across the health board area.

A copy of all documentation was submitted to the Research & Development (R&D) Department. Full R&D approval was in operation throughout the research

period which included access to the relevant clinical sites. Annual reports were submitted to the required R&D department as part of the approval requirements.

4.10 Sample

This thesis contains a feasibility study and an exploratory study. The feasibility study aimed to examine the feasibility of a RCT which would test the impact of a menu-based CR programme, on individuals diagnosed with ACSLT, against standard care. This feasibility study also included staff views. There are therefore two target groups of recruitment within the feasibility study: patients and staff.

Recruitment within the patient group took place whilst they were in hospital. The patients recruited to the feasibility study also took part in the exploratory study and the recruitment process for both studies is described in chapter 4:13.

The staff group, involved in the feasibility study, included 8 participants drawn from 60 staff employed within the cardiology wards and 6 staff drawn from 15 staff employed within the CR service within NHS Ayrshire and Arran. They were recruited to elicit their views on the feasibility of a RCT of CR through focus groups. The inclusion criteria for this element of the feasibility study were:

- Working within cardiology or CR during the full period of the feasibility study

The exclusion criteria were:

- Having a first degree relative who had been through CR

The exploratory study was a repeated measures longitudinal case-control study that aimed to explore the impact that CR can have on this client group through the use of both standardised questionnaires and qualitative data collected at interviews with the participants. This two group study aimed to compare patients who received CR (intervention) with patients who did not (control). Recruitment within the patient group took place whilst they were in hospital. The recruitment process for both studies is described in chapter 4:13.

Predicted recruitment was based on current admissions to the two hospitals within NHS Ayrshire and Arran. It was anticipated that 100 participants would be recruited over the timescale proposed. It was thought that fifty would be recruited from site one and fifty from site two. The first twenty five on each site were to be in the control group and the rest were to be allocated to the treatment arm. It was planned to perform both between group and between site analysis. As there was little research in this area a power calculation was not possible. It was hoped that this work would inform the power calculation for a RCT. All patients of both sexes, who were admitted to two hospitals sites within NHS Ayrshire and Arran and diagnosed with ACSLT, were considered for inclusion in these studies. Participation in these studies was entirely voluntary and participants were free to withdraw at any time without prejudicing their medical care and without having to justify their reasons for doing so. Diagnosis was established by one or more of the following:

- Clinical History
- Ischaemic ECG changes
- Cardiac troponin release or raised serum Creatinine Kinase-MB(CK-MB) enzyme demonstrated at any time during admission

As a key element of the studies was the CR intervention, it was important that patients who would normally be referred for CR and who had previous experience of CR were not included.

The inclusion criteria for patients within both studies were:

- Patients who are living in NHS Ayrshire and Arran
- Able to speak, read and understand English
- Aged 16 or over
- Diagnosed as ACSLT by criteria above

The exclusion criteria for patients within both studies were:

- Classified as MI as they would normally receive CR follow-up
- Housebound
- Previous attendance at CR
- Currently receiving treatment for a terminal illness

4.11 Cardiac Rehabilitation in NHS Ayrshire and Arran

The CR programme within NHS Ayrshire and Arran was established in 1990 with the appointment of a specialist nurse to provide care at site two for 400 individuals with MI. Since then it has expanded to include both hospitals, and those who have had a cardiac event such as CABG, valve surgery, PCI, HF, or are referred from a rapid access chest pain clinic, as well as the original population of post MI. The CR team is managed by a consultant nurse and all the staff within the team have had more than ten years experience in cardiac care, with at least five years experience within CR.

Currently, the staff within the team support 1400 individuals with CHD following an acute event. They provide 12 exercise classes and 4 nurse led clinics across the area in both hospital and community sites. In addition, the team is supported as required by: cardiologists, pharmacists, dieticians, smoking cessation specialists, and social workers. The team consists of the following permanent staff as noted in Table 4:1.

Table 4:1 CR staffing

Title	Band	WTE
Consultant Nurse	8b	1
Advanced Specialist Nurse	7	2
Specialist Nurse	6	2.5
Specialist Physiotherapist	7	2
Physiotherapist	6	1
Physiotherapy assistant	2	1
Psychologist	7	0.5
Medical secretary	4	1.5

4.12 A Menu-based Cardiac Rehabilitation intervention

As has been described in chapter 3:9, CR, as it is provided across the UK, varies widely from service to service due to funding constraints and local arrangements. This is in contrast to the evidence base which has focused on studies, with clearly defined interventions, for specific timescales. A key element of the feasibility study was to examine the feasibility of a RCT of a menu-based CR intervention for the participants, which was the same as that which would be given to any other individual referred to this CR service. For this reason the

intervention was not prescribed for the participants (group one), but was in fact agreed between the specialist staff and the participant at the assessment stage.

Group one (CR programme)

Following allocation to the intervention group, the participant was assessed by a specialist nurse in hospital and a programme of care agreed that would span from phase one to three of the CR phases (see Table 3:1). During phase one, for all the participants, this involved input from a specialist nurse, physiotherapist, and other members of the multi-disciplinary team on the ward. These discussions included family members where appropriate. The topics that were covered were:

- Structure of the heart and the process that causes ACS
- Identifying and modifying risk factors
- Behaviour change
- Gradual return to activities
- Goal setting and pacing
- Psychological assessment
- Medication advice

Before discharge, an assessment of the individual's physical, psychological and social needs was carried out and a care plan was agreed. The types of activities that could be prescribed during phase two included:

- Home visits
- Outpatient clinic visits
- Telephone support

The types of activities that could be prescribed during phase three included:

- Moderate intensity exercise rehabilitation for 13 weeks in a class setting
- Low intensity exercise rehabilitation for 13 weeks in a class setting
- Home exercise plan

At any time during the CR programme, additional support could be sought from topic experts dependent on participant need. These could include:

- Referral to psychologist
- Referral to specialist smoking cessation advisor
- Referral to dietician
- Referral to social work

Following completion of the programme, participants were referred onto local voluntary providers of phase four that aimed to reinforce the behaviours gained through the CR programme.

Group two (standard care):

Participants in this group received the same medical care as the intervention group. They were in hospital for similar lengths of time and received routine input from ward nursing staff during their stay. The clinical care, information and support provided by the nursing staff were similar for both groups and included information on the disease process, risk factor management and recovery. The input all participants received varied depending on ward allocation, skill mix and workload at that time. The standard care group however, did not receive input from the specialist CR team.

4.13 Recruitment of participants for feasibility and exploratory studies

The ward nurse in charge provided information to all patients admitted to the coronary care units in both hospitals. Potential subjects were then identified to the researcher. As soon as the ward nurse was able to confirm the diagnosis and that the individual met the inclusion/exclusion criteria set by the studies, she approached the individual and asked for consent to contact the researcher. The researcher provided an information pack on the studies which was developed according to requirements of the NHS Ayrshire and Arran Research Ethics Committee in relation to format and content. She discussed the studies with the individual and allowed time for questions and feedback. The researcher reinforced that the individual could withdraw at any time and that whatever their decision, the clinical care that they received would not be affected. The patients were given 24 hours to consult with their families and to consider if they wished to be involved. They were informed that the protocols for the studies required us to inform their general practitioner and asked for their permission to do so. Once the patient had time to consider and if they agreed, consent to take part was completed by the patient and written information sent to general practitioner and cardiologist.

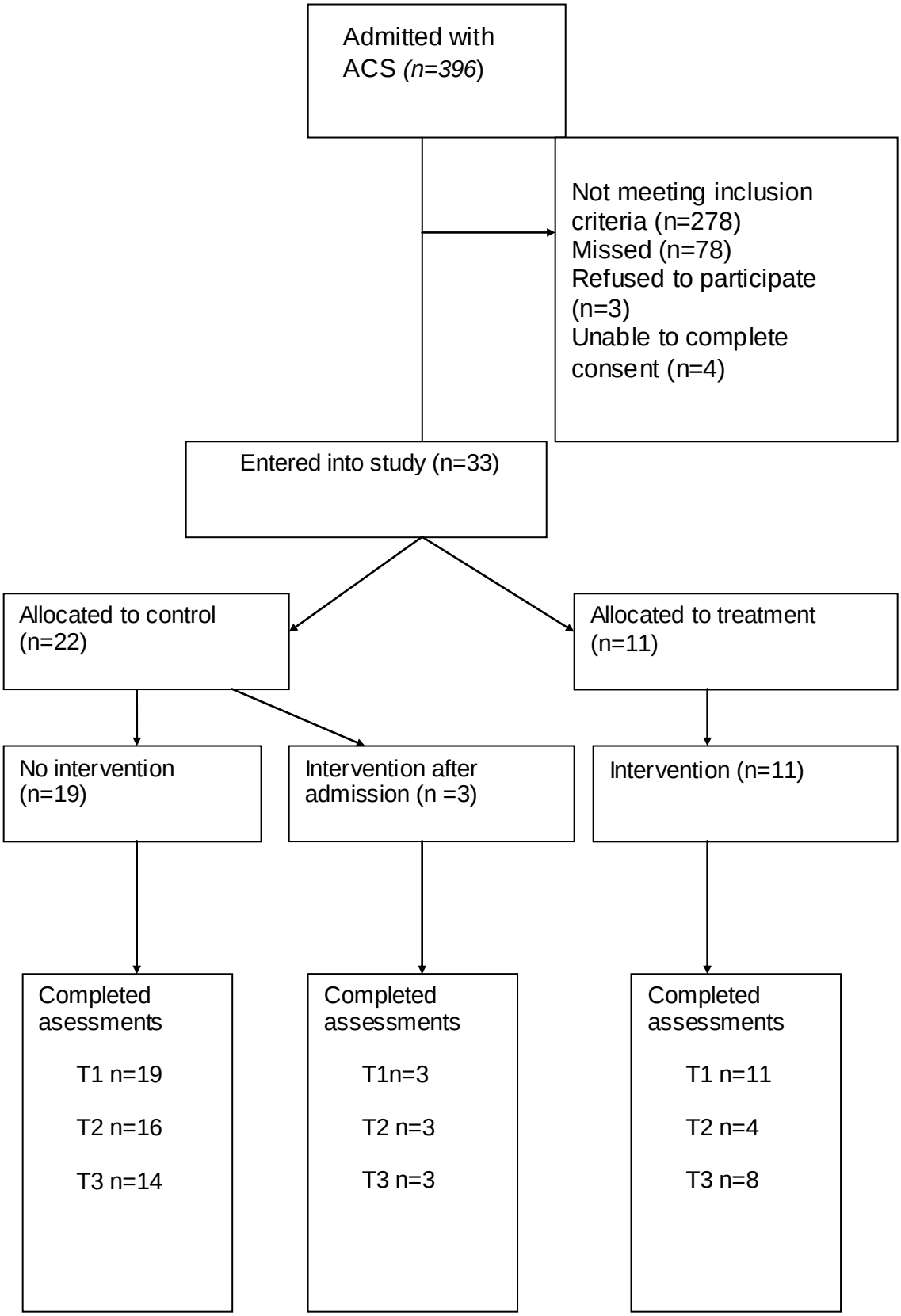
During the year of the studies, as shown in Figure 4:1, there were 396 individuals admitted to hospital with ACSLT. Only 118 patients were eligible for the studies. The reasons for this are documented in Figure 4:1. Of these 118, only 40 patients were referred, three refused and four were unable to complete consent. 33 participants consented to take part. The reasons for the large number of missed participants will be discussed in chapter 5:2-5:3.

During the course of the studies, eight participants withdrew. This included one participant who went on to have a MI, one whose diagnosis was changed, one who developed HF and did not feel well enough to take part and two who died prior to their final assessment. Three participants were lost to follow up at the final review appointment and could not be contacted. In addition three participants who were allocated to the control group then returned with a further cardiac event which meant they automatically received CR.

4.14 Recruitment of staff for feasibility study

Invitations were sent to all staff within the cardiology wards and the CR team and two focus groups were held with those who accepted the invitation. The first focus group contained six CR professionals involved in the provision of care for the participants in the intervention group. This included two senior nurses, two senior physiotherapists and two physiotherapy assistants. The second focus group consisted of eight ward staff, from both sites and from cardiology wards.

Figure 4:1 Flow Chart of patient recruitment



4.15 Data collection

This thesis contains a feasibility study and an exploratory study. A range of data was collected over the period of the research which was utilised within both studies. An appropriate data collection sheet was designed to collate this data. The data collection instruments are documented in Table 4:2. The participants were assessed at four time points:

- T1-On entry to the study during hospital admission
- T2-eight weeks after their discharge
- T3-nine months after their discharge
- T4-A case-note only review took place at two years

There were three types of data collected: baseline, feasibility, and outcome. Baseline data, as shown in table 4:1, included demographic data, clinical data and risk stratification. Demographic data were collected from the participants at the time that they consented to participate in the studies. This was important since this information was used to describe the samples and was also used in the comparative analysis between the groups. These data were easily accessed through the case-notes. Ethnic origin was that stated by the participant on admission and deprivation category was established using the participants' postcode and was determined according to deprivation categories measured by the Carstairs scores for Scottish postcode sectors (Carstairs and Morris 1991) using data from the 2001 census (McLoone 2004). Data on risk factors for CHD were collected at T1 from both case-notes and self-reporting by participants. Blood pressure, smoking status and activity scores were collected at each assessment. Cholesterol levels were only collected at T1. It was intended that information on dietary habits and weekly activity would also be collected

through diaries and pedometers, however participants found it difficult to comply with this aspect of the data collection and the data that were collected was limited in its use, therefore it is not reported in this thesis.

Clinical factors and risk stratification data were accessed through the case-notes and through case-notes and self-report in the case of readmissions. Risk of future events was calculated using the GRACE score at time of discharge. This is a widely accepted method of determining risk and has been discussed previously in chapter 2:5.

Feasibility data were collected to identify how acceptable the research design and the intervention were to the participants and staff. Feedback on content and acceptability of methods was assessed using a questionnaire. In addition two focus groups were carried out with staff. The first focus group included CR specialist staff and the second took place with staff from the cardiology wards. Outcome data as described in Table 4:2 were also collected.

Table 4:2 Data collection instruments

Type of data	Data item	Source	Questionnaire No
Baseline	Demographic details	Casenotes	n/a
	Clinical factors	Casenotes	n/a
	Risk stratification	Casenotes	n/a
Feasibility	design of studies	Acceptability questionnaire Staff focus groups Exit discussion with participants	6
Outcome	Misconceptions	York angina belief questionnaire v2 (YABQv2)	1
	Symptoms	Cardiac Limitations and Symptoms Profile (CLASP)	2
	Anxiety and depression	Hospital and Anxiety Scale (HADS)	3
	HRQoL	Schedule for the Evaluation of Quality of Life-Direct Weighing (SEIQoL-DW) Medical Outcomes Trust Short Form (SF36v2)	4 5
	Patient perceptions	discussion with participants at T2 and T3	

In chapter 3:12, the researcher identified key outcomes that would be necessary to measure. These are: cardiac misconceptions, symptoms, anxiety, depression and HRQoL. In addition, data on the experiences of the participants were collected at two data collection points. Information was gathered using open questions during interviews and this is documented in Appendix one.

Within the feasibility study, options for instruments that could be used successfully in a large RCT were examined and piloted. These included both quantitative and qualitative instruments and these will be examined in greater detail in chapter 4:15-4:16.

4.16 Quantitative data

The key areas that were identified as important to measure within this section were cardiac misconceptions, symptoms, anxiety,depression and HRQoL. The choice of questionnaire for each section involved a review of the instruments available and their suitability for the population being studied.

If we consider the area of cardiac misconceptions, individuals can hold misconceived or maladaptive beliefs regarding the impact of CHD on their life and this can have a negative impact on their HRQoL. However, as documented in chapter 3:4, very little attention has been paid to misconceptions in the CR literature. Yet, if we are to utilise a theoretical framework as documented in chapter 3:11, it is important to address the misconceptions that are held by the individual. When deciding on a tool to measure this within the exploratory study, two instruments were considered, the Cardiac Misconception Scale (CMS), (Maeland and Havik 1988) and York Angina Beliefs Questionnaire v2 (YABQv2) (Furze 2003).

The CMS is a 10 item questionnaire which details common misconceptions about MI. It has been used to demonstrate the potential effect that misconceptions about MI can have on recovery (Maeland and Havik, 1987, 1988, 1989). The participants within these studies have ACSLT and are not classified as having a MI. So to use the CMS would suggest to the participants that they have had an MI. This left the YABQv2, which was designed as a quick tool to assist in identifying misconceptions about CHD in clinical practice. Furze et al (2003) argue that beliefs about angina are significantly associated with functional and psychological status. People with more misconceived or maladaptive beliefs are more anxious and physically limited than are people with fewer such beliefs (Furze et al 2003).

The YABQv2 was developed from belief statements elicited in an interview study by Furze et al (2001). They were used to form a pilot version of the questionnaire which was completed by 105 angina sufferers and was factor analysed. Two items were removed following this pilot and the 14 item questionnaire was formed (YABQv2).

This questionnaire, which produces an overall score plus two sub-scales scores, which measure coping and threat, has been validated in the stable angina population (Furze et al 2003). The perception of threat sub-scale and total score was shown to have good internal consistency, while that of the coping sub-scale was deemed adequate. Test–retest reliability for both sub-scales and total score was good. Face validity was established by using items directly derived from the patient interviews and checked by presenting the items to an expert panel. Construct validity appeared to be reasonable as there were moderate, but significant, correlations between the sub-scales and total scores

of the YABQ2 with both sub-scales of the HADS and the physical limitations sub-scale of the SAQ. Discriminant validity was demonstrated by the ability of the sub-scales and total score to discriminate between those who had undergone education about misconceptions and those who had not. The correlations were as predicted, that is, people who scored more highly on the perception of anginal threat sub-scale were more anxious and/or depressed; people who held more misconceived coping beliefs were more physically limited. The results from the psychometric analysis showed that the total YABQ2 score has good internal consistency, test–retest reliability and discriminant validity. Subsequent reviews of this questionnaire found that the YABQv2 had good internal reliability, with a Cronbach's alpha score of 0.81 and stability (r = 0.85) in a study of British people waiting for CABG surgery (Furze & Lewin 2006) and among Taiwanese cardiac patients with a Cronbach's alpha score of 0.73 (Lin et al 2009). The questions contained within the YABQv2 were also appropriate for the population to be studied. The focus on perception of threat and coping were considered to be valuable to the understanding of individuals with ACSLT. It was therefore decided to utilise the YABQv2.

The measurement of symptoms was also an important clinical outcome. Many questionnaires have been devised to assess a specific cardiac condition such as angina, MI, or HF. The Cardiac Limitations And Symptoms Profile (CLASP) is unique in that it can be used across all these cardiac conditions (Lewin et al 2002). The 37 questions that comprise CLASP yield four symptom subscales (angina, shortness of breath, ankle swelling, tiredness) and five subscales focused on functional limitations (mobility, social life and leisure activities, activities within the home, concerns and worries, gender). Each

domain is represented by a subscale with four to six questions. Each subscale can be categorised as mild, moderate, severe. It can serve as an outcome measure indicating the burden of symptoms. The questionnaire was validated in a cohort of patients undergoing angiography at two large hospitals. The reliability of the CLASP was assessed with a Cronbach's alpha score of 0.80 (Lewin et al 2002). However in this thesis, only three of the sub-scales of the CLASP are used. These sub-scales were: angina, breathlessness and oedema. These sub-scales are very simple and are a quick method of clinically assessing a patient. These sub-scales are recommended for general clinical use (SIGN 2002), but further research in different populations was required with this instrument.

Within the study by Lewin et al (2002), pearson correlation coefficents were calculated for the symptom subscales at T1. The angina subscales were significantly co-related with the number of angina episodes, and the shortness of breath and ankle swelling subscale scores were significantly correlated with total treadmill time. Sensitivity was measured looking at 3 groups over 2 time-points and observation of significant time interactions ($p<0.001$). This showed that the measure was highly sensitive to treatment effects as a function of group type. The CLASP was therefore shown to be a reliable, valid, and sensitive, disease specific measure in patients with stable angina (Lewin et al 2002).

The impact of anxiety and depression on individuals with CHD has been discussed in chapter 2:6 and the possible impact of CR in this area has been discussed in chapter 3:4. There are several well established self-report measures available for assessing anxiety and depression. The most commonly

utilised within CR research are the State-Trait Anxiety Inventory (STAI) (Spielberger 1983), The Beck Depression Inventory II (BDI) (Beck et al 1996) and the Hospital Anxiety and Depression Scale (HADS) (Zigmond and Snaith 1983). The BDI and STAI have been identified as appropriate instruments for assessing the psychological status of hospital patients (Kocovski et al 2004), despite being developed to assess symptoms in psychiatric patients. However, the HADS was specifically developed to detect anxiety and depression in hospital and outpatient settings. Recommendations from SIGN suggest that HADS has been well validated for use in the cardiac population and it is used extensively as an assessment tool within CR (SIGN 2002). It is a 14 item self-report questionnaire which contains 7 items measuring depression and 7 measuring anxiety. Scores of 0-7 are considered normal with 8-10 considered borderline and 11 and over indicating either anxiety or depression. HADS does not include items of a somatic nature that could be caused by physical disease as much as mood disturbance (Bjelland et al 2002).

A psychometric evaluation of the HADS in a post-MI population by Martin and Thompson (2000) found that the levels of anxiety and depression reported, using the recommended cut-off points, would suggest that the HADS and, in particular, the HADS-A and HADS-D sub-scales provide a clinically useful and quick to administer measure of affective state. Cronbach's alpha estimations of the HADS (all items) and the HADS-A and HADS-D sub-scales were all adequate and provide a statistically robust corroborative account of the HADS as an internally reliable affective state assessment tool.

In a review of the HADS by Bjelland et al (2002), the authors argue that HADS, despite its brevity, exhibited similar sensitivity and specificity to longer versions of the General Health Questionnaire. When compared to other questionnaires for anxiety and depression in common use, such as the STAI, and the BDI, the correlation of the BDI to HADS-D and the STAI to HADS-A, respectively, were between 0.60 and 0.80, which should be characterised as medium to strong correlations. The conclusion they reached was that the concurrent validity of HADS was good to very good. It was therefore decided to utilise the HADS, as this would be quick and easy to use within this population and it would measure both anxiety and depression on the same questionnaire. In addition, it had been used extensively with the MI population in NHS Ayrshire and Arran for more than eight years, which would allow for comparative data with other populations.

As discussed previously HRQoL represents the effect of an illness and its treatment as perceived by the patient. The measurement of HRQoL can be achieved by using a disease specific, generic, or an individualised instrument. However, since this thesis looked at a new and novel population that had not been studied before, it was felt that a full review of the tools available should be carried out to decide which tool would be most appropriate for the RCT.

As there is no disease specific tool designed for ACSLT, the nearest disease specific tools would be the Quality of Life after MI (QLMI-2) (Hillers et al 1994), Seattle Angina Questionnaire (SAQ) (Garratt et al 2001), and the CLASP (Lewin et al 2002). The QLMI-2 is divided into three different domains, social functioning, physical function and emotional functioning. Dempster et al (2002) in their review of this measure found that two out of three of the QLMI-2 scales

lacked evidence of sensitivity or reliability. It was also designed to be used in the post MI population.

The SAQ has been assessed as a good disease specific instrument designed to assess the functional status of patients with angina, in five clinically relevant domains: physical limitations, angina stability, angina frequency, treatment satisfaction, disease perception and QoL (Garratt et al 2001, Thompson and Cheuk-Man 2003).

As discussed previously, the CLASP has been shown to be a reliable, valid, sensitive, disease specific measure of HRQoL in patients with stable angina (Lewin et al 2002). However it was also unique in that it could be used across all cardiac conditions (Lewin et al 2002). Further research was required with this tool in different populations and it was decided that this population would be a useful population to further research its utility. So the CLASP was chosen as a disease specific measure. Difficulties did arise within the studies regarding this measure. There was a great deal of similarity between the CLASP and the SF36v2 and the timescales were different. The CLASP is over two weeks and the SF36v2 looks at the last four weeks. This caused some difficulty for the participants and therefore data relating to HRQoL is not presented, only those relating to symptoms.

Three commonly used generic instruments in CHD were reviewed by Dempster and Donnolly (2000). They found that the Nottingham Health Profile (Hunt et al 1980) had major floor and ceiling effects, (bias by respondents answering in the top or bottom few categories of an instrument) and poor responsiveness to change in part one of the instrument. The Sickness Impact

Profile (Bergner et al 1976) had few floor or ceiling effects, but data concerning its 12 separate sub-scales were limited, therefore only total domain scores could be achieved. This has the potential to reduce the instruments ability to detect a change in health status. The Short Form 36 v2 (SF36v2) Health Survey (Ware and Sherbourne 1992) achieved the best results, but demonstrated reduced sensitivity in the mental health and general health scales, and ceiling effects in the role emotional and role physical scales.

The development of the SF36v2 relies on a long history of health surveys and the need to develop a questionnaire that could collect useful data without an unnecessary burden on the respondent. The SF36v2 aims to assess the following concepts: physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional, and mental health. This comprehensive short-form with only 36 questions yields an 8-scale health profile as well as measures of HRQoL. The scales of each question are coded summarised and transformed into a scale of 0 (the worst possible QoL) to 100 (the best possible). The SF36v2 also provides a summary of several of the scales to two components: physical summary and mental health summary.

Internal reliability testing of the SF36v2 has been reported in 14 studies involving more than 20,000 patients (Ware and Sherbourne 1992). Cronbach's alpha reliabilities ranged from 0.65 to 0.96 on all subscales. The SF36v2 has been validated against the National Survey of Functional Health Status and the General Social Survey in diverse populations of individuals with chronic health problems, including heart disease, and in healthy individuals (Dougherty et al 1998). Normative levels have been established for patients with both physical

and mental health problems, including hypertension, HF, Type II diabetes, recent MI, and clinical depression.

A questionnaire containing the SF36v2 was administered to a cohort of over 10,000 civil servants (Roberts et al 1997). Administration was repeated on a subset of 289 civil servants four weeks later. Clinical groups were distinguished by self-report measures of health. Data showed high internal consistency (alpha 0.75-0.35**).** Test-reset reliability was poor for role limitations due to physical problems **(**0.38**),** though acceptable for all other scales (range 0.60-0.89). Validation of the scales against criterion groups, defined on the basis of self-reported health, indicated that physical functioning, social functioning and general mental health had good discriminant validity.

The SF36v2 has also been tested across different ethnic backgrounds, with the Chinese version being tested for its psychometric properties (Yang et al 2012). The Chinese version was evaluated by indicators such as validity and reliability. Test-retest reliability coefficients for all domains were higher than 0.80. Five of the eight domains, as well as the physical and mental health subscale summaries, all had statistically significant changes after treatment. The authors concluded the Chinese SF36v2 showed good validity and reliability, but small responsiveness when used in patients.

The SF36v2 has been used in a wide variety of cardiac populations when assessing HRQoL (Lavie and Milani 1995, Morrin et al 2000, Mendes de Leon et al 2001). The reliability and validity of the SF36v2 in cardiac populations and in CR has also been extensively well tested (Ware et al 1993, DeVon and Ferrans 2003, Brown 2003). It has proven useful in monitoring general and specific populations, comparing the burden of different diseases, differentiating

the health benefits produced by different treatments, and in screening individual patients. Dempster and Donnelly (2000) came to the conclusion that the SF36v2 is the most appropriate generic instrument to assess HRQoL of cardiac populations. The SF36v2 was therefore chosen as the generic measure for measuring HRQoL.

As has been stated, individuals with this diagnosis have not been studied in this way before and it was therefore decided to add an individual measure that looks at global QoL. This would further explore the issues around QoL for this group of participants. It was intended to carry out this measure on a subset of the participants, but due to the small numbers recruited, most participants completed the measure at T1 and T3. The measure chosen was the Schedule for the Evaluation of Individual Quality of Life (SEIQoL-DW) by Hickey et al (1996). This is a QoL measure which is derived from the Schedule for the Evaluation of Individual Quality of Life (SEIQoL) (O'Boyle et al 1993). It is a short form of the original and was validated against the original by Hickey et al (1996). It provides both quantitative and qualitative data, as it gives both an overall score on QoL, but also identifies areas that contribute to this outcome. The practicality and brevity of this measure make it useful in clinical situations where QoL is important. It has been shown to have high levels of consistency and validity with older medical patients, stroke, cancer and palliative care patients, and has been found to be acceptable and practical to use with these patient populations (Hickey et al 1996, O'Boyle and Waldron 1997, Waldron et al 1999, Campbell and Whyte 1999, LeVasseur et al 2005). The measure allows respondents to nominate the areas of life which are most important, rate their level of functioning or satisfaction with each, and indicate the relative

importance of each to their overall QoL. An overall QoL score can then be calculated. In a review of published studies regarding the use, feasibility and psychometric performance of SEIQoL-DW by Wettergren et al (2009), the authors conclude that the SEIQoL-DW is a feasible and valid complement to standardised measures for use in clinical research. However, they also argue that some aspects, such as responsiveness over time, require further investigation. The total number of reviewed papers is small (n = 39), reflecting the overall limited number of studies using the SEIQoL-DW compared to traditional measures. The individual nature of this measure appeared to offer another dimension to the understanding of QoL and to give insight into personal differences between patients that might influence the success of CR.

The questionnaires chosen were therefore: YABv2, CLASP, HADS, SF36v2 and SEIQoL-DW. The statistical analysis of this data will be discussed in 4.18.

4.17 Qualitative data

Qualitative research is suitable for exploring new areas of inquiry. It can help to gather information and generate hypotheses for the main quantitative phase. Qualitative research can also add detail and depth to the understanding of any issue, as it strives for holistic and detailed descriptions. Within this study, two types of qualitative research were carried out. These were focus groups with the staff and interviews with the participants.

As part of the design of the feasibility study, two focus groups were planned with staff working within cardiology and the CR team. The focus group protocol is included in Appendix 1.1. The use of focus groups as a tool within nursing research is becoming increasingly popular (Doody et al 2013). Focus groups

can be used on their own as the primary method of data collection or with other methodologies (Stewart et al 2007) as is the case here. In nursing, focus groups can be used to explore a range of issues. The purpose is to understand rather than infer, to determine the range rather than generalise and to gain insight into how people in the groups perceive situations rather than make statements about the population (Krueger 1994).

There are several advantages to using focus groups. They are useful in obtaining detailed information about personal and group feelings, perceptions and opinions, they can provide a broader range of information, and give opportunity for clarification. However, as they are self-selecting, they may not be representative of the broader staff group. The staff focus groups in this research took place at the end of the feasibility study.

The focus groups needed to have enough staff to provide meaningful information, yet not so many that the researcher became overwhelmed by cumbersome data. The two focus groups, within the feasibility study, aimed to have 6-8 staff. They were led by the researcher and moderated alone, without an assistant. This enabled staff to feel at ease during the discussions. Staff were assured that the entire discussion would be confidential and no-one would be identified by name within any of the written documentation. Each focus group lasted approximately 60 minutes and refreshments were provided during this time.

Each focus group was structured in three stages. The first stage introduced the participants to the study. The second stage involved asking the participants questions and generating discussion, and the third stage examined the

conclusions reached. There were also opportunities at the end of each meeting for participants to make more specific inquiries about the project. Each focus group was recorded and subsequently transcribed.

A group of themes for the focus groups was devised to stimulate discussion and to inform the feasibility study. The themes chosen were:

- Expectations of the research process
- Barriers to participation
- Perceived impact of CR on the participants
- Provision of the CR programme (CR focus group only)

The data gathered during the focus groups was analysed using thematic analysis as described in Chapter 4.19 and is reported in Chapter 5.4

Within the exploratory study, qualitative data was collected through interviews with participants. The protocol for the semi-structured interview is included in Appendix 1.2. Interview data was collected from 17 participants at two home visits (T2 and T3), and from eight participants at one home visit only (T3). Time was taken to facilitate participants trust and confidence rather than distrust in the researchers intentions. The researcher stressed to participants there was no intention to judge performance or report 'bad' practice within the healthcare system, but purely to understand the experiences that they had had. Any initial tensions appeared to resolve as the participants started to answer the questions. Interviews were transcribed verbatim. The interviews consisted of open ended questions, with further discussion led by the participants. These data added depth to the understanding of the experiences of the participants.

The data gathered during the interviews was analysed using thematic analysis as described in Chapter 4.19 and is reported in Chapter 6.6

4.18 Data handling

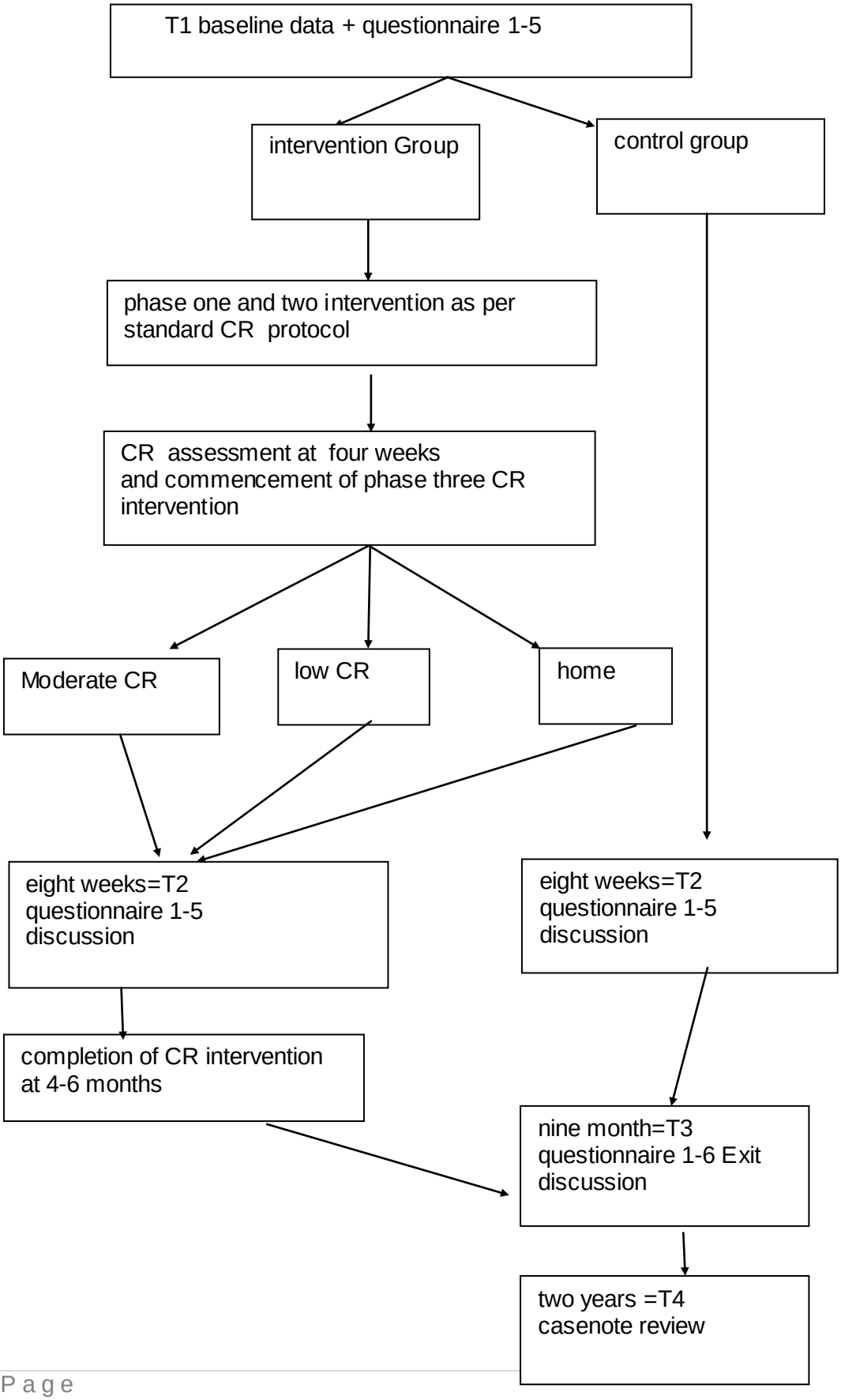
The participants were assessed at four time points:

- T1-On entry to the studies during hospital admission
- T2-eight weeks after their discharge
- T3-nine months after their discharge
- T4-A case-note only review took place at two years

The schedule for which assessment tools were used at each time point is documented in Figure 4:2. These time-points were chosen to reflect the pathway that the participants would experience. Baseline (T1) was during their index admission and T2 would be the time-point at which the individual would be expected to have recovered from their illness. By then they would be discharged from medical follow up and would be looking to go back to work. Those who were receiving the intervention would have been assessed and a package of care would be well underway. The third time point (T3) was chosen to reflect a time beyond which CR would have finished, but not too soon that the impact of the intervention was still at the forefront of the participants thoughts. It is important to review the longer term impact of a complex intervention such as CR and if six months had been chosen, then it is possible that some participants would have still been under the care of the CR team. There is also the possibility that participants would still be receiving further investigations and treatment for their condition at this point. This was in fact the case for three of the participants. Nine months (T3) was therefore chosen as long enough from the initial event to ensure treatment was complete, but not so long that

participants would be lost to follow up. It was also intended to review the outcomes for participants at two years (T4). Data collection were carried out, in both groups, while the participants were still in hospital, prior to the commencement of the CR programme at T1. The CR team then started a package of care for those participants in the intervention group prior to their discharge from hospital. The assessments at T2 and T3 were carried out in the participants' home at a time suitable to them. Recruitment took place over a 12 month period between November 2006 and November 2007. Follow-up questionnaires were completed by September 2008. Each participant was identified only by a number, which identified the site and the order in which they were recruited. The first number referred to the site and the second and third number referred to the participant. The researcher, following manual collation and tabulation of the results, entered the data. All data fields were numbered according to a predetermined coding system. Following data entry, checks were made to ensure accuracy.

Figure 4:2 Data collection timescales



4.19 Data analysis

There were two elements of data analysis within these studies: quantitative and qualitative. Quantitative data consisted of data from the registration form, record sheets and participant questionnaires, which were entered into SPSS (version 15). The planned approach was to report on each of the variables using frequency distributions and graphical displays, as appropriate and to report the composition of the sample highlighting characteristics such as age, sex, marital status, clinical variables etc. Summary statistics included measures of central tendency such as means and medians, and measures of variability such as the range, variance and standard deviation and confidence intervals. A variety of parametric and non-parametric statistical tests were planned: the paired-sample *t*-test, pearson's correlation, and chi-squared, which allowed for exploration of differences between the groups and to test the effect of time. To explore whether socio-demographics, clinical characteristics, HRQoL and social and psychological variables were associated with the outcomes, a series of correlation matrixes were constructed to test the inter-relationships among variables. Statistical tests therefore included exploration of the differences and similarities between and within the groups. Statistical significance was set at p=0.05. However, due to the small numbers within the exploratory study, limited parametric data analysis is presented.

Qualitative data was collected from staff focus groups and participant interviews and the method of analysis for both was thematic analysis. It has been argued by Braun and Clarke (2006) that although thematic analysis is widely used, there is no clear agreement about what thematic analysis is and how you go about doing it. It could be seen as a very poorly "branded" method,

in that it does not appear to exist as a "named" analysis in the same way that other methods do (e.g., narrative analysis, grounded theory). Braun and Clarke (2006) however argue that thematic analysis should be a method in its own right and can and should be used for identifying, analysing and reporting patterns or themes within data. One of the advantages of this type of analysis is its theoretical freedom and flexibility. Thematic analysis can be used to analyse classifications and present themes that relate to the data. It illustrates the data in great detail and deals with diverse subjects via interpretation (Boysatzis 1998). Thematic analysis gives an opportunity to understand the potential of any issue more widely (Marks and Yardley 2004). As thematic analysis does not require the detailed theoretical and technological knowledge of approaches such as grounded theory, it was considered a more suitable form of analysis for the qualitative element of this thesis.

Braun and Clarke (2006) argue that a rigorous thematic approach can produce an insightful analysis that answers particular research questions. They provide guidelines for researchers to undertake thematic analysis that is theoretically and methodologically sound (Appendix 1.3.) These guidelines were used as the basis for the thematic analyses carried out within these studies on both the focus group and interview data.

The set up and content of the focus groups have been described in Chapter 4:17. The data collected was recorded and the transcribing of each focus group recording took between two to three hours and was carried out by secretarial support staff. Each transcript was then audited against the original recording to ensure accuracy. As part of the analysis of the focus group data, written notes and information collected on the day were also read through. A preliminary

analysis was undertaken, the transcriptions were reviewed and initial codes were generated and analysed manually. The two focus groups were then compared to identify shared and differing approaches to the themes that had been set for the focus groups. A graphic representation of the themes and their interconnections was drawn (Appendix 1.4). These themes were then used as the basis for describing the results:

- Expectations of the research process
- Barriers to participation
- Perceived impact of CR on the patient participants
- Provision of the CR programme (CR focus group only)

As the researcher, it was important that my own preconceived ideas were acknowledged by myself and that the difference between, what I expected to be said, and what was actually said, was recognised. I attended staff meetings following the focus groups to provide staff with the opportunity to raise any questions or issues of concern regarding the results.

As part of the exploratory study interview data was collected from 17 participants at two home visits (T2 and T3), and from eight participants at one home visit only (T3). The data collected was recorded and transcribed. This took between one to two hours and was carried out by secretarial support staff. Each transcript was then audited by the researcher against the original data. Apart from ensuring that transcripts represented what had been said, the auditing helped the researcher to gain a close contact and familiarity with the data (Boyatzis 1998). Following transcription, participants were invited to check transcripts. All of the participants declined. After each transcript was

transcribed and audited, it was given an identity marker representing participant identity (e.g. Male/Female, control/treatment, age)

A preliminary analysis was undertaken and initial codes were generated and analysed manually. An example of a preliminary coding of an interview can be seen in Figure 4:3. The results were reviewed by an independent researcher within the department. After the initial coding, codes were merged into larger units that were similar in meaning. This merging of codes into larger units persisted until only a few remained. However, the next step in the analysis - integrating codes into themes- proved to be more difficult. A theme was defined in this research as the smallest unit that could express the codes that were included in it in a meaningful way. At the end, four themes were formed, highlighting how the participants described their experiences. A graphic representation of the themes and their interconnections was drawn (Appendix 1.5). Finally, data extracts were chosen to illustrate the resulting themes. Thematic analysis is flexible and the importance of a theme is not necessarily dependent on prevalence, but can be determined by its relevance to the research question and by researcher judgment (Braun & Clarke, 2006). In the current studies repetitions of the themes across individual transcripts were taken to indicate their relevance in the experience of the participants in relation to the topic under investigation. In line with Braun and Clarke (2006) the inclusion of a theme was also based on the researcher's judgement of its relevance to the research question and to future practice. This approach emphasises the participant's perceptions, feelings and experiences as the object of study.

Figure 4:3 Coding process

Data extract from Participant 203 T2	Coded for
Quite well really, the GP came out and sorted out my tablets, although there was a little bit of a debate about what I should be on as I wasn't very sure and they had stopped some and restarted others.	1. Feeling fine 2. Uncertainty 3. Lack of knowledge 4. Communication
But I haven't had any pain which is a bonus. I don't have to back to the hospital so that's a good thing, just see my GP.	1. Relief 2. Well
They thought at first it had been a heart attack and I wouldn't have been surprised if it was as the pain was bad but they said the blood tests came back negative so I can just get back to normal.	3. Relief 4. Return to normal 5. Pain
I haven't been very well for a while and I didn't really know what was wrong with me, but the doctors say I have angina and it is nothing to worry about.	1. Unwell 2. Lack of knowledge
I don't really feel normal. I am very tired. I haven't been far from the house as I am not really sure what I am able to do.	1. Unwell 2. Lack of confidence 3. Lack of knowledge
Well I suppose things were a bit confused for a while but I didn't know what to expect when I came home and it was a bit scary	1. Uncertainty 2. Lack of knowledge 3. Fear

4.20 Funding

This thesis was funded by NHS Ayrshire and Arran, who paid for the researcher to undertake a clinical doctorate at the University of Stirling, through the learning and development fund, but who also supported the research through the MCN for CHD, which bought any resources required, and funded backfill to allow the researcher to undertake some of the work.

4.21 Conclusion

In summary, CR is a complex intervention and the design and evaluation of complex interventions is problematic. There are a large number of diverse components within CR, which act, and interact, with one another to achieve a range of outcomes for the participant. The choice of research methods has been determined by the MRC framework, which suggests that a RCT is the gold standard for researching complex interventions. A feasibility study for a RCT is necessary to test the design, instruments used, and the intervention itself, in terms of its acceptability to the participants and staff. The exploratory study is also necessary to explore the experience of participants. There are few previously published studies or existing data on CR in ACSLT.

Full Ethics and R&D approval was in operation throughout the period of the studies, which included access to the relevant clinical sites. All patients of both sexes, who were admitted to two hospitals sites within NHS Ayrshire and Arran and diagnosed with ACSLT, were considered for inclusion in the feasibility and exploratory studies. A menu-based CR programme was provided for the participants in the intervention group

The feasibility study design was an exploratory repeated measures longitudinal case-control study which included staff views on issues of feasibility and CR through the use of focus groups. The exploratory study aimed to explore the impact that CR can have on this client group; through the use of both the standardised questionnaires being used within the feasibility study, and qualitative data collected at interviews with the participants. The questionnaires chosen for both studies were: YABv2, CLASP, HADS, SF36v2 and SEIQoL-DW as they were assessed as being valid and reliable. Data analysis was planned using both statistical analysis of the quantitative data and thematic analysis of the qualitative data.

In conclusion this chapter has described the methodology employed to meet the aims of the studies, taking into account the MRC framework for complex interventions, the clinical context and information from the literature. The design of the studies has been discussed. This was followed by a description of the ethical considerations, recruitment, and the rational for the choice of instruments. The process for data collection and analysis has been discussed along with timescales and funding.

Chapter Five Feasibility study

5.1 Introduction

This thesis contains a feasibility study and an exploratory study. The feasibility study aimed to examine the feasibility of a RCT which would test the impact of a menu-based CR programme, on individuals diagnosed with ACSLT, against standard care. This feasibility study also included staff views. The exploratory study aimed to explore the impact that ACSLT and CR can have on this client group.

In the previous chapter, the methodology to meet the stated aims of this thesis has been outlined. In this chapter, the results of the feasibility study will be examined and chapter six will focus on the results of the exploratory study. The four areas of feasibility that will be discussed are: participants, the CR intervention, staff, and measures.

5.2 Participants

When considering the participants, there are three areas that need to be examined, the ability to recruit, being able to retain the participants, and having a sample that is reflective of the population from which it is drawn. The initial target for recruitment set within the studies was 100 participants as described in chapter 4:10. This was a large target number for a feasibility study, but was based on the number of current admissions to the two hospitals in NHS Ayrshire and Arran. The CHD MCN that was funding the studies, was keen that both hospital sites were included, as they wanted information that would guide future service development for individuals with this diagnosis.

During the period November 2006 to October 2007, 396 individuals were admitted to hospital in NHS Ayrshire and Arran with ACSLT. From local data it was established that 128 of these had previously been under the care of the CR team. In addition, 150 patients were diagnosed as having a MI and were referred for CR during their admission. This left 118 potential recruits for the studies of whom only 40 patients were approached. Time was spent with each participant explaining the process and the impact of the studies. Every participant was given 24 hours to discuss their participation with family. Three patients decided on reflection, and on discussion with their family, not to proceed with the studies. A further four patients had pain and could not complete the consent process. This left 33 participants who were consented and completed the initial assessments at T1. This included 22 participants in the control group and 11 participants in the intervention group at T1. The majority of potentially eligible ward patients (78 out of a potential 118) were still not identified and referred. It is difficult to know why this was the case, but it could have been because the ward staff were busy with priorities related to patient care. Often there was a delay in making a diagnosis and the time left before discharge was not long enough to complete the consent protocol. It is recognised that the presence of the researcher on the ward may have helped to identify potential patients. This was, however, not possible due to the short time the patient spent in hospital, on average two to three days, and the increasing work commitments of the researcher. An additional problem was the need to visit two separate hospitals to recruit. A potential participant could be in site one and the researcher in site two.

There appear to be several key linked issues within this that need to be mentioned:

- Availability of a researcher to check wards daily
- Patients short stay in hospital
- Difficulties of obtaining a diagnosis of ACSLT in time to start the consent process

Initially, ward staff were meant to contact the researcher when a suitable patient was identified. However, it soon became apparent that ward staff were not remembering to contact the researcher when a suitable patient was admitted. The two site model meant that recruitment at the site one was even more difficult as the researcher was based at the site two and it takes more than 30 minutes to travel between hospitals. Of 33 participants to enter the studies, only seven were from site one. The nursing and medical staff were aware that if participants were recruited during the control phase, they would receive no intervention from the CR team. This meant that, where some debate arose over diagnosis, the ward staff preferred to wait to see if patients would be eligible for CR, rather than enter them into research which would ensure they did not receive CR for nine months. Many of the patients were only in hospital for two or three days. During this time ward staff had clinical priorities in terms of diagnosis and care. Often the diagnosis was delayed until Troponin T results were obtained and this could be at least 24 hours after the index admission. Even then the patient might only be told their diagnosis just prior to discharge, making it impossible to approach them for consent. In addition, no patients were recruited from the first site from February 2007 due to changes in protocols for

the diagnosis of ACSLT at that hospital site. This will be discussed further on pages 113-114.

The combination of these factors meant that recruitment was very limited in the first six months compared to the number eligible as can be seen in Table 5:1.

Table 5:1 Participants recruited from Nov 2006 till Oct 2007

06-07	Nov	Dec	Jan	Feb	Mar	Apr	Ma	Jun	Jul	Aug	Sep	Oct	**tot**
Admit	15	14	16	15	12	8	9	7	5	5	7	5	118
Refer	3	4	2	2	4	3	1	6	3	4	4	4	40
Decline	0	0	0	0	1	1	0	1	0	0	0	0	3
Unfit	1	0	0	0	0	1	0	1	0	0	1	0	4
Recruit	2	4	2	2	3	1	1	4	3	4	3	4	33

Despite education and awareness-raising sessions for ward staff, recruitment remained slow. In an attempt to improve recruitment, two nurses already working within the department, one each site, were tasked with the job of identifying individuals that would be suitable for the trial and assisting with the consent process. There was a slight improvement during the next six months in the numbers that were recruited for the studies compared to the number eligible (Table 5:1).

By the time the nurses were in place, a new problem for recruitment had arisen. The researcher wanted to look at a group of patients who did not qualify for CR under the referral criteria at that time. This was those with ACSLT.

Diagnosis of ACSLT was established by one or more of the following:

- Clinical History
- Ischaemic ECG changes,
- Cardiac troponin release or raised CK-MB enzyme demonstrated at any time during admission

The key difference between patients eligible for the studies and patients diagnosed as MI and therefore eligible for CR related to the level of cardiac troponin release. According to BCS guidelines (see Table 2.1), at the time of the commencement of the studies in 2006, if the level of Troponin T was equal to or greater than one, the patient was diagnosed as having a MI. If it was greater than 0.01 and less than 1.0 the patient would have ACSLT and would be eligible for the studies. However, there was a lot of debate amongst clinicians. This was fueled by ESC/ACC guidelines which argued that any rise in troponin meant that the individual had sustained an MI, as the risk of death at six months was similar (see Table 2:1). By Feb 2007 clinicians at site one had started using the ESC/ACC guidelines, while site two started using these guidelines by November 2007.

Many medical and nursing staff were confused by these changing opinions. Consultants were applying different criteria for the diagnosis of MI, some were using the ESC/ACC definitions and some were using the BCS definitions. Some patients who met the criteria for the studies, with a Troponin T release of less than 1.0, were being diagnosed as having a MI. Referral protocols for CR stated that patients diagnosed as MI should be referred to the service. This automatically made them ineligible for the studies. Consultants and ward staff

were aware of this and of the fact that, during the control phase, patients would not receive any input from the team. This made them reluctant to make a diagnosis which made individuals ineligible for CR. In addition, the diagnosis would often change depending on who was doing the ward round and this made it difficult for ward staff to know whether to refer to the studies or not. By the time the decision was made, it was often too late to complete the recruitment process, particularly in terms of informed consent. Allowing for the extra time to speak to their families meant that some went home before they could be seen again and informed consent completed.

By Nov 2007 the BCS had changed the definition of MI to be used throughout the NHS to bring it in line with the ESC/ACC guidelines. This meant that recruitment to the studies had to stop as all patients were now eligible for CR.

There are therefore three key issues with regards to the feasibility of recruiting a sample which are: if a different researcher had been used it could have been possible to recruit enough participants, if recruitment had continued after discharge then numbers could have been increased, and the changes in definition make it now unlikely that a suitable sample could be recruited for a RCT.

If we now consider retention, we can see that 33 participants agreed to take part, of whom, 25 completed the final assessments. Eight were lost to follow up between T1 and T3, the reasons for which are clarified below.

The control group lost five out of 22 to follow up (22%), the intervention group lost three out of 11 (27%) to follow-up. In addition, three participants from the control group received a CR intervention due to a further cardiac event.

Of the eight who withdrew, three withdrew due to further health problems (1c, 2int), two died (1c, 1int), and three (3c) could not be contacted for further assessment. Several phone calls and a written letter received no response from this last group of participants. All three were in the control group. The time lag between T2 and T3 was felt to be a key reason for the three participants who dropped out from the control group. There was no contact with the research team for seven months. The intervention group did not have the same drop-out rate and they would have had a longer contact with the healthcare system.

As can be seen from Table 5:2, assessments were completed at three time points (T1, T2, T3). Seventeen participants in the control group completed all three assessments (T1,T2,T3). In the intervention group, 2 participants completed all 3 assessments (T1,T2,T3) and an additional six completed both T1 and T3 but not T2. This was not due to lack of interest on the part of the participants. The second questionnaire had to be completed during a short time scale at eight weeks and the researcher was unable to make this deadline for this group of participants. If a researcher had been employed to undertake the research, or the timescale set for the data collection had been broader, it is likely that all questionnaires would have been completed at this time-point. Over the period of the studies, as documented previously, 5 participants were withdrawn due to health reasons (see Figure 5:1).

Table 5:2 Drop-out rates and stage of drop out

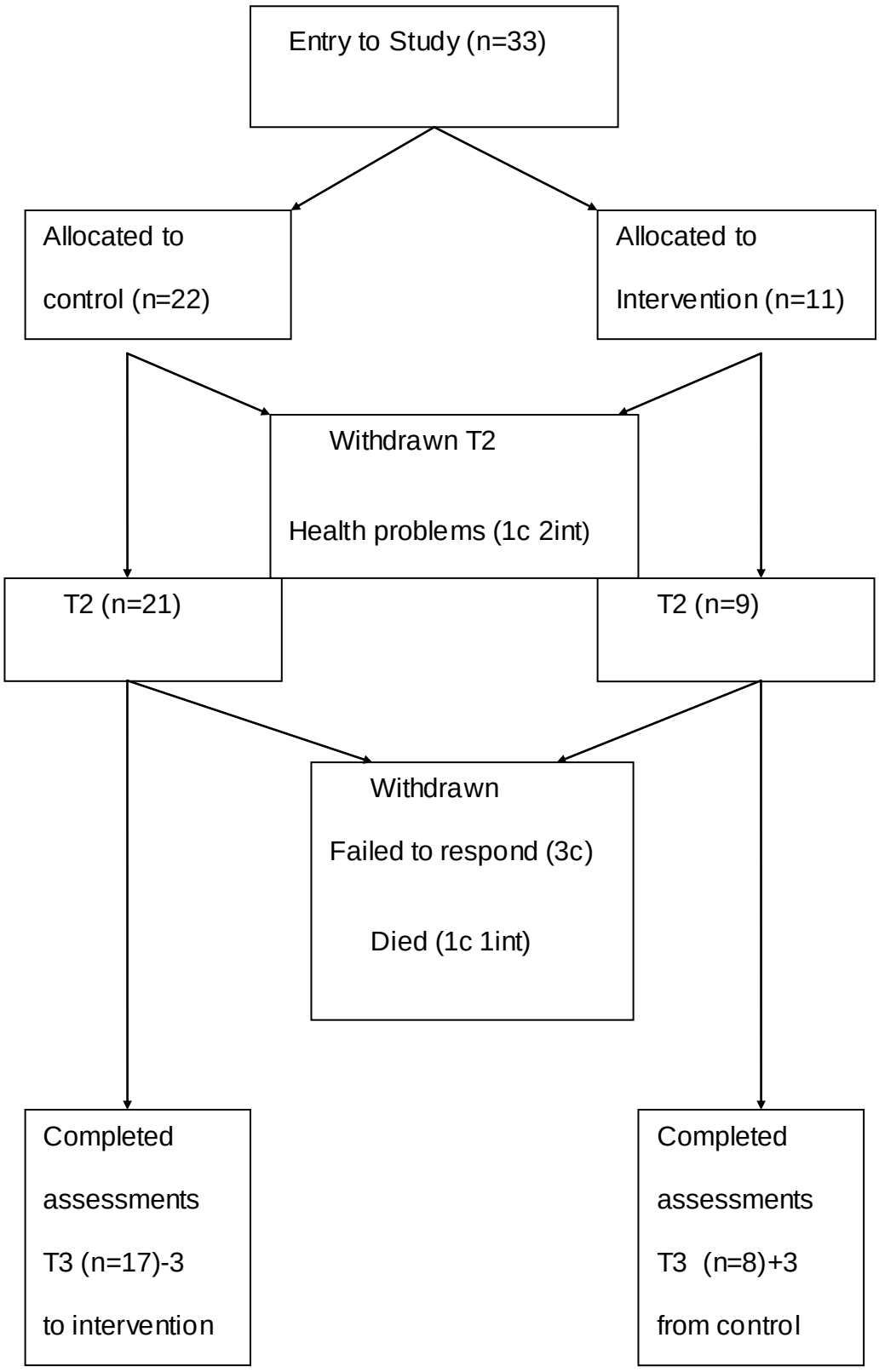
	Control	Intervention	Total
Identification	25	15	40
Consented	22	11	33
Completed 1st assessment	22	11	33
Completed 2nd assessment	20	2*	22
Completed 3rd assessment	17	8	25
Dropout/withdrawn	5(22%)	3 (27%)	8 (24%)
Received CR following event	3	8 (+3 from control)	11
Final group totals	14	11	25

*researcher on leave of absence

An additional three of the participants within the control arm actually received a CR intervention between T1 and T3 due to another cardiac event. One participant had CABG and two participants had PCI. Within the intervention arm, this incidence of a further cardiac event was also seen with one participant having CABG and one participant having PCI. This meant that of 25 participants to complete the studies (17 control and 8 intervention) there were 14 participants in the studies who received no intervention and 11 who did.

There are therefore three issues with regards to the feasibility of retaining this sample. Firstly, the drop-out rate from the studies due to ill health was higher than expected. Secondly, there was crossover between the groups due to further cardiac events. Thirdly, the time span of the studies and timing of the questionnaires, with limited contact with participants in between, could have reduced the willingness of individuals to continue.

Figure 5:1 Flow chart of withdrawals



The issues of recruitment and retention have been considered and the final issue relating to the participants is; how representative was the sample of the population from which it was drawn. Data on individuals admitted with ACSLT during this time period, and available through medical records, was analysed to define the wider population that the sample was drawn from and the results are displayed in Table 5:3. It would appear that the sample recruited within the studies were younger, more likely to be male, married and on sickness benefits than the population they were representing. If this was replicated in a RCT, it would have obvious implications for the applicability of the results.

An additional issue that need to be considered is the impact of the dropout rate. There appears to be limited differences between the participants who completed the assessments at T3 (25) and the participants at T1 (33). The key differences were that the final sample at T3 contained: more women, more over 70, less deprived, more married, more retired. The numbers recruited are small, but if this change in the participant population, due to drop outs, was reflected in a RCT, then there would implications for the applicability of any results.

In summary, if we consider the participants, in terms of the feasibility of a RCT, we can see that, if a different researcher had been used, it could have been possible to recruit enough participants. If recruitment had continued after discharge, then numbers could also have been increased. The drop-out rate from the studies due to ill health was higher than expected and there was also crossover between the groups due to further cardiac events. This is useful information that would inform any future RCT.

Table 5:3 A comparison of participants and population from which they were drawn

		Study Sample N=33			ACSLT Sample N=396	
		%	Count		%	Count
Gender	M	72.7%	24		66%	263
	F	27.3%	9		33%	133
Group total			33			396
Age group	<50	19%	6		9.6%	38
	50-59	38%	13		18%	70
	60-69	25%	8		25.6%	101
	>70	18%	6		47%	187
Group total			33			396
Marital status	Single /divorced/wid	27.3%	9		39%	155
	Married	72.7%	24		61%	241
Group total			33			396
Employment	Working	33.3%	11		29%	115
	Sick	30.3%	10		5%	20
	Unemployed	3%	1		5%	20
	Retired	33.3%	11		61%	241
Group total			33			396

The time span of the studies and timing of the questionnaires, with limited contact with participants in between, could have reduced the willingness of individuals to continue and this would need to be altered to reduce the drop-out rate. It would appear that the sample recruited were younger, more likely to be male, married and on sickness benefits than the population they were representing. If this was replicated in a RCT it would have obvious implications for the applicability of the results. But the changes in definition of ACSLT make it now unlikely that a suitable sample could be recruited for a RCT.

5.3 Cardiac Rehabilitation intervention

The second element of feasibility to be considered is that of the CR intervention itself. It is important to ensure that the intervention reflects menu-based practice and to assess how acceptable this part of the feasibility study was to participants. The CR intervention, that was used in the feasibility study, is described in detail earlier in chapter 4:11, however it was designed to replicate real life practice of menu based CR, and to use the skills of staff already experienced in this field. The intervention was delivered by a multi-disciplinary team comprising of a nurse, physiotherapist, dietician, pharmacist and clinical psychologist. Individuals allocated to the intervention group were reviewed by the CR team and interventions appropriate to their condition were prescribed by the relevant member of staff. Eight participants, originally assigned to the intervention group, and three, who were in the control group, but received a package of CR due to a further cardiac event, were included in this analysis. The CR intervention spanned the first three phases of CR as described in chapter 3:9 and onward referral was made for phase four to

voluntary and local authority providers. The elements that each participant received are documented in Table 5:4.

This table shows that all participants received an education package on their illness and the implications for them as individuals but, in addition, if they needed specialist smoking cessation advice or a psychological intervention this was provided. Individuals assessed as requiring an exercise component were offered this element.

Of eleven participants in the intervention group, all received input in hospital from the specialist nursing staff and physiotherapists. All participants felt they had received a lot of useful information while in hospital, while one felt he hadn't received enough input. The provision of the programme within hospital was simple to organise and carry out. The additional elements of the programme, and in particular the exercise component was more complex to deliver and had more variability in compliance. Of eleven participants, three were not offered an exercise class because of health problems and eight participants were offered the exercise component. Of this eight, two received a home programme, one refused to attend, two attended for part of the class and three completed the exercise component. The reasons given for not completing the exercise component of the programme were mainly due to family circumstances. One participant had returned to work, one had a family illness and one participant refused to attend as he did not feel like travelling to the hospital. Although only five of the eleven participants can be said to have completed a full CR programme, the mixture of input does reflect practice within menu-based CR programmes in Scotland (ISD 2012).

5:4 Cardiac Rehabilitation interventions

Participant code/Intervention group	219	220	222	223	224	225	106	107	108	109	110
Education (nurse)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Risk factor management (nurse)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Exercise advice (physio)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Medication advice (nurse/pharmacist)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Healthy eating (nurse/dietician)		✓		✓	✓		✓	✓	✓	✓	✓
Specialist smoking cessation advice (smoking cessation advisor)	✓	✓									
Outpatient programme or Home programme		✓	✓	1/2	✓		✓	1/2	✓		
Number of interventions carried out per participant	5	7	5	6	6	4	6	6	6	5	5

The CR intervention can be seen to have replicated usual clinical practice of menu-based CR as was a stated aim of the thesis.

All participants, who completed the feasibility study, were given an acceptability questionnaire at the T3 assessment. This asked a number of questions around the feasibility study and its acceptability for participants. They were asked to assess the usefulness and clarity of the information and to expand on any issues they felt had been difficult. However, all participants were very positive and felt that they had been happy to be involved. There was no-one who expressed any concern about taking part. At this point, participants in the control group, were offered a CR intervention. One participant took this offer up. Participants in the intervention group were asked several additional questions. They were asked if the intervention had been acceptable and had provided benefit. They all agreed that this was the case.

In summary, the CR intervention within this feasibility study reflects clinical practice and was acceptable to the participants within the intervention group. In addition, participants within the control group found taking part in the feasibility study acceptable.

5.4 Staff

As part of this feasibility study, focus groups were conducted with two separate groups of staff to elicit their views on the feasibility of a RCT of CR. The process for this has been documented in 4:13 and 4:18. The first focus group contained six CR professionals involved in the provision of care for the participants in the intervention group. This included two senior nurses, two senior physiotherapists and two physiotherapy assistants. The second focus

group consisted of eight ward staff, from both sites and from cardiology wards. Both focus groups were asked to consider the following topics:

- Expectations of the research process
- Barriers to participation
- Perceived impact of CR on this group

In addition the CR focus group were asked to consider

- The provision of the CR programme

Expectations of the research process

The CR focus group appeared to have a clear understanding of the research process and the reasons behind the design that had been chosen. They were familiar with the evidence base for the topic and with previous studies that had been conducted. This is likely due to the fact that they had been more involved in the discussions relating to the feasibility study. The second focus group on the other hand were not familiar with research methodology and had had little previous involvement in research. They did recognise that they had been given information on the feasibility study and its aims, but did not identify themselves as being involved in the process.

Barriers to participation

The CR focus group did not identify any barriers to participation in research. They did, however, raise the issue of low rates of referral from the ward staff to CR. This made it more difficult for them to gain consistent experience with this population. The second focus group expressed the view that, the time that participants were in hospital was too short to facilitate recruitment, and that they

had so much to do during this time, that it was difficult to remember the needs of the feasibility study. The difficulties with diagnosis were also raised as an issue. They were confused by the problems with definition that have been described previously and by the different opinions of the cardiologists across the two sites. Although supportive of the intervention, they expressed the view that, by carrying out a RCT, we would be preventing participants who could benefit from receiving CR. They seemed to have little understanding of the resource implications or professional challenges that this would bring to the CR team. They did not appear to value the feasibility study, as they felt that there was no need for further research to prove the benefits of CR.

Perceived impact of CR on this group

Both focus groups identified CR as important to the well-being of this client group. The second focus group were convinced that CR was needed for this group of participants and that it should be provided. They felt that the participants would benefit from the intervention, even if they had not had an MI. In contrast, the CR staff were concerned over what to tell the participants. This was not something that worried the ward staff. They assumed that the information would be the same and that it would be provided by the CR staff.

Provision of the CR programme

Discussions had taken place prior to the commencement of the intervention to clarify how the diagnosis would be explained and what care would be provided. The CR staff were asked to discuss how they felt this had worked in practice. The CR staff felt that they had provided care in exactly the way that

they would have for the usual caseload. They had assessed individual need and implemented a programme of care which had been different for each individual. This was based on the theoretical framework. However, they did identify several issues for further discussion. These included; problems with explaining the diagnosis, difficulties in giving advice on specific issues such as work and exercise, due to the lack of evidence in these areas, and variation in follow-up arrangements. The team found that participants were very confused about their diagnosis, many expressing that there was nothing wrong with them, while others thought they had had a heart attack. This was difficult for the staff to deal with and to explain to participants. As stated, a clear strategy for this had been agreed prior to the commencement of the intervention, and the staff had been prepared for it. However, they felt it had caused more difficulties than expected. At the time of the feasibility study there was no official advice available on issues such as returning to work and driving, and the staff felt they had to rely on their own expertise in assessing the capabilities of the individual. As this was a small feasibility study, the provision and timing of medical follow-up could not be altered, and the staff had no control over when or where this took place. This was different to the provision of CR in the MI population where the team control the follow-up. The staff reported that this led to delays in getting agreement for participants to attend the exercise component of the programme. The staff were supportive of the feasibility study and felt that it was important to gather more information on this population. They had struggled to provide evidenced based care for the participants and had to rely on their clinical judgement. They also expressed concern about the changing definitions

and what it could mean in terms of workload for the team. They were worried about a large increase in referrals and how they would cope.

In summary, the CR staff were supportive of the feasibility study and felt that it was important to gather more information on this population, as they had struggled to provide evidenced based care for the participants and had to rely on their clinical judgement. The ward staff were supportive of the intervention, but felt that a RCT wasn't necessary as they believed this client group should already be receiving CR.

5.5 Measures

Further discussion of the data collected using the outcome measures will take place in the next chapter. However it is important to consider whether the measures chosen were suitable to be used in any future RCT. Data from these outcome measures was collected at three assessments. Five validated measures were utilised, in addition to, self-reported measures on risk factors, health service utilisation and medication (see Table 4:1). The completion rate of each assessment is included in Figure 5:1. An acceptability questionnaire was also filled out at completion of the studies and this was discussed in chapter 5.3.

The YABQv2 was completed at all assessments with participants appearing to understand the questions. However, on several occasions, it was necessary to reinforce that 'don't know' was a valid answer. Participants felt that it was important to choose an answer even when they weren't sure. This was then included in the verbal instructions given prior to completion of the questionnaire.

All participants appeared to understand the questions and answer fully. The questionnaire took about five minutes to complete.

The CLASP asked questions about symptoms that the participant had experienced in the previous two weeks, including chest pain, breathlessness, oedema, and physical functioning. Each question was scored and a total score for each symptom calculated. Some of the questions were very similar to questions within the physical functioning section of the SF36v2. The main difference was the timescale involved. The SF36v2 asks questions about the last four weeks, while the CLASP uses the last two weeks as a reference. This caused difficulties as the studies progressed with participants feeling that they were answering the same questions twice. Most declined to answer the section on sexual habits and it was decided to use only the chest pain, breathlessness and oedema sub-scales of the CLASP in the data analysis.

The HADS was completed with few difficulties by the participants. It was clearly explained prior to completion and assistance given to those who required it, due to poor eyesight or difficulty in reading. The time taken was usually between five to ten minutes.

There were no unforeseen problems in the completion of the SF36v2. There was some cross-over in questions with the CLASP as previously mentioned, which caused some weariness during the initial assessments. The researcher then ensured that the SF36v2 was administered first, to guarantee that these data were complete and accurate, and could be compared, and contrasted, with that of the SEIQoL-DW. This instrument took about 10-15 minutes to complete.

SEIQoL-DW requires a lot more explanation for participants than the others, as it requires the participant to identify five key elements of their QoL. Then they rate their level of functioning or satisfaction with each, on a scale of 0-100 with 100 being totally satisfied and 0 being totally unsatisfied. The participant then indicated the relative importance of each to their overall QoL. They have 100 points to divide between the five factors, in order of their importance. An overall QoL score can then be calculated. The administration of SEIQoL-DW took between 20-30 minutes and the whole procedure had to be completed at each assessment. There were four occasions when this was not possible out of 81 assessments. In all cases this was due to the health of the participant. They were unable to concentrate fully on the process and it was decided to abandon it rather than to put them through additional stress and collect information that would not be a true reflection of their current QoL. Once the concept had been explained to the rest of the participants, there did not seem to be any real difficulty in coping with the task. Many were quickly able to identify five parts of their life which affected their QoL. However some participants found it difficult to identify as many as five items. They could think of three without too much difficulty, these were often, family, health or work. However the last two sometimes took a bit longer to identify. If they were unable to think of anything, then there were prompts that could be used to encourage them. At each assessment, participants were asked to identify again five areas of their life, and only if they were having difficulty, were they prompted with the list from previous assessments. In the main, there was a lot of consistency with the categories that they identified and their ability to carry out the allotted task.

Table 5:5 is an example of one participant's score on SEIQoL-DW. This shows that family and holidays were the two most important factors in determining this individual's QoL and accounted for 70% of the score.

Table 5:5 Worked Example of SEIQoL-DW

Factor	Score	Weighting out of 100	Score out of 100
Family	80	50	40
Holidays	40	20	8
Driving	60	15	9
Health	20	10	2
Pets	90	5	4.5
Total score			63.5

Participants were asked to complete weekly diaries which monitored their dietary intake and activity levels. However the completion rate for this part of the exploratory study was very poor. They were given diaries at each intervention and asked to post them back after a week. However participants had problems using the pedometers and frequently forgot to keep their food diaries up to date. This part of the data collection then had to be abandoned as no reliable information was being produced.

In conclusion all the measures, with the exception of the self-reporting diaries were easily used and accepted by the participants. However the use of three HRQoL measures was not feasible for the participants and SF36v2 and CLASP appeared very similar. The choice of SF36v2 would allow for

comparisons with other populations. SEIQoL-DW took the longest time to complete, but was interesting to the participants and most were able to carry out the exercise.

5.6 Conclusion

In summary, the feasibility study was designed to examine the feasibility of a RCT which would test the impact of a menu-based CR programme, on individuals diagnosed with ACSLT, against standard care. This includes the staff views on issues of feasibility. The feasibility study was successful in its aim of testing the CR intervention and protocols for a further RCT. Information gathered within the feasibility study has shown that recruitment to the studies was problematic. Withdrawals were also more than expected.

If we consider the participants, in terms of the feasibility of a RCT, we can see that, if a different researcher had been used, it could have been possible to recruit enough participants. If recruitment had continued after discharge, then numbers could also have been increased. The drop-out rate from the studies due to ill health was higher than expected and there was also crossover between the groups due to further cardiac events. This is useful information that would inform any future RCT. The time span of the studies and the timing of the questionnaires, with limited contact with participants in between, could have reduced the willingness of individuals to continue and this would need to be altered to reduce the drop-out rate. It would appear that the sample recruited within the studies were younger, more likely to be male, married and on sickness benefits than the population they were representing. If this was replicated in a RCT it would have obvious implications for the applicability of the

results. But the changes in definition of ACSLT make it now unlikely that a suitable sample could be recruited for a RCT.

The CR intervention, within this feasibility study, reflects clinical practice and was acceptable to the participants within the intervention group. In addition participants within the control group found taking part in the studies acceptable. The menu based application of the interventions led to a degree of variability in the programme, provided to individuals, as had been expected. This would have implications for the sample size needed to detect differences between groups in any RCT. The CR staff were supportive of the research and felt that it was important to gather more information on this population as they had struggled to provide evidenced based care for the participants and had to rely on their clinical judgement. The ward staff were supportive of the intervention, but felt that a RCT wasn't necessary, as they believed this client group should already be receiving CR.

All the measures, with the exception of the self-reporting diaries were easily used and accepted by the participants. However the use of three HRQoL measures was not feasible for the participants and SF36v2 and CLASP appeared very similar. The choice of SF36v2 would allow for comparisons with other populations. SEIQoL-DW took the longest time to complete, but was interesting to the participants and most were able to carry out the exercise. Data obtained from these measures will be discussed in chapter 6:5. However, the changes in diagnostic categories led by government and clinical expert agencies means that a RCT is no longer feasible. Recruitment would no longer be possible for ethical reasons as has been described.

In conclusion, the feasibility study was successful in its aim of testing the CR intervention and protocols for a further RCT. However due to changes in diagnostic categories a RCT is no longer possible.

Chapter Six Exploratory study

6.1 Introduction

As has been discussed in previous chapters, individuals with ACSLT are a novel population for CR and there is limited data about the impact the CR might have on this group. In chapter 5:2-5:5, we discussed the first aim of this thesis, which was to examine the feasibility of a RCT which would test the impact of a menu-based CR programme, on individuals diagnosed with ACSLT, against standard care. This feasibility study also included staff views. The conclusion was that, although a RCT of CR in ACSLT was feasible, current healthcare policy made it no longer possible.

A secondary aim of this thesis was to carry out an exploratory study that aimed to explore the impact that ACSLT and CR can have on this client group. A wealth of data was collected on the participants over a two year period which, although only exploratory in nature, does point to areas that require further study. Significant problems in recruitment and retention were experienced and therefore the numbers of participants who completed the exploratory study was small. The data must therefore be treated with caution and can only be seen as exploratory in nature.

This chapter will explore the data collected on the 25 participants who completed the exploratory study. Due to the problems with data collection at T2, these outcome data will not be presented here, although some information obtained at T2 in the interviews will be presented. However the data obtained using clinical outcome questionnaires at T1 and T3 and from the case-notes at T4 will be discussed.

As discussed previously in chapter 5:2, 33 participants started the exploratory study, eight participants were withdrawn, and 25 participants completed. Initially, 17 were allocated to the control group and eight to the intervention group. However, three of the control group participants received input from the CR team following a further admission. The data could have been analysed on an 'intention to treat basis', which would have given groups as above. However, the exploratory study was exploring the impact of a CR programme, as it is delivered in real life, and this issue of crossover in groups is one that often happens in real-life practice. It was felt that, by including participants who received CR later in their care, a clearer picture would be seen of the impact that CR has in real life programmes. Therefore, in the data explored in chapter 6:3-6:7, the 14 who received no additional input to usual care are described as the control group. The eight who received input from the CR team during their initial event, and the three who received input from the CR team following a second cardiac event, are described as the intervention group. The data will therefore be analysed on the basis of 14 participants in the control group and 11 in the intervention group.

6.2 Participants demographic data

All participants in the studies were of white Scottish ethnic origin. The baseline demographic factors can be seen in Table 6:1 and there were no statistically significant differences between the control and intervention groups in any of the variables. The expected gender balance in the sample would be 2:1 male to female, as this would reflect the incidence of CHD in Scotland (ISD 2010).

Table 6:1 Baseline demographic factors on admission

	Study groups				Overall total		
	Control group		Intervention			total	sig
	%	count	%	count	%	Count	
Gender							
M	78.5	11	63.6	7	72	18	ns
F	21.5	3	36.4	4	28	7	
Age group							
<50	7.1	1	27.2	3	16	4	ns
50-59	42.8	6	36.4	4	40	10	
60-69	28.5	4	18.2	2	24	6	
70-79	7.1	1	9.1	1	8	2	
>79	14.2	2	9.1	1	12	3	
Mean age		61.7		57.2		59.7	
Marital status							
Living alone	21.4	3	9.1	1	16	4	ns
Married/with partner	78.6	11	91	10	84	21	
Employment status							
Working	28.6	4	45.4	5	36	9	ns
On Sick	35.7	5	9.2	1	24	6	
Retired	35.7	5	45.4	5	40	10	
Depcat class							
1-2	14.3	2	18.2	2	16	4	ns
3-4	28.6	4	27.3	3	28	7	
5-6	57.1	8	54.5	6	56	14	
Age at leaving full-time education							
16 or under	85.8	12	63.6	7	76	19	ns
17-18	0.0	0	36.4	4	16	4	
Over 18	14.2	2	0	0	8	2	

However, the control group had more men than expected, whereas the intervention group reflected the national average. The mean age of the control group was slightly older than the mean age of the intervention group.

The majority of the participants were married or living with a partner. In this sample no participants were unemployed, which does not reflect the local population, where unemployment rates are currently 8% (Office of National Statistics, 2012). As the mean age of the sample was 59.7 years, it is not unexpected that 40% were retired and an additional 24% had ill health and were unable to work. The occupations most noted were skilled tradesmen, and administrative and clerical staff. Only two participants were professionals. The incidence of sickness benefit was higher in the control group and the numbers working full-time was higher in the intervention group. The majority of the sample (92%) left school at 16 or younger, with only two participants going on to further education. The intervention group had four participants who stayed on at school for a fifth or sixth year and none who went on to further education. The control group had two who went to further education, but none who left after fifth or sixth year.

Deprivation status was determined according to deprivation categories measured by the Carstairs scores for Scottish postcodes (Carstairs and Morris 1991). Each postcode is classified as one of seven categories. Categories 1-2 are classified as affluent, 3-4 as middle category and 5-7 as deprived. Currently the Ayrshire population is classified as having 14% in the affluent group, 46% in the middle group and 40% in the deprived group (ONS, 2012). In this sample the groupings were: affluent 16%, middle 28% and deprived 56%.

The larger number of participants within the deprived grouping as compared to the Ayrshire population was not an unexpected finding as CHD is more prevalent in deprived populations (BHF 2012a).

6.3 Baseline clinical factors

The sample was assessed using standardised measures for a wide range of clinical factors at baseline. As can be seen in Table 6:2, both control and intervention groups were similar for: co-morbidities, BMI, Systolic BP, number of cigarettes per day, activity score and levels of cholesterol. The GRACE score gives an indication of a % clinical risk of future cardiac events and that the risk score is low for both groups and there are no statistically significant differences between them.

Table: 6:2 Baseline clinical factors

	Study groups		
	Control	**Intervention**	**Sig**
Total N=25	N=14	N=11	
	Mean(SD)	Mean(SD)	
Co-morbidity	2.0(1.69)	1.9(1.1)	ns
BMI	30.8(5.3)	29.6(5.25)	ns
Diastolic BP	80.08(14.38)	71.4(13.43)	ns
Systolic BP	136.75(23.16)	134.4(30.85)	ns
Cigarette/day	8.35(8.05)	9.54(11.92))	ns
Active	5.2(0.89)	5.9(1.7)	ns
Cholesterol	5.13(0.58)	5.62(1.7)	ns
TropT	0.33(0.27)	0.31(0.25)	ns
GRACE	5.9%(6.68))	8.75%(12.0)	ns

6.4 Medical treatment

The medical treatment for CHD consists of five main groups of drugs and these are highlighted in Table 6:3 below. The discharge prescriptions for the sample were exactly as would be expected from local discharge data and from clinical practice. The control and intervention groups discharge drugs are similar across all prescribing data. The follow-up data would appear to show a lower rate of follow-up and a higher rate of investigations within the intervention group. Three participants from the control group moved to the intervention group and all three had further investigations. This accounts for the higher investigation rate in the intervention group. However, if we exclude the three participants who were moved into the intervention group, due to a further event, the groups are similar.

Table 6:3 Medical treatment

	Study groups				**Overall**		**sig**
	Control		**Intervention**		**Total**		
	%	count	%	count	%	count	
Aspirin	100	14	100	11	100	25	ns
Clopidogrel	85	12	100	11	92	23	ns
Ace-inhibitor	64	9	64	7	64	16	ns
Betablocker	85	12	81	9	84	21	ns
Statin	92	13	90	10	92	23	ns
Cardiac outpatients	78	11	55	6	68	17	ns
Cardiac Investigations	21	3	45	5	32	8	ns

6.5 Outcome measures

The choice of outcome measures and the rationale for these has been described in chapter 4:16 and the feasibility of their use in a RCT has been outlined in chapter 5:5. This section will outline the results obtained at T1 and T3 on the five outcome measures:

- YABQv2
- CLASP
- HADS
- SEIQoL-DW
- SF36v2

A high score on the YABQv2 relates to a high level of misconceptions. Within the participants (both control and intervention), the range of scores on misconceptions was 30%-71% at T1 and 21%-71% at T3 (see Table 6:4). This indicates quite a wide range of misunderstanding amongst the participants. In Table 6:4, we can see that there was only a slight change in the misconceptions score for the control group over the exploratory study, with a slightly larger change in the intervention group.

This slight gap between the two groups is also reflected in both the coping and perception of anginal threat sub-scales. A high score on these scales denotes poor coping or high levels of perceived anginal threat. If we consider coping first, we see that the range of scores in the control group varies very little from T1 to T3, however in the intervention group, there is a reduction in the range of scores between T1 and T3 and a change of mean scores of -2.57 in the control group compared to -8.36 in the intervention group.

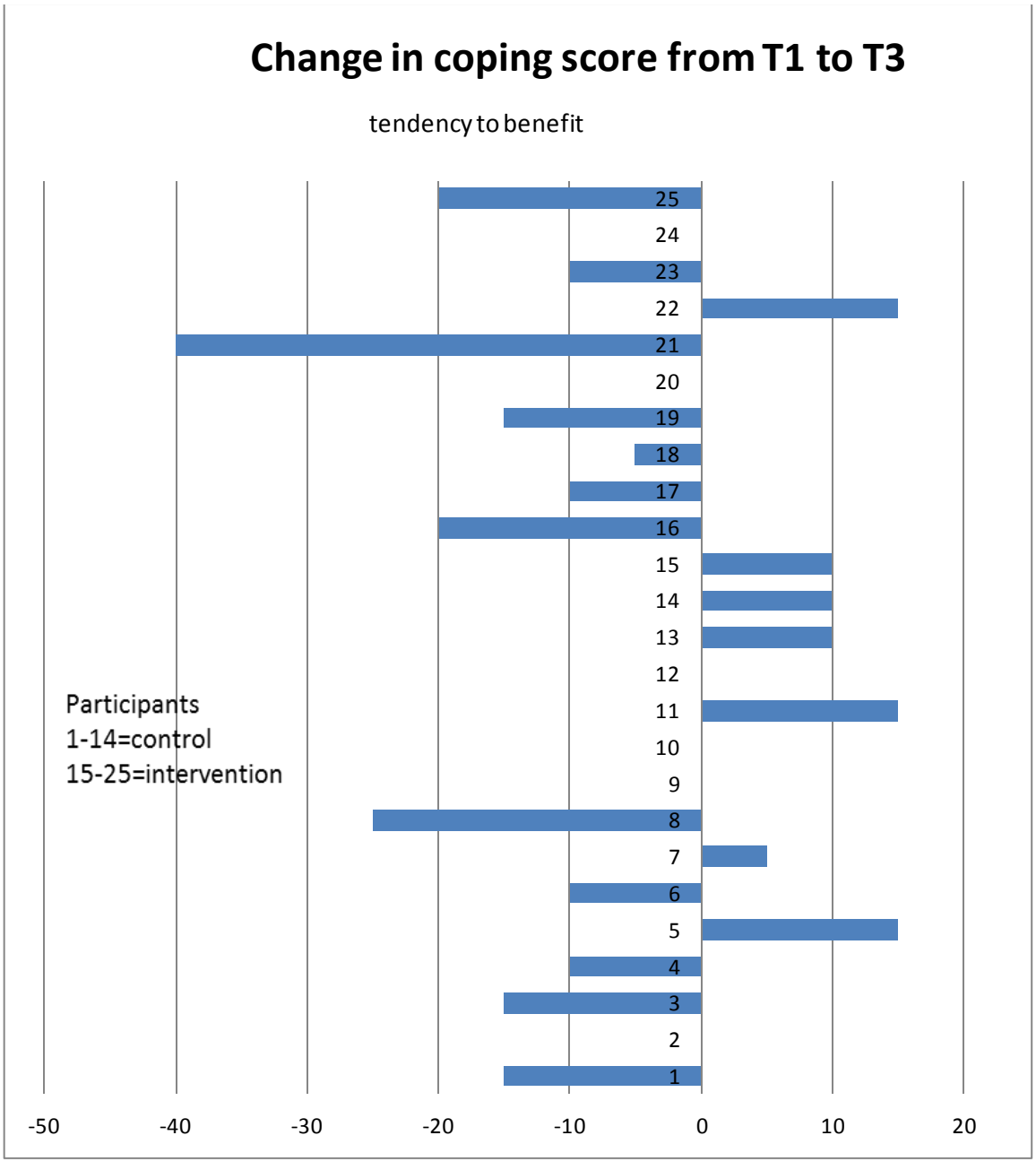
Table 6:4 Outcome measures

	Control group N=14			Intervention group N=11			
	T1	T3		T1	T3		
	mean (SD)	mean (SD)	change	mean (SD)	mean(SD)	change	significance
YABQv2 (Benefit=Reduction)							
Misconceptions	53.78(11.46)	51.15(9.6)	-2.63	47.85(8.02)	41.78(14.81)	-6.07	ns
Anginal threat	50.50(14.18)	50.17(13.08)	+0.33	45.39(14.01)	39.08(17.33)	-5.3	ns
Coping	57.14(11.55)	55.71(12.06)	-2.57	55.45(14.01)	46.81(13.65)	-8.36	ns
CLASP (benefit=reduction)							
Angina	7.43(3.1)	2.43(3.52)	-5	9.18(2.82)	1.91(2.70)	-7.27	ns
Breathlessness	7.29(4.4)	5.64(4.1)	-1.65	7.09(5.33)	3.11(3.01)	-3.98	ns
Oedema	1.57(2.62)	1.00(2.1)	-0.57	1.82(3.1)	0.89(1.833)	-0.93	ns
HADS (benefit=reduction)							
Anxiety	7.29(4.69)	7.21(5.01)	-0.08	8.18(3.06)	5.45(4.22)	-2.73	ns
Depression	6.57(4.8)	5.85(4.24)	-0.72	4.73(2.49)	3.36(3.13)	-1.37	ns
SEIQoL-DW (benefit =increase)							
Global QoL	64.88(16.46)	70.23(14.70)	+5.35	69.20(15.34)	77.67(11.53)	+8.47	ns
SF36 v2 (benefit =increase)							
SF36v2 Physical	39.88(10.45)	39.75(14.03)	-0.13	36.09(8.09)	44.09(10.36)	+8.0	ns
SF36v2 Mental	39.05(15.98)	43.99(14.03)	+4.94	48.97(8.17)	51.63(10.74)	+3.64	ns

T1=at baseline T3=at nine month

We can see from Figure 6:1 below that seven participants (5 control and 2 intervention) had a deterioration in their coping scores over the period of the study.

Figure 6:1 Change in coping score



T1 =baseline T3 =9 months later

The picture of greater reduction in the intervention group continues, on the subscale looking at anginal threat, with mean scores (-0.33 v -5.3) reducing more in the intervention group. Across all three scales of this questionnaire, we see a similar picture of small amounts of improvement between T1 and T3 in the control group, with larger changes in the intervention group (see Table 6:4).

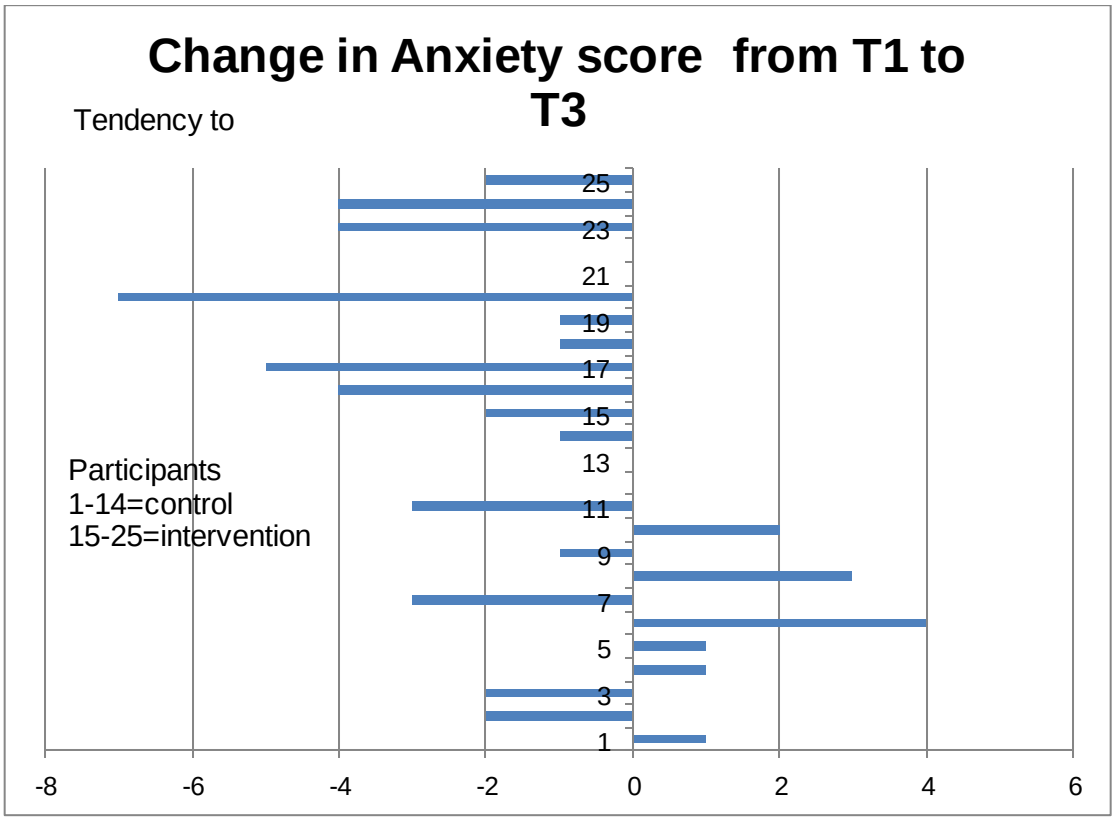
The elements of the CLASP that measured clinical symptoms, including angina, breathlessness and oedema are presented in Table 6:4. A score is calculated according to the frequency and severity of symptoms, the higher the score, the higher the level of symptoms, with the maximum score obtainable being 20. Angina is a key symptom for patients with this clinical diagnosis and it can be seen that the scores across both groups reduced from T1 to T3, with a change of 5.0 in the control group compared to 7.27 in the intervention group. Only one participant suffered deterioration in their pain score and this respondent was undergoing further investigations and treatment.

Breathlessness can be linked to angina, and both groups reported moderate levels of breathlessness at T1 and at T3. There is a reduction in both groups with changes of -1.65 in the control group compared to -3.98 in the intervention group.

Oedema in the cardiac population is usually related to the presence of HF and would not be routinely expected in this population. This is reflected in the low incidence at both T1 and T3 with changes in both groups of 0.57 and 0.93 respectively.

The HADS measures two key psychological factors, namely anxiety and depression. The results are displayed in Table 6:4. If we consider anxiety first, we can see that there is little change in mean anxiety levels between T1 and T3 in the control group. However, the intervention group had higher levels of mean anxiety at T1 and this had reversed at T3. The relative change between the two time points was 0.08 in the control group and 2.73 in the intervention group. We can see from Figure 6:2 below that there is a wide variation in individual scores in the control group between T1 and T3, with half the control group showing a worsening of anxiety levels and half showing improvement, therefore leading to little mean change.

Figure 6:2 Change in anxiety score

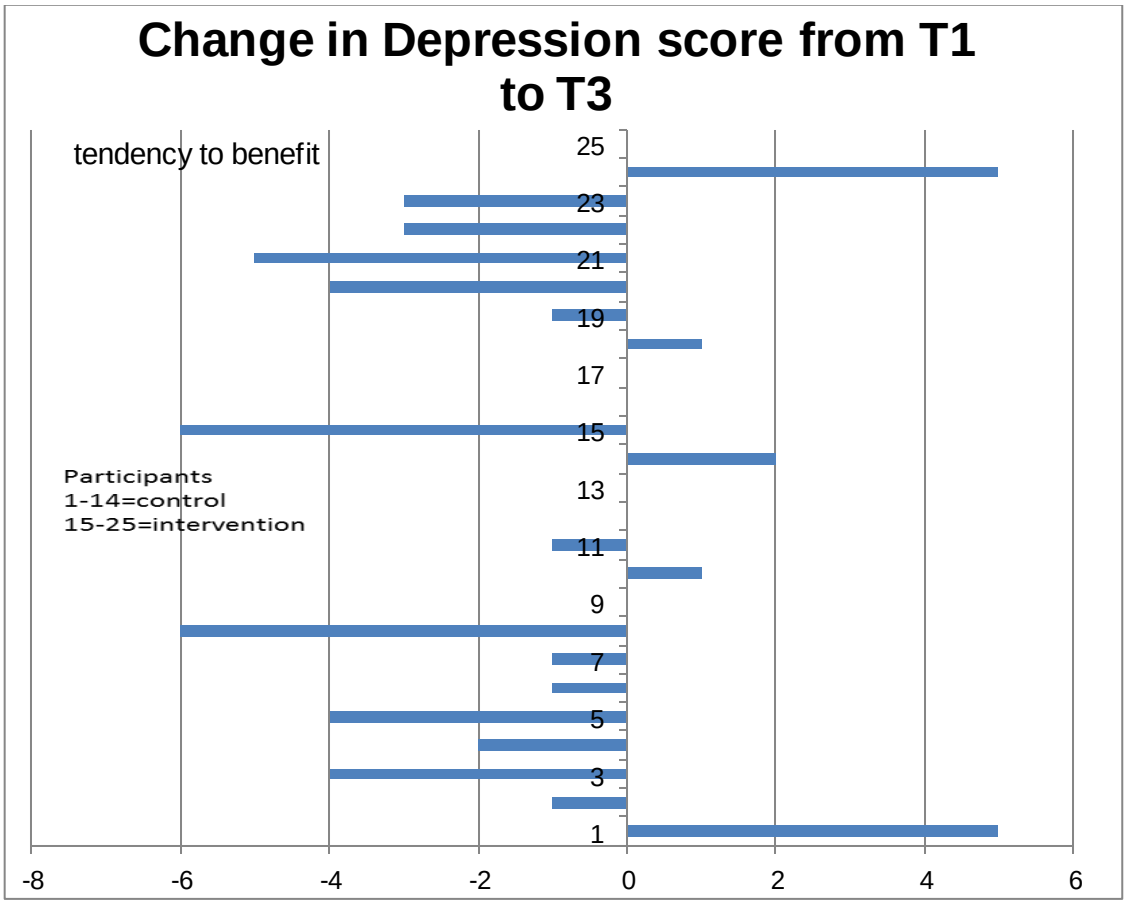


T1 =baseline T3 =9 months later

The picture is however different if we consider the intervention group, here we see that all the scores across the group improved, and it is this that is responsible for the differences noted in the mean scores above.

If we then consider depression, we see a slightly different picture. The relative change between T1 and T3 was 0.73 in the control group and 1.4 in the intervention group (see Table 6:4). In Figure 6:3 we can see that both groups have individuals whose scores deteriorate over the period from T1 to T3.

Figure 6:3 Change in depression score



T1 =baseline T3 =9 months later

From Table 6:5, we can see that the control group was more depressed at T1 and at T3. It is important to note that within the control group there were four participants who presented with scores greater than nine. This level of depression would be treated as clinically significant. Of these four participants, two had reduced their score below nine and the other two continued to score high levels of depression at T3. In addition, one respondent within the control group developed a significant depression score between T1 and T3, with no corresponding deterioration in health. Within the intervention group there were no individual scores above nine at T1 and only one at T3. This individual had suffered additional serious health problems in the intervening time.

Table: 6:5 Depression Scores by category at T1 and T3

	Control				intervention			
	T1		T3		T1		T3	
	%	count	%	count	%	count	%	count
0<7	57	8	57	8	82	9	91	10
7-9	14	2	21.5	3	18	2	0	0
>9	29	4	21.5	3	0	0	9	1

Quality of life was measured using two validated instruments, the SEIQoL-DW and SF36v2. Twenty four participants completed a SEIQoL-DW at T1 and T3. They had to identify five variables that made a difference to their QoL. Of these, 19 stated that their family was the main contributing variable to their QoL, rising to 21 at T3, with most suggesting that it represented around 50% of the total score. Three participants at T1 stated that their health was the main contributor to their QoL, with an additional one stating faith and one work.

The second most important contributor was often defined as health with 11 participants identifying this and three picking work. The five who had not picked family as variable one, did choose it as variable two. In many cases, the second variable represented around 20-30% of the total score.

The last three variables picked by the participants varied quite a lot, but can be summarised as social arrangements. These could be holidays, pets, hobbies or a range of other items which related to entertainment. These often had values of between 5-15% of the total score.

Any differences between the groups at T1 and T3 did not reach statistical significance. However, we can see that both groups had an improvement in their QoL as measured by SEIQoL-DW across the time of the exploratory study, with the mean change being 5.35 in the control group and 8.47 in the intervention group (Table 6:4).

The second instrument to be used was the SF36v2. This instrument has several different components and can be analysed compared to a variety of populations. Two key scales are the physical care summary and mental health care summary scales. The small improvement in QoL noted by the SEIQoL-DW in both groups is also reflected in the mental health scale of the SF36v2, with the control group improving slightly more than the intervention. However, the control group started from a lower baseline on this scale. This may reflect the results found on the HADS scale that showed a higher level of depression in the control group. The results, on the physical summary scale, show a slightly different picture, here the control group stay the same and the intervention group improve by 8.

There are eight sub-scales of the SF36v2 and these are laid out in Table 6:6. If we consider the control group, we see a mixed picture of improvement and deterioration. Physical functioning, role physical, and general health seem to deteriorate, and vitality, social functioning and role emotional improve. In the intervention group only general health appears to deteriorate. All other factors appear to improve.

Information on norms within different groups is available for the SF3v2. If we consider the two groups against the CHD norms, we can see that at T1 the control group was worse than the norms on all factors except role physical. The intervention group was worse than the norm on everything except general health, role emotional and physical functioning. At T3 the control group is below the norm on all factors except bodily pain, role emotional and the physical summary scale. The intervention group is consistently above the norms across all factors.

Table 6:6 HRQoL

SF36v2									
Norm based scoring		Control			Intervention				
Total N=25		N=14			N=11			CHD norm	sig
		T1	T3	change	T1	T3	change		
		Mean(SD)	Mean(SD)		Mean(SD)	Mean(SD)			
Physical functioning		38.89(11.55)	38.54(10.41)	*-0.34*	39.81(11.08)	46.12(11.74)	*+6.31*	38.87(11.24)	ns
Role physical		41.46(12.82)	40.06(11.07)	*-1.4*	37.26(10.15)	45.05(9.59)	*+7.79*	40.09(10.74)	ns
Bodily pain		38.42(10.1)	47.93(12.63)	*+9.51*	37.22(7.79)	50.32(8.91)	*+13.1*	43.54(9.85)	ns
General health		37.47(8.88)	36.72(9.44)	*-0.75*	43.57(9.1)	41.10(10.07)	*-2.47*	40.86(9.86)	ns
Vitality		37.59(13.5)	37.81(12.1)	*+0.22*	39.88(11.20)	45.84(10.44)	*+5.96*	45.36(9.52)	ns
Social functioning		37.76(13.98)	42.02(13.98)	*+4.26*	41.97(10.37)	51.39(12.19)	*+9.43*	44.16(11.38)	ns
Role emotional		39.49(15.85)	45.05(11.52)	*+5.56*	47.39(13.10)	50.57(11.12)	*+3.18*	43.59(12.67)	ns
Mental health		39.95(14.68)	43.57(13.72)	*+2.62*	48.72(6.46)	50.77(11.12)	*+2.05*	48.48(10.13)	ns
Physical summary		39.88(10.45)	39.75(14.03)	*-0.13*	36.09(8.09)	44.09(10.36)	*+8*	38.91(10.05)	ns
Mental health summary		39.05(15.98)	43.99(14.03)	*+4.94*	48.97(8.17)	51.63(10.74)	*+2.66*	48.34(10.68)	ns

T1=at baseline T3=at nine months

6.6 Participant interviews

As described in chapter 4:16, as part of the follow-up at T2 and T3, participants took part in a semi-structured interview. The interview protocol is included in Appendix 1.2. The process of data analysis is documented in Chapter 4.19. There was no overarching theme which joined all the participants, but several themes did present themselves within the two groups. These are displayed in a thematic map in Appendix 1:5

The control group consisted of 14 participants. The key themes within this group appeared to be; difficulties in making the diagnosis, lack of information on what to expect, and feeling as if their life was on hold.

If we consider the issue of diagnosis first, many of the participants in the control group expressed concerns around their diagnosis. They seemed to have been given different diagnoses at various stages of their recovery. They had been told by one healthcare professional that their admission was due to angina and then by another healthcare professional that it was due to an MI.

'They told me in the hospital that I had had an angina attack and my GP told me last week that the letter says it was a heart attack,' (participant 204)

'one doctor says one thing and another doctor says something else, it was a heart attack and then it wasn't' (participant 207)

This uncertainty amongst staff appears to have affected more than one hospital and department and also to have impacted on the care from primary care teams. There was no consistency in the information being given to the participants. For some, this lack of clarity and explanation, was taken to mean that there was nothing to worry about. If the doctors didn't know for sure, then it

couldn't be anything serious. This led to some participants not taking tablets, or following advice, as they minimised the impact of their illness. These participants distanced the event from what they saw as a true serious event i.e. a heart attack.

'It's not like a heart attack or anything' (participant 102)

'It was only an angina attack and I have not had any more (pain) so I don't see the point in taking more tablets' (participant 104)

This lack of information made it difficult for many to move forward and many of the participants at T3 continue to describe a sense of confusion as to what to do now. They expressed concerns about not understanding what they were dealing with.

Many of the participants described a feeling of putting their life on hold, not going on holiday, or avoiding their usual hobbies. This was especially difficult for those waiting on tests, who describe living in limbo until the next hospital appointment, or the next test, and not knowing what to expect.

'I am kind of in limbo, I'm not sure what I should be doing or if I am doing too much. I mean I have had health problems before and If it was my chest or my bones, I would know what to do but the heart is different, you only have one heart and I don't want to do anything wrong' (participant 101).

The interviews appeared to suggest that, in the control group, not only was there a lot of uncertainty among staff about the diagnosis, but this led to the participants struggling to make sense of what they had suffered as well.

The intervention group consisted of 11 participants, five of whom had either PCI or CABG during the period of the exploratory study. Of these, three had originally been in the control group before their procedure. They expressed no uncertainty around their diagnosis. It is possible that by having another procedure this uncertainty was minimised for these individuals. For the remaining six participants within the intervention group, this concept of uncertainty around diagnosis also doesn't appear to have been a concern. Only one participant in this group expressed concerns around diagnosis.

'I didn't really remember what the CR team said, I have a lot of unanswered questions' (Participant 225).

For the intervention group the key theme was the future and what it would be like. Those who had undergone cardiac intervention were worried about whether it would work. The focus for many others, within this group was the need to get back to normal and the belief that they could. There was a lot of discussion around what they could achieve and how they were managing their life. The impression was of looking forward instead of back.

Another theme to emerge, from the interviews with the intervention group participants, was the benefit that had been perceived in the CR intervention. This focused in some cases on the provision of information around how to manage their illness or on the recognition of the need for active management of issues around their illness that were on-going and required expertise to solve.

'The specialist nurse came out when I got home and went over everything for me, so I kind of knew what to do.' (participant 220)

The interviews appear to suggest that in the intervention group the participants were making sense of their illness, but were still trying to deal with uncertainty around the future and what it would bring. They identified the intervention as helping them to come to terms with the situation.

6.7 Two year follow-up

All 25 participants, who remained in the exploratory study at T3, had their case-notes reviewed at two years following admission. Information was gathered on readmissions, and any additional health problems. Two of the participants (1C, 1INT) had died, both from complications of heart disease. Mr (104) was an elderly man who had suffered a further heart attack and Mr (108) had suffered extensively from HF. These two participants had the highest GRACE score at T1. Four participants had developed cancer (3C 1INT) and this accounts for many of the readmissions to hospital. An additional four participants had further investigations and treatment for CHD and two participants had suffered from gallbladder and stomach problems. Five participants had one admission, two had two admissions, four participants had between five and nine admissions, and one participant had 20 admissions.

Table 6:7 Readmissions at two years since index admission

	Control	Intervention	Sig
Total N=25	N=14	N=11	
	Mean(SD)	Mean(SD)	
Number of all cause readmissions	3.09 (6.68)	2.87 (3.35)	ns
Total days	12.0 (25.83)	14.50 (21.68)	ns

If we compare the two groups, there would appear to be no significant differences, either in number of readmissions or total number of days spent in hospital in two years. However there seems to have been more than expected ill health within the participants in both groups.

6.8 Conclusion

A secondary aim of this thesis was to explore the impact that ACSLT and CR can have on this client group. A wealth of data was collected on the participants over a two year period which, although only exploratory in nature, does point to areas that require further study. Significant problems in recruitment and retention were found and therefore the numbers of participants who completed the studies was small. The data must therefore be treated with caution and can only be seen as exploratory in nature.

There were no statistically significant differences between the control and intervention groups on any of the demographic variables. Both control and intervention group scores were similar for: co-morbidities, BMI, Systolic BP,

number of cigarettes per day, activity score and levels of cholesterol. The risk score for future cardiac events is low for both groups and they received similar medical treatment.

Within the participants (both control and intervention), the range of scores on misconceptions indicates quite a wide range of misunderstanding. There was only a slight change in the misconceptions score for the control group, with a slightly larger change in the intervention group. This slight gap between the two groups is also reflected in both the coping and perception of anginal threat sub-scales. Across all three scales of this questionnaire, we see a similar picture of small amounts of improvement between T1 and T3 in the control group, with larger changes in the intervention group.

Angina is a key symptom for participants with this clinical diagnosis and it can be seen that the scores across both groups reduced, with a slightly larger reduction in the intervention group. This pattern is reflected in both breathlessness and oedema scores.

If we consider anxiety and depression, we can see that there is little change in mean anxiety levels between T1 and T3 in the control group. However, the intervention group had higher levels of mean anxiety at T1 and this had reversed at T3. All the scores across the intervention group improved. The control group was more depressed at T1 and at T3, but the relative change between T1 and T3 favoured the intervention group. However 30% of all the participants had clinically significant depression scores.

Quality of life was measured using two validated instruments, the SEIQoL-DW and SF36v2. Both groups had an improvement in their QoL as measured

by SEIQoL-DW, across the time of the exploratory study, with the mean change being 5.35 in the control group and 8.47 in the intervention group. This is reflected in the SF36v2. If we consider the two groups against the CHD norms, we can see that, at T1 the control group was worse than the norms on all factors except role physical, and the intervention group was worse than the norm on everything except general health, role emotional and physical functioning. At T3, the control group is below the norm on all factors except bodily pain, role emotional and the physical summary scale and the intervention group is consistently above the norms across all factors.

The interviews with participants appear to suggest that the key themes within the control group appeared to be; difficulties in making the diagnosis, lack of information on what to expect, and feeling as if their life was on hold. In the intervention group, the participants were making sense of their illness, but were still trying to deal with uncertainty around the future and what it would bring. They identified the intervention as helping them to come to terms with the situation.

At the two year follow-up there would appear to be no significant differences, either in number of readmissions, or total number of days spent in hospital. However, there seems to have been more than expected ill health within the participants in both groups.

In conclusion, outcome data was collected, at four time points, on a new and novel population, that has not been studied within the CR evidence base previously. There were significant problems in recruitment and retention and

this meant that the number of participants who completed the studies was small. There were no significant differences between the groups at T1 and no statistically significant benefit can be detected across the clinical outcome indicators, due to the small numbers. Any data must therefore be treated with caution and can only be seen as exploratory in nature. However, a wealth of data was collected on the participants over a two year period and it does suggest areas that require further investigation. The data obtained using clinical outcome questionnaires at T1 and T3 and from the case-notes at T4 have been explored and it can be seen that, although the numbers within the exploratory study were small, the intervention group do appear to have improved more than the control group across almost all indicators. This warrants further study.

Volume Two

Chapter Seven Discussion

7.1 Introduction

This thesis contains a feasibility study and an exploratory study. The feasibility study aimed to examine the feasibility of a RCT, which would test the impact of a menu-based CR programme, on individuals diagnosed with ACSLT, against standard care. This feasibility study included staff views. The exploratory study aimed to explore the impact that ACSLT and CR can have on this client group.

The impetus for this thesis was the growing pressure on CR teams to provide care for a wide range of individuals with varying diagnoses, but particularly for those with ACSLT. There was however, a lack of evidence on the impact, and the best method of provision of menu-based CR, for this population. The preceding chapters have reviewed the theoretical basis, have modeled the intervention, and have documented the outcome of the overall aims of the research stated above. This chapter aims to discuss the limitations of the studies and the three main findings in depth. The three main findings that require further discussion are as follows: firstly, that the feasibility study was successful in its aim of testing the protocols and the CR intervention for a further RCT. Several improvements were identified that could enhance the design of the studies. However the feasibility study also highlighted that, due to changes in healthcare policy and service provision, a RCT of menu-based CR in ACSLT would no longer be possible within the UK.

Secondly, this thesis has explored the impact of menu-based CR on a unique population, that of ACSLT, and although the exploratory study was not

powered to detect statistically significant differences between groups, there appears to be a tendency to benefit that would warrant further study in this area.

Finally, this thesis has highlighted the degree of uncertainty experienced by participants during this time of change within cardiac services. The confusion over the changing definitions of MI was a unique situation and the impact that this had on participants has been documented within the exploratory study. However, the wider implications of the concept of uncertainty and its impact on the theoretical framework need further consideration.

The chapter will then discuss changes in the CR evidence base, the implications of the thesis for clinical practice, and make suggestions for further research.

7.2 Limitations of the studies

This thesis contains a feasibility study and an exploratory study which involved only 33 participants. The feasibility study also involved 14 staff. Although the studies provide useful information for practice, their limitations must be acknowledged. The small size of the sample made it unlikely that significant results could be found. Previously, little data existed on this population. However, there are several interesting trends within the data that require exploration in a further study.

The studies were carried out by a single researcher with limited additional funding. This had implications for the design. It is possible that if this had been a funded project, then decisions taken on the design would have been different. One example was the choice of a case-control rather than a randomised

design. If a randomised design had been chosen, it may have strengthened the studies, however the practicalities of organising and delivering an intervention meant that a case control design was the better choice, as it concentrated the professional resource that was needed into a short time span and this allowed the staff to develop and practice the skills required for this population.

Another example of practical issues influencing design choices was the choice of time-points. It is possible that, if an additional time point had been introduced at 6 months; different data would have been obtained, as it would have been closer to the end of the intervention. In addition, at T4 only data from the case-notes was obtained and if a further interview had been carried out at this point, utilising standardised questionnaires and qualitative methods, then this could have strengthened the exploratory study.

The use of standardised questionnaires was a strength of the exploratory study, as this allowed comparisons with previous work to take place. However, the use of both CLASP and SF36v2 was too challenging for the participants and it would have been better to have focused on one instrument. If a pilot study of these HRQoL measures had been carried out, this difficulty could have been avoided.

These studies were carried out at two hospitals in the west coast of Scotland and the findings may not generalise to areas where clinical practice is different. If the studies had been carried out at one hospital, then it is possible that recruitment would have been better. However, the use of two hospitals was at the request of NHS Ayrshire and Arran, who wished to explore the service issues.

Due to the difficulties with recruitment and retention, the participants may not have been representative of the population from which they were drawn. The sample was small and no significant differences were found. If the sample had been larger this may not have been the case. The participants included a high number of males versus females. The experiences of the women may not have been adequately reflected within the data that was collected. In addition, all the participants came from a white Scottish ethnic background. This reflects the local population, but limits the applicability of the results to other ethnic populations.

The control and intervention groups had substantial drop outs throughout the course of the research due to ill health. There were also three participants, who crossed from the control to intervention group, due to further cardiac events. This was a useful finding for any future study, but was one that had not been anticipated at the design stage.

The use of focus groups and interviews was an additional element of the studies and was limited in its scope. Only two focus groups were held with staff and if further focus groups had been carried out, it is possible that the data would have given more understanding of the issues. However, it is also possible that similar views would have been expressed.

The interview data was limited in its scope, as it took place as part of the session involving the completion of the standardised questionnaires, and the participants may have been tired of answering questions at this point. In addition, it focused on a small number of questions due to the limited time available. A deeper understanding of the experiences of this group of

participants could have been achieved by making the qualitative approach a key element of the design.

The issue of uncertainty, especially around diagnosis, had not been anticipated and its impact on the results is unknown. This is an area that has not been studied within the CHD population, to any great extent, and these studies were not designed to do so. However, this is an interesting area for future research.

In summary, the studies provide useful information for practice, but their limitations must be acknowledged. The small size of the sample made it unlikely that statistically significant results could be found. The studies were carried out at two hospitals in the west coast of Scotland and the findings may not generalise to areas where clinical practice is different. Due to the difficulties with recruitment and retention, the participants may not have been representative of the population from which they were drawn. The participants consisted of a high number of males versus females and the experiences of the women may not have been adequately reflected within the data that was collected. In addition, all the participants came from a white Scottish ethnic background. This limits the applicability of the results to other ethnic populations. The design itself had limitations due to funding and staffing and the qualitative aspect of the studies needed to be expanded. The issue of uncertainty was unexpected within the exploratory study and is an area for further research. These studies do however contribute to the evidence base on a population about which little is known and do provide information on areas that require further study.

7.3 Feasibility of a randomised controlled trial

The rationale behind carrying out a feasibility study for a RCT has been explained in chapter 4:3 and follows the original MRC framework for complex interventions (MRC 2000). As stated previously, the feasibility study was successful in its aim of testing the CR intervention and the protocols for a further RCT.

The strengths of the feasibility study design included the acceptability of the CR intervention, commitment from the specialist CR staff to the process, the use of validated tools that were easy to administer and which the participants found acceptable, and the collection of a wide range of data on a group not previously studied.

A core component of the design was the CR intervention itself. As described in chapter 3:8-3:9, CR has developed rapidly over the last two decades and has extended beyond the exercise-only models that form much of the initial evidence for CR, to a multi-disciplinary menu-based model that addresses a wide range of need within the individual treated. This menu-based approach has not been studied in the same depth as exercise based CR.

This feasibility study aimed to test a menu-based intervention used in everyday practice, and see how feasible it would be to replicate the intervention in a further trial. The participants received input throughout the four phases of menu-based CR, as described in table 5:4. This reflects current practice within the specialist CR team. A recently published audit of all Scottish CR programmes shows that current CR practice across Scotland is multi-dimensional and includes all the elements that were included in the

CR intervention provided in this research (ISD 2012). At T3, no participants from the intervention group expressed any concerns about the CR intervention and this established the acceptability of the intervention to ACSLT participants.

Another strength of the feasibility study was the commitment expressed by the specialist staff to providing an appropriate CR intervention for ACSLT. They were keen to provide the intervention and to take part in the feasibility study. They had no difficulty with providing health behaviour change interventions and the exercise prescription advice. However, there was uncertainty amongst the CR staff on what advice to give on issues relating to recovery. There was limited advice available on issues such as driving, holidays and work. The CR staff were concerned about the information on these topics that they were providing and the lack of an evidence base in this population. They were not convinced that they could advise the participants in the same manner as individuals with MI and they were keen for evidence-based information to be developed.

The challenges found within the design of the studies were around recruitment and retention of the participants. If we consider recruitment first, this is seen as one of the key hurdles for any research and in these studies it was not possible to recruit an appropriate sample. The researcher had underestimated the number of patients with ACSLT, who had participated in CR in the past, and this excluded a large number of potential participants. Although, the CR team had information on all previous participants at CR, it was not possible to access data on individuals admitted with ACSLT due to coding difficulties. Therefore this data could not be cross-referenced to give a reliable

estimate. The information gathered within the feasibility study, on the number of patients admitted with ACSLT, who had a previous history of CHD, would help to inform any future calculations on recruitment. The key issues affecting recruitment would appear to have been related to the wider healthcare community. The issues were: clinical gatekeeping, diagnostic difficulties, and timescales.

If we consider clinical gatekeeping first, this has been defined as the process whereby healthcare providers prevent access to eligible patients for research recruitment (Hudson et al 2005). The concept of clinical gate-keeping as a barrier to recruitment has been raised in two studies (Hudson 2005, Fayter et al 2007). Recruiting participants to studies like these requires collaboration between researchers and clinical staff. The eligibility criteria included defined physiological criteria, i.e. Troponin T level and the cardiologist had to make a clear diagnosis, which fitted with the research protocol, before the patient could be approached. This criterion was approved by the ethics committee. In a systematic review of barriers to recruitment, Ross et al (1999) noted eight barriers for clinicians that prevented recruitment to a RCT. Four of these barriers were identified in the studies. These were: time constraints, lack of staff and training, concern for patients, and an insufficiently interesting question. The barriers identified by Ross et al (1999) not found within the studies were: worry about the doctor/patient relationship, loss of autonomy, difficulties with consent procedure, lack of rewards or recognition.

An important issue was the time constraints for recruitment and for consent. Many patients were only in hospital two or three days and it took some time to

reach a diagnosis. Healthcare staff within the wards did not notify the researcher of suitable patients and many patients were missed prior to consent. Without the ward staff identifying suitable patients and making the initial approach, recruitment was difficult. The researcher's time was certainly an area of difficulty and the inability to be around, when suitable participants were in the wards, was problematic. The ward staff were busy and this client group was only one of many that they were dealing with. This could have made it difficult for them to remember the inclusion criteria.

Training had been carried out at the beginning of recruitment, but this was not repeated while the studies were running. The ward staff expressed support for CR during the focus groups, but also expressed a feeling that further research was not needed. They felt that all patients should receive it, regardless of the lack of an evidence base. This translated into a delay in assessing patients, particularly during the control group phase. The staff felt that, if they waited long enough, the diagnosis would be changed and the patient would be eligible for CR. This is not surprising given the difficulties in diagnosis that will be discussed in the next section. The research questions held particular interest for the CR clinicians, but were not important to the other clinicians within the team as it would have no impact on their workload.

Sharkey et al (2010) suggest that this issue of clinician gate keeping can be minimised by the appointment of a professional researcher to solve the difficulties with the recruitment processes. This would reduce the demands on the staff. In an attempt to improve recruitment, two nurses were tasked with visiting the wards every day to check for potential participants.

This did start to improve recruitment, and it is possible that, if this had been built in from the beginning, then the anticipated recruitment would have been possible. Also, if the studies had taken place on one site, this would have reduced the available pool of suitable participants, but could have improved the pickup rate, as it would have concentrated resources in one place.

The ward staff were not aware that participants would receive CR regardless of which group they were allocated to. Those in the control group were offered CR following the completion of the studies. If more had been made of this fact, recruitment might have been improved.

The lack of an understanding of the importance of the research question was another area in which improvements could have been made. The training undertaken with the staff could have emphasised the importance of the studies to clinical practice and to issues such as service development and funding. These issues would need to be addressed in a further study.

Hudson (2005) argues that it is collaboration in research design that is likely to solve the problem of lack of interest. Where professionals have been involved, in the formulation and development of a study, they are more likely to commit to that study. No clinicians apart from the researcher were involved in the design stage and this may be why the cardiologists and cardiac nurses did not feel involved in the research, or in the recruitment of participants.

Diagnostic difficulty was the second area of concern relating to recruitment. In the early stages of the studies, when the control group was being recruited, if the patient was diagnosed as a MI, they would automatically receive a package of care from CR. If they were diagnosed as meeting the research protocol, they

wouldn't. There were examples of staff not being keen to approach a patient about the research, as they were hoping that Troponin T levels would make them eligible for the routine CR programme. There were also examples of differing opinions amongst the cardiologists, about diagnostic criteria, prior to the implementation of governmental policy. Only 11 participants were recruited at site 1 and 22 at site 2. This does not reflect the workload of the two hospitals, but does reflect the diagnostic preferences of the cardiologists and therefore the available pool of potential participants. It is possible that, if more education around the basis for the research had been undertaken with all the healthcare staff in the department, they would have understood the rationale and benefit to both the participants and the organisation.

The timescales built into the design also caused problems for recruitment, with many patients not being in hospital long enough after the diagnosis was reached to ensure informed consent. The ability to recruit after discharge would have given more time for obtaining consent and could have increased the available pool of participants. However, this would have changed the implementation of the CR intervention which commences prior to discharge. As a key element of the exploratory study was to examine menu-based CR, as it is usually provided, recruitment following discharge was not considered in the design of the studies.

Following on from recruitment, it is important to ensure that participants stay in both studies. The researcher had several problems, with retention of participants, that had not been adequately predicted. A key element was the difficulty in retaining participants due to ill health. Of eight participants (24%)

withdrawn from the studies, two died, three withdrew due to further health problems, and three withdrew for personal reasons. In addition there was also crossover between the groups as three participants (9%) had a further cardiac event and received CR. However, the small number of participants meant that every drop-out had a large impact on the total percentage. There is little that the researcher could have done to change the level of ill health within the participants, as this level of ill health is consistent with a serious illness such as ACSLT, however these data are useful in determining recruitment numbers for any RCT.

The impact of losses to follow up, or drop out, has only been examined in a few trials of CR. Jolly et al (2009) looked at 1207 patients who were eligible for home exercise and consented 525. They had an attrition rate of 8.5% and an additional 11 patients (4%) crossed over from the home to a hospital programme. This is well below the attrition rate within these studies. In a paper by Zwisler et al (2008), looking at a RCT of CR in Denmark, a 16% drop out rate was noted, but no description of the reasons for drop out was given. In a Cochrane review of exercise rehabilitation by Jolliffe et al (2001), it was noted that losses to follow up within many trials were high, but often not adequately described. This was also noted in a systematic review of home-based CR versus hospital, where losses to follow up varied considerably across all the studies (Taylor et al 2010). The issue of crossover was dealt with in many studies by appearing to undertake an intention to treat analysis, in that groups were analysed according to initial random allocation. In the feasibility study a final group design was used, in that the data was analysed by the final outcome

for the individual, control or treatment. The reasons for this are explained in chapter 6:2.

An additional problem for the studies was the timing of the questionnaires. Three participants chose not to continue between T1 and T3. There was limited contact with participants in between the assessment periods and this could have reduced the willingness of individuals to continue. It is possible that if contact with the participants had been made, at regular intervals, by phone, or letter, that these three withdrawals could have been avoided.

There are several lessons that can be learnt from this feasibility study when designing a future RCT. This feasibility study could have been more successful, if a researcher had been employed to recruit participants and if more training had been carried out with the healthcare staff on the wards. If these staff had been included in the development of the proposal, they would possibly have been more open to assisting with recruitment. If time had been taken to keep in contact with the control participants, then the attrition rate within this group might have been smaller. Information was collected within the feasibility study on: the high mortality and morbidity within the participants, the crossover between groups, the limited time span for consent and the difficulties with diagnosis. These data will contribute to the revision of the design for any further study.

Healthcare policy and service provision had an overriding impact on this thesis, as recruitment was halted at 25 participants due to changes in the diagnostic categories. The debate about the definition of MI was one that caused uncertainty throughout the life of the studies. This was a debate that

had arisen as early as 2000 with the publication of a new definition of MI (Table 2:1). The BCS however, did not agree with this definition of MI. This was due in part to a belief that the change in definition would affect comparisons with previous reference studies and epidemiological cohorts (Fox et al 2004). This change in definition, it was believed by the BCS (Fox et al 2004), would have important implications for patients who could be given unjustifiable prognostic information based on historical comparisons, be barred from certain occupations, and be inappropriately penalised or rewarded by financial and insurance institutions. Fox et al (2004) argued that the term “clinical MI” should be reserved for patients who would previously have been diagnosed as MI and also had an increase in Troponin T above a threshold set at 1.0 ng/ml. They argued that the ESC/ACC guidelines were overly dependent on troponin assays, which were not reliable enough. Fox et al (2004) also argued that the term ‘‘ACS with myocyte necrosis’’, or ACSLT as defined within this thesis, should be reserved for patients with a typical clinical syndrome plus an increased troponin concentration below the diagnostic threshold (that is, Troponin T< 1.0 ng/ml). This meant that a group of patients with Troponin T results between 0.01 and 0.99 would be classed as MI in Europe and America but not in the UK, where they would be diagnosed as ACSLT. It was on this basis that the inclusion criteria were set.

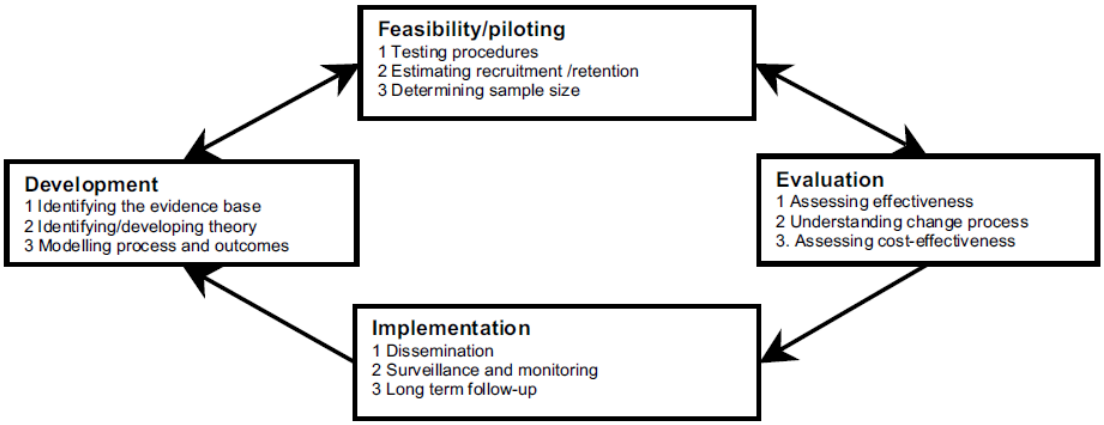
As the research progressed, the gap between the BCS criteria and ESC/ACC criteria produced a lot of confusion for clinicians across the UK. This continuing debate was clear, even as late as the beginning of 2007, with the publication of the SIGN guideline for ACS (SIGN 2007). This continued to show the differing definitions in the evidence and highlighted the mortality risk of all

groups as seen in Table 2:1. A cornerstone of the differing opinion was the belief that the lower range of troponin rises meant less risk. However, in their study of 2499 patients, Das et al (2006) had found this not to be the case. They found that at six months, mortality rates for patients with ACSLT, had risen to the same level as those for patients with clinical MI. Das et al (2006) also found significant differences in the treatment of patients with ACSLT, with less prescription of recommended drugs such as beta-blockers, ace-inhibitors and statins. The relatively limited use of interventional strategies and of short term and secondary prevention drugs further suggested that patients with ACSLT could benefit both from early identification and from being treated more aggressively. Their findings supported the value of the revised ACC/ESC definition of MI, as the additional cohort of patients identified by the new diagnosis of MI had a prognosis identical to those covered by the old definition. By late 2007, the Scottish Government had issued guidance to health boards stating that any troponin rise was to be treated as an MI and they followed this up in the publication of the CHD and Stroke strategy (SGHD, 2009). This strategy argued that, although a diagnosis of MI has a range of potentially significant implications for patients and their families, with respect to psychological effects, life insurance, careers and lifestyle, a more precise diagnosis, and recognition that even minor elevation in troponin is associated with poorer prognosis, means that more appropriate initial and long term treatment can be offered. This definition of MI became standard practice within the research centres at the end of 2007. The decision to classify this group of patients (ACSLT) as having suffered an MI, in line with ESC/ACC guidelines, meant however that CR had to be routinely offered, to patients with ASCLT

within NHS Scotland. Therefore, it would no longer be ethical to withdraw this intervention as part of a RCT.

The rationale behind carrying out a feasibility study for a RCT has been explained in chapter 4:3 and follows the MRC framework for complex interventions (MRC 2000). The results of the feasibility study have been documented in chapter 5:2-5:5 and the strengths and challenges have been further discussed in this chapter. However, since the original studies were designed, a number of limitations in the MRC framework have been identified and a revised framework has been published (MRC 2008). One limitation, identified in the original framework, was the use of a linear model that had traditionally been used to evaluate the effects of medicines. Other limitations identified included the fact that there was little guidance in the original MRC framework (2000) on how to approach developmental and implementation phase studies, which this was, and an assumption that conventional trials provided a template for different approaches to evaluation. The authors of the revised framework made the point that there had been a lack of guidance on how to tackle highly complex interventions. There was also a lack of attention to the social, political and geographical context in which interventions take place. All these limitations of the framework had implications for the design of this thesis. The new framework (see Figure 7:1) no longer places reliance on the linear model of research and on the gold standard of RCT. It considers differing options for research methods and guides researchers on which method to choose and at what stage of the developmental process. It is possible that, if this thesis had been designed according to the new framework, then some of the difficulties it encountered could have been avoided.

Figure 7:1 New MRC Framework for evaluation of Complex interventions



MRC (2008)

The focus in the previous MRC framework was that a RCT was the gold standard. However, a lot of the issues within these studies, especially with regards to recruitment, related to the need to have a control group. If the studies had not required a control group, but instead had considered a comparative study of CR outcomes for ACSLT and for MI, then some of the issues related to recruitment would not have occurred. Participants would all have been receiving the intervention as routine clinical practice and healthcare staff could have been more amenable to approaching potential participants. The diagnosis issues would no longer have made any difference, in the initial stages, as all participants would receive CR, and the focus of the research would have been on delivering the intervention and on the outcomes it could achieve, in both groups.

One of the elements of the new MRC framework is the attention paid to changing circumstances and the recognition that circumstances may change after a study has begun. The new framework recognises the need to develop a good understanding of the context in which a study is being carried out, and to monitor and document any significant changes. Examples of significant changes could be the introduction of some new policy or, in the case of trials with long-term follow-up, more fundamental changes in the economic or political context.

In summary, a key finding of this thesis is that the feasibility study was successful in its aim of testing the CR intervention and the protocols for a further RCT. The strengths of the feasibility study included the acceptability of the CR intervention, commitment from the specialist CR staff to the process, the use of validated tools that were easy to administer and which the participants found acceptable, and the collection of a wide range of data on a group not previously studied. The challenges the feasibility study faced were recruitment, retention, and changes in healthcare policy and provision. This feasibility study could have been more successful, if the healthcare staff had been active partners and if a researcher had been employed to recruit participants. If time had been taken to keep in contact with the control participants, then the attrition rate within this group might have been smaller. The information collected within the feasibility study on mortality and morbidity and crossover between groups, could inform any further calculations of sample sizes for a RCT. The implications of changes in healthcare policy and service provision mean that a RCT of menu-based CR in ACSLT is no longer possible within the UK.

However the new MRC framework offers opportunities for evaluating CR in ACSLT in a different way.

7.4 Cardiac Rehabilitation and Acute Coronary Syndrome with Low Troponin

This thesis contains a feasibility study and an exploratory study. The feasibility study has been discussed in chapter 7:3. The second element was the exploratory study, which aimed to explore the impact that ACSLT and CR can have on this client group.

As has been stated previously, the exploratory study did not achieve statistically significant results in any of the key outcome measures of misconceptions, symptoms, anxiety, depression and HRQoL. However a tendency to benefit was noted that favoured the intervention group. This finding must be treated with caution due to the limitations of this thesis noted earlier in chapter 7:2. This trend does however, reflect the evidence that has been found in previous studies of CR in non-standard populations.

In this exploratory study, the YABQv2 was used to examine misconceptions, anginal threat and coping. As documented in Table 6:4, across all three scales of this questionnaire, a picture of small amounts of change can be seen between T1 and T3 in the control group with larger changes in the intervention group. None of these changes were statistically significant.

The YABQv2 has previously been used by Furze et al (2003) in a study of 133 participants comparing a control group, with a group who received the Angina Plan, a cognitive behavioural intervention. Following the intervention, statistically significant differences between the groups were found.

The scores on the questionnaire were 48 in the control group and 40 in the intervention group as compared to 51 and 41 respectively in this exploratory study.

The scores found by Furze et al (2003) on the two sub-scales are also similar to the results found within this exploratory study. The coping subscale scores were 48 in the control group and 37 in the intervention group. In this exploratory study, the corresponding scores were 55 and 46. This similarity is continued if we look at the perception of threat subscale. Here the scores were 47 in the control group and 37 in the intervention group as compared to 50 and 39 respectively in this exploratory study.

As had been stated previously, both control and intervention groups in this exploratory study had high scores across all the scales of misconceptions, anginal threat and coping at T1 (Table 6:5) and the intervention group had a greater reduction in these scores than the control group at T3. This could indicate a change in misconceptions over the timescale of the exploratory study and would certainly merit further investigation, particularly given the similarity to the scores within Furze et al (2003).

A high prevalence of psychological symptoms and disorders in patients with CHD has been documented in several papers (Rugulies 2002, Carney and Shibeshi 2007, Freedland 2008). In a recent meta-analysis, looking at anxiety as a predictor of medical prognosis after MI, Roest et al (2010) found that post MI anxiety is consistently related to adverse cardiac events. Within this exploratory study, several participants reported high levels of anxiety and depression. As part of the CR intervention, participants in the intervention group

had access to a psychologist, if necessary, and received an intervention that used the CSM as its guiding framework. This exploratory study found that mean scores, in both control and intervention groups, were mildly anxious at T1 and that in the control group they remained mildly anxious at T3. Anxiety levels in the intervention group had fallen to within normal ranges at T3 (Table 6:5).

Changes in anxiety levels, with the addition of a CR programme, have been noted in other studies, as shown in a recent Cochrane review of psychological interventions in CHD. Whalley et al (2010) found that where anxiety was measured, a small but significant reduction in anxiety was associated with a psychological intervention.

A study by Yohannes et al (2010) used the HADS to measure anxiety and depression in participants attending a CR programme. The authors found that mean scores at baseline for anxiety were 7.87. The corresponding scores within the exploratory study were 6.35 (c) and 7.87 (I). Yohannes et al (2010) also found that scores dropped over the course of the intervention and that anxiety scores were 6.35 at six months and 6.51 at 12 months. Within the exploratory study, anxiety was measured at nine months and scores were 6.51(c) and 5.71 (I) respectively.

In a review of outcomes within a CR programme, Turner et al (2002) found that mean anxiety scores, measured by the HADS, fell from 6 to 4.9 over the course of the programme. In a comparison of home versus hospital CR, Dalal et al (2007) found baseline anxiety scores of between 5.67 and 7.46 and a reduction in both groups of approximately 1.0 at nine months. The results, within this exploratory study, are therefore similar to the results found in

previous studies. Across the timescale of this exploratory study, there was a reduction in anxiety in both groups, with the tendency to benefit favouring the intervention group. It is possible that, if a larger sample had been recruited, significant results may have been found.

Between 31-45% of patients with CHD, including those with stable and UA or MI, suffer from clinically significant depressive symptoms (Lesperance 2000, Carney 2008, Thombs 2008). Depression was measured in this exploratory study and the mean scores do not indicate significant levels of depression. They do reflect scores found in previous studies utilising the HADS. Dalal et al (2007) found baseline depression scores of between 2.84 and 4.12, with a reduction over the study of 0.23 in both groups. Turner et al (2002) found mean scores of 3.8 with a reduction of 1.3 after CR and Yohannes et al (2010) found baseline scores of 7.35 with a reduction of 2.08 after six months. This exploratory study reported levels of depression at T1 of 6.57 in the control group and 4.73 in the intervention group, with a corresponding reduction at nine months of 0.72 and 1.37 respectively. Although there are a wide range of scores within these papers, all are within normal limits and all report reductions in scores across the period of CR.

If however, we consider the individual scores within this exploratory study, we can see that four participants in the control group had clinically significant levels of depression and approximately 21-25% of the participants had some degree of depression throughout the period of the studies (Table 6:4). Whalley et al (2011) in their review argued that psychological interventions appear to be effective in reducing psychological symptoms in patients with CHD.

This was despite the fact that many of the patients treated were not diagnosed with any specific psychological condition, and many may not have met conventional diagnostic criteria for depression. Within this exploratory study, we have found comparable levels of anxiety and depression and a suggestion of benefit for a CR intervention that is mirrored in the studies reviewed by Whalley et al (2011).

HRQoL was an important area of interest within this exploratory study. Frank et al (2011) argue that the factors that are most predicative of change in HRQoL within CR are primarily clinical and functional in nature; those with the poorest exercise capacities at entrance to CR make the greatest gains in HRQoL over the length of the programme. If we consider that clinical symptoms may play a part in the level of HRQoL, then it is important to consider the results obtained on angina using the CLASP. Angina is a key symptom for individuals with ACSLT. It would be expected that angina symptoms would improve, as the participant recovered, and it can be seen (Table 6:4) that the scores across both groups improved from T1 to T3, with a slightly larger change in the intervention group.

The CLASP was utilised by Zetta et al (2011) in a trial of the Angina Plan, a cognitive behavioural, nurse-facilitated, self-help intervention. The authors found scores of 9.4-9.5 on the angina subscale reducing to 8.2-8.7 at six months. Within this exploratory study, the corresponding scores were 7.43-9.18 reducing to 2.43-1.91 at nine months. Breathlessness shows a similar picture with Zetta et al (2011) reporting scores of 8.7-9.6 at baseline and 8.51-8.33 at

six months. The exploratory study reported scores of 7.29-5.64 at T1 and 7.09 - 3.22 at T3. Any comparison of the study of angina by Zetta et al (2011) and this exploratory study of ACSLT has to take in account the different time scales for data collection. However it does highlight that more work is needed to understand the experiences of individuals with ACSLT. The improvement in scores in this exploratory study compared to Zetta et al (2011) may be due to the intervention or it may simply be a result of differences in the clinical condition. Individuals with ACSLT would be considered to have had a more serious illness, when in hospital, compared to those with angina, but the results here show that the individuals in this exploratory study had fewer symptoms of angina and breathlessness and improved more over the timescale than those in the study by Zetta et al (2011).

Some research studies have suggested that participation in CR improves the HRQoL of patients with CHD (Belardinelli et al 2001, Pasquali et al 2003). Within this exploratory study, the main instruments used to measure HRQoL were SEIQoL-DW and SF36v2. It had been intended to also use CLASP, but this proved impractical as discussed in chapter 4:15 and 5:5. If we consider SEIQoL-DW first, we can see that the areas identified by the participants as most important were family and health, followed by social activities. Family is mentioned by all patients and ranked highly. This reflects the literature (O'Boyle et al 1993, Hickey et al 1996). This pattern of family, health, followed by social activities has also been noted in patients with cancer (Campbell and Whyte 1999, Willner and Hantikainen 2005), and diabetes (Walker and Bradley 2002).

The results from this exploratory study show that both groups had an improvement in their global QoL as measured by SEIQoL-DW, across the time

of the exploratory study, with slightly larger changes in the intervention group (Table 6:5). The mean scores were 64.8-69.2 at T1 and 70.2-77.6 at T3. If we compare this to the study by Campbell and Whyte (1999) in a group of cancer patients, we find that the mean index score for this group of patients was 58.4 (SD 21.59).

There are limited studies utilising SEIQoL-DW within cardiology. However, Dempster et al (2010), in a study looking at patients attending CR, found that the five key areas were family, leisure, social life, health and work. This reflects the information found within this exploratory study. Dempster et al (2010) argue that, when asked to retrospectively rate their functioning at baseline, patients rated their functioning to be significantly lower than their original rating at baseline, indicating that a response shift had occurred. It would appear that patients may have changed their internal standards and perhaps had higher goals than they did at pre-test. Dempster et al (2010) argue that, when patients who have completed a CR programme look back on their QoL before CR, they believe they were functioning at a lower level than they reported at that time. It is therefore important that future research and clinical evaluations of CR programmes consider an assessment of response shift, in order to accurately estimate the effect of a CR intervention.

An improvement in the participants HRQoL is reflected in the scores on the SF36v2. The use of the SF36v2 is advantageous in allowing comparisons across disease states. In a recent review of exercise in the HF population, Davies et al (2010a) argued that regardless of the measure used, there is evidence of a significant improvement in HRQoL in patients with HF following an exercise programme. The scores presented in Table 6:6 show that, in this

exploratory study, the intervention group had lower scores than the CHD norm at T1 and higher scores than the CHD norm at T3. The control group scored lower than the CHD norm at T1 and T3 on 7 out of 10 scales.

Chan et al (2005) examined HRQoL in a group of 182 CR participants that included patients with ACSLT. They found highly significant differences were found in SF-36v2 scores for all eight sub-scales at the 6-month assessment, as compared with baseline data for those who received an intervention. The range of scores, on the SF36v2 at baseline, were 35-76 compared to 52-89 at six months. The lowest score at baseline was bodily pain and this was also the domain with the largest improvement, increasing to 89 at six months. The lowest score at six months was general health, which also had the smallest change (8) from baseline. The range of improvement across the scores was from 8-21, with bodily pain being an outlier with an improvement of 64.

In a study looking at scores on the SF36v2 following phase three CR, McKee (2009) found positive increases, six months following CR, of between 1 to 20 from baseline. The lowest score at baseline was physical role and this was also the domain with the largest improvement. The lowest score at six months was vitality, while the smallest domain improvement was for general health. The group studied by McKee (2009) had scores ranging from 63-83 at six months post intervention.

Within this exploratory study, the improvements noted within the intervention group ranged from 2 to 13.1, with a reduction in general health of -2.47 and with the biggest improvement being in bodily pain (13.1). The score range at T3 was 41-51. There are therefore several similarities in scores on the SF36v2 across

all three studies with the general health domain showing little improvement. Both the study by Chan et al (2005) and this exploratory study noted improvements across bodily pain.

A key difference in the results within this exploratory study is that; the level of scores both at T1 and at T3 seems to be at least 10-20 points lower than those in the other two studies. Only some of the intervention group within this exploratory study took part in phase three CR, so this could explain the different focus for the improvements. However, given the small numbers in this exploratory study and the lack of data on those with ACSLT, it is an area that requires further study.

The results found within this exploratory study support the findings that have been described above. Despite the difficulties in assessing the evidence base, HRQoL has become one of the outcomes measures recommended for everyday use in measuring the effectiveness of CR programmes (BACR 2007).

In summary, as has been stated previously, this exploratory study did not achieve statistically significant results in any of the key outcome measures, however a tendency to benefit was noted that favours the intervention group. Although this exploratory study had small numbers and the data has to be treated with a great deal of caution, it does reflect the evidence found in other studies on the impact of CR within different cardiac populations.

7.5 Cardiac Rehabilitation and uncertainty

These studies were conducted at a time of great change within cardiac services and an additional finding within the exploratory study related to the concept of uncertainty. As previously noted in chapter 6:6, the majority of participants highlighted the level of uncertainty that they had experienced following their admission to hospital. The uncertainty they experienced was both around the diagnosis itself and the implications for them as individuals. In this section, these two areas of uncertainty will be discussed, along with the impact of uncertainty on the theoretical framework underpinning the CR intervention.

Neville (2003), in her review of uncertainty theory, argues that professional uncertainty is based on real difficulties in diagnosis and prognosis (Davis 1960, McIntosh 1974). Jette and Jette (1997) argue that the consequence of professional uncertainty in clinical care is a broad variation in treatments. Professional uncertainty around the diagnosis itself was evident due to differing opinions within cardiology worldwide on the diagnosis of ACSLT. During the period of the research, participants received a wide variety of information from clinicians and this information was often contradictory in nature. The impact this had on the participants has been highlighted previously in chapter 6:6. Since the diagnosis of ACSLT has disappeared, due to its amalgamation with the diagnosis of MI, it could be argued that the lack of an evidence base for ACSLT, outwith medical treatment, is no longer a problem. However this would be to assume that outcomes of CR for those with ACSLT are the same as for those with the traditional diagnosis of MI. Yet there is little evidence to support this.

The second theme within uncertainty was the impact of the illness itself on the participants. The theme of uncertainty and its impact on recovery has been reported to be a common experience of people experiencing illness or receiving medical treatment (McCormick 2002). Uncertainty can be seen as major component of the illness experience and can dramatically affect psychosocial adaptation and outcomes of disease states (McCormick 2002). There has been extensive research into experiences with uncertainty in both acute and chronic illnesses. Much of the research base looks at uncertainty in cancer, particularly in two patient populations: breast and prostate cancer (Nelson 1996, Germino et al 1998, Wonghongkul et al 2000, Gill et al 2004). This research suggests that uncertainty undermines the patients ability to sustain an acceptable HRQoL (Germino et al 1998, Sammarco & Konecny 2008). Breast cancer survivors face uncertainty, as a result of living daily with a pre-existing disease and the possibility of recurrence, and this affects their ability to plan for the future (Nelson, 1996, Wonghongkul et al 2000). The inability to distinguish symptoms of their illness, or recurrence from normal bodily changes, has also been reported as a source of uncertainty in this cancer population (Hilton 1988).

The causes of uncertainty have also been studied in populations with rheumatoid arthritis, asthma, and AIDS. It has been shown that the erratic nature of symptom onset and disease progression and the inability to distinguish symptoms from normal bodily changes were sources of anxiety for patients (Weitz 1989, Braden 1990). However, there has been limited focus on the impact that uncertainty has on people living with CHD and it has largely been ignored in the CR literature.

In their study of Chinese men undergoing angiography, Taylor-Piliae & Molassiotis (2001) found that the participants experienced high levels of uncertainty. This correlated significantly with total mood disturbance. All negative mood sub-scales demonstrated strong relationships with uncertainty. These findings are consistent with previous research among Chinese CHD patients and those living in North America (Christman et al 1988, Webster and Christman 1988, Dougherty & Shaver 1995, White and Frasure-Smith 1995).

Kang (2005) aimed to examine the effects of uncertainty on patients with atrial fibrillation. He found that individuals with greater symptom severity perceived more uncertainty and that this uncertainty was appraised as a danger rather than opportunity. He found that uncertainty had a significant impact on the perception of mental health, through danger appraisal, identifying a possible area for nursing interventions.

McCormick et al (2006) in their study of 42 individuals waiting on CABG found that uncertainty was present at moderate levels and was associated with moderate deterioration of functional status. They found that symptom distress had a strong relationship to both uncertainty and anxiety. Yet they also found that anxiety, functional status and uncertainty did not have a statistically significant relationship with the level of angina.

Uncertainty is also found as a theme within patients living with HF. Winters (1999) found high levels of uncertainty in this population, which increased with symptoms, or when treatments changed, or information was incomplete. Greater uncertainty was also noted during the initial diagnostic stage.

Uncertainty was influenced by the availability of information, trust in health care providers and social support.

Early uncertainty and adjustment levels after hospital discharge was a strong predictor of long term adjustment among first time ICD patients more than 9 years later (Mauro 2008). Uncertainty was also found to be related to poor QoL in patients with an ICD at long term follow-up (Flemme et al 2005).

The concept of uncertainty is also found in work by Hallas et al (2009). They looked at patients requiring support for advanced cardiac disease, who were concerned with being unable to plan for the future, with worry about the future development of the disease, and the impact on their families.

Within the exploratory study, concerns around uncertainty were raised consistently within the control group, whereas the intervention group appeared to focus on normalisation of their life and the impact of the intervention (Appendix 1). Coping was measured in the YABQv2 (Table 6:5) and has been discussed in chapter 6:5 and 7:4, but it is interesting to note that, within the intervention group, coping scores improved from T1 to T3. The control group had only slight improvement on their coping scores in the same period.

Studies aimed at identifying and managing uncertainty, through nursing-specific interventions in non-cancer populations, have been conducted in pregnant women with multiple sclerosis (Smeltzer 1994), women with rheumatoid arthritis (Bailey and Nielson 1993), and adolescents with diabetes (Hoff et al 2002). Hallas et al (2009) argued that supportive communication and information gathering, which increases decision making, helps to decrease uncertainty, and increases perceived control. Yet little attention has been paid

to this concept within the CR literature. From the information gathered during the exploratory study, it would appear that this theory should be studied further within CR.

The third area of discussion related to uncertainty is the implications for the theoretical framework (CSM) underpinning the CR intervention. The five key elements of this theory are identity, timeline, cause, consequences and cure/control. Identity refers to the label a person uses or to the symptoms that they view as being part of their illness. Timeline refers to an individual's beliefs about how long the illness will last. Cause describes an individual's personal ideas about the cause of the health problem. Consequences relate to an individual's beliefs about the likely impact of the illness on QoL or functional ability. Control/cure relates to the individuals beliefs about whether the condition can be cured or kept under control and the degree in which the individual plays a part in achieving this (Leventhal et al 2003). An individual will include both abstract and concrete information in their understanding of an illness. If we consider the presentation of MI, there is a clear identity and understanding within the community of what it means. It is seen as a sudden episode of central chest pain often linked to sweating and nausea. This is portrayed both in the media and in health promotion messages. It is seen as something that you get over in a specific timeframe and the causes of MI are well rehearsed in the media. CR specialist staff know what to advise individuals about what to expect of their recovery. The consequences of MI are also well rehearsed with individuals being aware of many friends and family who have recovered from just such an event. In contrast, the diagnosis and therefore the identity of ACSLT was unclear. The term ACSLT was not one that was clearly understood

by health professionals and even less by the community at large. There was no clear understanding among the participants of how long the recovery should be and many had no clear idea of the causes of their illness. It was therefore difficult for them to analyse the consequences for their lifestyle and future. Since the CR specialist staff were also unsure of their ability to advise participants about a return to normal activities, due to a lack of an evidence base for this condition, it was difficult to control the illness.

The impact of uncertainty in this exploratory study was seen in all five elements of the CSM. Since the CSM had been selected as the theoretical framework for the CR intervention, the impact that uncertainty had on the participants was clearly of importance and needs further investigation.

The key work within the nursing theory on uncertainty is the work of Mishel and Braden (1988), who defined uncertainty as the inability to determine the meaning of illness-related events because of a lack of sufficient cues. These cues allow individuals to assign value to objects or events and accurately predict outcomes. They have developed the Reconceptualisation of Uncertainty in Illness Theory (RUIT), which applies to enduring uncertainty in chronic illness, or illness with the possibility of recurrence, and where self-management is the primary focus for treatment. The desired outcome from the RUIT is that the person grows to accept a new value system, which incorporates the changes brought about by the illness. The five components of the RUIT are: antecedents of uncertainty, appraisal of uncertainty, coping with uncertainty, self-organisation, and probabilistic thinking.

If we consider the participants, in terms of the RUIT (Mishel and Braden 1988), we can see that there are several areas which influence the level of uncertainty and its impact on this group in terms of adaptation and coping. The antecedents of uncertainty include symptom pattern, event familiarity and event congruency. The participants were admitted to hospital for a period of days with a delay in reaching a diagnosis. The healthcare providers themselves showed professional uncertainty over the diagnosis and the recovery. This was made worse by the differing information provided to the participants. Not only did healthcare professionals have difficulties in making diagnoses, but in addition there were several examples where healthcare professionals contradicted each other. This undermined their credibility and had a large impact on the participants (Appendix one).

The second major theme in the RUIT is the appraisal of uncertainty. Here there are two components, inference which relates to the evaluation of uncertainty using general knowledge experience and contextual clues and illusion which refers to the construction of beliefs that have a positive outlook. The result of appraisal is the valuing of uncertainty as a danger or opportunity.

If we consider inference first, we can see that ACSLT is a recent term with a confused history. Individuals cannot relate to it in the same way they can relate to the term MI. In many cases, within the participants, it was the first time that individuals had had a cardiac event. They did not suffer the 'usual' and 'expected' symptoms of a MI, thereby having no recognised clues that they could analyse their condition with or establish a pattern for their symptoms.

The construction of beliefs that have a positive outlook is important in this context, due to the limited impact that inference can have. The content of programmes such as CR could be seen as a providing support, during this process, that assists with the identification of uncertainty in a positive manner. Yet there is little research in this area.

This appraisal of the uncertainty leads on to the third theme within the model that of coping. Dependent on the individual's assessment of the uncertainty, it can be seen as either positive or negative. If it is seen as a positive, then buffering coping strategies are used to maintain it. If it is seen as a negative, then uncertainty implies harm and problem focused strategies are used to reduce it. If the coping strategies are effective then adaptation occurs, and if there is difficulty in adapting, this would appear to suggest an inability to manipulate uncertainty in the desired direction. Coping has been examined in this exploratory study as it relates to ACSLT and the impact of CR on coping scores has been discussed in chapter 7:4. This is an area of CR practice that warrants further study.

Self-organisation and probabilistic thinking are the additional elements of the RUIT that are central when dealing with long term illness. Self-organisation relates to the formulation of a new sense of order, resulting from the integration of uncertainty into a new order of life. This is influenced by prior life experience, physiological status, social resources and health care providers. The person evaluates uncertainty gradually from a negative experience to one of opportunity. Uncertainty then becomes part of the new order and a part of life. Probabilistic thinking is a belief in a world where uncertainty and unpredictability

is the norm. The RUIT therefore represents the gradual acceptance of uncertainty and the restructuring of reality as important elements of learning to live with a long term condition.

In summary, the exploratory study has suggested that uncertainty within ACSLT needs further research. The participants experienced professional uncertainty around their diagnosis, which had an impact on their recovery. This professional uncertainty may be resolved by the change in diagnosis of ACSLT to MI. However the lack of an evidence base on the outcomes for individuals with ACSLT will continue to be an issue for professionals. The theme of uncertainty and its impact on recovery has been reported to be a common experience of people experiencing illness or receiving medical treatment. Yet, while there is some research on uncertainty in cardiology, it is largely ignored within the CR literature. The concept of uncertainty will however be important for CR professionals due to the broadening of the definition of MI. Uncertainty theory does not give us a theoretical framework on which to base a multi-disciplinary intervention, however the exploratory study suggests that the impact of uncertainty needs further exploration, particularly around the impact that it has on frameworks such as CSM and on the design of CR interventions.

7.6 The future for Cardiac Rehabilitation research

In chapter 1:4, the importance of an effective research base for clinicians working within CR was highlighted. This thesis therefore contains a feasibility study and an exploratory study. This thesis has added to the research by examining the feasibility of a RCT which would test the impact of a menu-based CR programme, on individuals diagnosed with ACSLT, against standard care.

This feasibility study included staff views. It has also added to the research by exploring the impact that ACSLT and CR can have on this client group.

As stated previously in section 7.2, a main finding of this thesis is that the feasibility study was successful in its aim of testing the CR intervention and the protocols for a further RCT. However, due to changes in healthcare policy and provision, it would no longer be feasible to carry this research out.

An additional finding, as stated previously in section 7.4 and 7.5, is that this thesis has explored the impact of menu-based CR on a unique population, that of ACSLT, and provided an insight into the experiences of the participants at a time of change within CHD clinical care. Before discussing the implications of this thesis for clinical practice, it is important to consider the changes that have taken place in both the evidence base for CR and in current healthcare provision, since the literature review carried out in 2004 and discussed in chapter 3:2-3:10.

The literature review carried out in 2004 found that the evidence base for the exercise component of CR as it is delivered in the RCT's was comprehensive and compelling, and although there was some evidence of benefit from psychological interventions, the evidence base was ambiguous and there was a need for further research into misconceptions, anxiety and depression, and HRQoL. In addition, it stated that educational interventions, as part of CR, can provide health gain, but that further exploration of the role that education can play in a modern individualised programme of CR and the different benefits that could bring were required. The 2004 literature review also found that the evidence base for under-represented groups such as the elderly, women, and

ethnic minorities was limited and that information on modes of delivery required further clarification. Despite the challenges faced by researchers within CR, in identifying and documenting the outcomes of this complex intervention, CR has become an accepted part of routine care, due to both strategic direction and voluntary sector campaigning and funding.

A challenge to the provision of these services has been raised by West et al (2012), who conducted a multi-centred RCT of CR in England and Wales recruiting 1813 participants between 1997 and 2000. Recruitment was halted early, in a manner reminiscent of this thesis, as the hospitals providing control groups wished to start providing CR. West et al (2012) found that, in their trial, there were no statistically significant differences between patients referred to CR and controls in mortality at 2 years or after 7-9 years. They also found no significant differences in number of cardiac events, on 7 out of 8 domains of the SF36v2 or on scores on the psychological general wellbeing scale. Patients in the intervention group also reported being less active. No differences between groups were reported in perceived overall quality of cardiac aftercare. They argue that that the value of CR as practised in the UK is open to question.

There are some limitations in the study by West et al (2012). Although 1813 participants were recruited, the study does not describe in detail the CR programmes and their component interventions. At the time West et al (2012) were recruiting, many CR programmes were new and CR staff were inexperienced. There is no information on the length of time these programmes had been running to indicate the expertise of the team. The CR programmes utilised in the study by West et al (2012) were developed more than 10 years

ago and there have been huge changes in this field of clinical practice since. West et al (2012) provide little information on the recruitment process and the numbers of possible participants who refused to take part. They also do not provide information on how many completed a programme, or dropped out, a regular problem for CR programmes. The participants were mainly male (72%) and young (mean age 65) and had suffered an MI. This is a criticism of CR research that has been highlighted previously, in the literature review in chapter 3:12-3:13. The study by West et al (2012) however highlights a debate that has raged within cardiology for more than 20 years, with those strongly in support of CR as a service, and those who have opposed it on the basis that the evidence base is limited. West et al (2012) also highlight the belief that a RCT is the only way to evaluate a complex healthcare intervention and has an underlying theme that mortality and morbidity are the main outcome measures to evaluate any healthcare interventions' utility. This paper has also stimulated debate within the CR community about the appropriate way to evaluate CR.

However, it is also important in this section to examine other changes in the evidence base from the literature review of 2004 for the exercise, psychological, and education domains and for under-represented groups, and mode of delivery.

In the previous literature review, it was noted that several meta-analysis of CR for CHD patients reported a statistically significant reduction in total and cardiac mortality, ranging from 20% to 32%, in patients receiving exercise therapy compared with usual medical care (Oldridge 1988, O'Connor 1989, Jolliffe 2001, Clark 2005). The original Cochrane review identified 35 RCT's with

8,440 patients (Jolliffe 2001). This review reported a reduction in total mortality with an exercise intervention compared to usual care. Improvements with exercise were also seen in cardiac death, non-fatal MI, lipid profile and BP. However this analysis was based on mainly low risk middle aged men following MI and this limited the applicability of the evidence. In addition, as argued by West et al (2012), many of the current drug therapies and treatments were not available at the time of some of the earlier studies and improvements in treatment could impact on the level of additional benefit that could be found with CR. There was also limited data on HRQoL within these studies.

An updated meta-analysis by Heran et al (2011) was recently published. This meta-analysis included an additional 17 studies making a total of 47 studies reporting data for a total of 10,794 patients. Although all exercise-based CR, 17 studies were judged to be exercise-only intervention trials and 29 were judged to be comprehensive CR (exercise plus psychosocial and/or educational interventions); one trial randomly assigned patients to both exercise-only CR and comprehensive CR. The ages of patients in the trials ranged from 46 to 84 years. Although over half of the trials (28 studies, 60%) included women, on average women accounted for only 20% of the patients recruited. In accord with the original Cochrane review and previous meta-analyses (Oldridge 1988, O'Connor 1989, Jolliffe 2001, Clark 2005) a reduction in both total and cardiac mortality was observed in CHD patients randomised to exercise-based rehabilitation. There was no difference between exercise-based CR and usual care groups in the risk of recurrent MI or revascularisation at any duration of follow-up. This new meta-analysis would appear to suggest that there is little change in the evidence base with regards to exercise and contradicts the

findings of West el al (2012). Although the study by West el al (2012) has provoked a great deal of debate within the CR community, the evidence in the meta-analyses above provides a stronger argument, as it is a synthesis of all the evidence in the field. This evidence base has been consistent for more than 20 years.

Individuals with HF is one area where RCT's of CR can still be carried out, as it is not yet common practice to offer CR to this group of patients. This is not due to a belief among CR professionals that it wouldn't work, but due to a more pragmatic issue of a lack of resources. Clinical trials conducted over the last 15 years have demonstrated that exercise-based CR improves exercise tolerance, disease-related symptoms, and QoL in patients with HF (Williams 2006), without negatively impacting on left ventricular function. No adverse exercise training–related effects have been reported, despite the fact that these patients would appear to be at higher risk for events given their left ventricular dysfunction and heightened state of sympathetic activity.

A recent trial, HF-ACTION, is the largest trial to look at exercise in the HF population with 2331 participants (O'Connor et al 2009). They found that there were non-significant reductions in the exercise training group for CVD mortality, CVD hospitalisation and HF hospitalisation. However, after adjustment for highly prognostic predictors of the primary end point, exercise training was associated with modest significant reductions for both all-cause mortality or hospitalisation and CVD mortality or HF hospitalisation.

A systematic review of exercise in HF by Davies et al (2010a) examined 19 RCT's, including HF-ACTION. The review encompassed a total of 3,647

participants. The authors concluded that exercise programmes did not significantly impact on all-cause mortality, however there was a significant reduction in hospitalisations due to HF and they observed significantly higher levels of HRQoL. However they state that the precise mechanism through which exercise training benefits HF patients is unclear.

In summary, it would appear that the evidence base for exercise CR remains in favour of the intervention, despite the negative data gathered during the trial by West et al (2012). The results do not seem to have changed significantly over the last 20 years. However, West et al (2012) have raised some interesting questions and have prompted discussion on the appropriate method to be used to evaluate a programme of care that might only last three months.

At the commencement of this thesis, the 2004 literature review found that there was some evidence of benefit from psychological interventions, however the evidence base was ambiguous and there was also a need for further research into misconceptions, anxiety and depression, and HRQoL. A review of the evidence base for psychological interventions in CHD undertaken by Rees et al (2004a) had found a wide range of interventions being used within clinical trials. Meta-analysis of all studies showed no strong evidence of an effect on total or cardiac mortality or revascularisation, although there was a significant reduction in the number of non-fatal infarctions in the intervention groups. Additionally, in some of the trials included in the original review by Rees et al (2004a), the intervention group received both psychological/psychosocial interventions alongside other components of CR (for example exercise or enhanced medical care) that were not available to control group participants. Thus, the 2004 review could not establish the independent effect of

psychological techniques for this patient group. A recent update by Whalley et al (2011) focused only on those studies which included psychological interventions. He argued that psychological treatments appear to be effective in reducing psychological symptoms in patients with CHD, although many of the patients treated were not diagnosed with any specific psychological condition, and many may not have met conventional diagnostic criteria for depression. In a further review of psychological interventions, Goulding et al (2010) argued that interventions to change beliefs can be successful, with cognitive behavioural interventions being the most consistently effective. The evidence of impact on psychological, functional and behavioural outcomes however was unclear. Goulding et al (2010) also argued that, it is negative illness perceptions rather than physiological factors that are the major cause of psychological and occupational disability in people with CHD. The evidence would therefore appear to suggest that there is a benefit to psychological interventions, but that more research is required into the link between psychological interventions and changes in attitudes and beliefs.

In the 2004 literature review it was argued that educational interventions as part of CR can provide health gain, but that further exploration of the role that education can play in a modern individualised programme of CR, and the different benefits that could bring were required. Lau-Walker (2007) in her study looking at the link between illness beliefs and self-efficiency indicated that different educational approaches to exercise and diet within current CR programmes have contrasting effects in terms of patient outcomes. The two CR programmes attended by patients in her study contained an individualised approach to exercise, allowing patients to work at their own pace, developing

skills and confidence to manage their exercise regime leading, it would appear, to increased patients' confidence in their ability to change their exercise lifestyle. The approach to the dietary education was however quite different. Generic educational information was given to the patients using leaflets and discussion groups. This approach did not individualise information or build skills, with the potential result of failing to increase patients' confidence to manage their dietary lifestyle changes. The patients' initial belief, following diagnosis, that the cardiac condition was controllable was shown to be an important factor in predicting patients' confidence in their ability to maintain exercise health behaviour in the long term. Therefore, the assessment and management of CHD patients' illness beliefs in the controllability of their condition at the initial phase of their cardiac illness is of particular importance.

This concept, that knowledge, attitudes and beliefs are inter-connected, and that for an educational programme to work, the impact has to be felt across all three domains, is one that has been examined by Tullman et al (2007), who looked at an intervention to reduce delay in seeking help for symptoms of MI. They found that knowledge and beliefs were improved by an intervention, but there was no change in attitudes. Buckley et al (2007) studied the effectiveness of an education and counseling intervention on knowledge, attitudes and beliefs about MI symptoms and the appropriate response to symptoms. He argued that the intervention resulted in improved knowledge of CHD, MI symptoms and an appropriate response to symptoms that was sustained to 12 months. He found no differences however between groups' attitudes and beliefs over time. The impact of CR educational programmes and how they are delivered for the most impact is one that requires further study.

The 2004 literature review stated that the CR evidence base consisted of trials that included mainly white middle class males, but found that this gap was gradually being addressed within the literature and the focus of research had shifted to identifying how CR could improve impact across diverse populations, such as the elderly, women, and those individuals who belong to ethnic minority populations.

Elderly patients are a group that remain under-represented within the trial data. Yet a survey by Giallauria el al (2010) found that, in Italy, 59% of patients admitted to CR programmes are aged >65 years and that 25% are aged >75 years. In the UK, this is also seen in survey data for CR programmes, with the mean age for men within the CR population being 65 and for women 70 (Lewin et al 2011). Average ages vary across the diagnostic groups, but in general many patients seen within CR programmes are in the age range of 45-85 (Lewin et al 2011). Complications of MI and myocardial revascularization procedures are more frequent at an elderly age, with the prolonged hospitalization for these events predisposing to physical deconditioning (Wenger 2008). In a study looking at patients older than 75, Audelin et al (2008) found that older patients were less likely to be referred. They found that longer transportation times to CR facilities, denial of illness severity and history of depression are also associated with poor participation rates in the elderly. However, if the older patients attended CR, they had higher exercise capacity, and higher levels of HRQoL. Tolmie et al (2009) argued that CR programmes were not meeting the needs of many older people, either in terms of risk factor education or programme uptake, and more appropriate programmes are

needed. Currently, there is no evidence of interventions to improve either uptake or adherence to CR in the older patient (NHS 2007).

It is clear from recent audit data (Lewin et al 2011) that women still do not attend CR as often as they could. This is despite the evidence that both genders receive equal benefit from participation in CR exercise training (Cannistra et al 1992, Williams et al 2006) and specifically, that women, whose functional capacity at entry into rehabilitation is often less favourable, are likely to attain greater benefit (Wenger 2008). A recent meta-analysis (Budnick et al 2009) looked at 37 studies with a combined sample of 3,807 women. Ten studies included an analysis of physiological effects of exercise. Aerobic, resistance, and combined exercise interventions, all yielded physiological benefits for women. Cardiac Rehabilitation yielded favourable HRQoL outcomes and women benefited from psychosocial support in both formal and informal environments. This programme recommended that programmes need to address the specific educational needs of women and a stronger emphasis needs to be placed on social support. Despite an improvement in the evidence base, there are still areas of uncertainty therefore about the impact on sub-groups of patients, such as the elderly and women.

In the literature review of 2004, the evidence base suggested that there were no significant differences between home-based and centre-based CR. In their review of home-based CR, Dalal et al (2007) found that the Heart Manual (Lewin et al 1992), a self-help home programme, was as effective as hospital-based CR for patients after MI. Patients admitted with uncomplicated MI were offered hospital-based rehabilitation classes over 8–10 weeks or a self-

help package of six weeks' duration (the Heart Manual) supported by a nurse. Primary outcomes at 9 months were mean depression and anxiety scores on the HADS, QLMI score and serum total cholesterol.

The mode of delivery has also been examined by Taylor et al (2010), with a systematic review of CR comparing either home-based or centre-based CR. This review identified 12 RCT's in 1,938 cardiac patients, most of them performed during the previous eight years. The majority of studies recruited lower risk patients following an MI and revascularisation. There was no difference in outcomes of home- versus centre-based CR in mortality risk, cardiac events, exercise capacity, as well as in modifiable risk factors (systolic BP; diastolic BP; total cholesterol; High Density Lipoprotein-cholesterol (HDL); LDL-cholesterol) or proportion of smokers at follow up or HRQoL. No evidence was found to support a difference in outcomes in cardiac patients either in the short-term (3-12 months) or longer-term (up to 24 months). The study populations, in the trials, were mainly male with a mean age of 51.6 to 69 years.

A recent small study carried out by Piotrowicz et al (2010) compared centre-based CR to tele-monitored home CR. They found that tele-monitored home CR was equally as effective as centre-based CR and provided similar improvements in HRQoL and that adherence was improved in the tele-monitored group. The current evidence base would appear therefore to suggest that there are no significant differences between home-based and centre-based CR and that this has not changed since the original literature review.

If we consider the provision of CR in the UK, we can see that there have been changes over the last 8 years. Many expert scientific groups around the world, from the WHO to the BCS, have reviewed CR; every one of these reviews has supported it unequivocally and called for it to become more widely available. The British Heart Foundation campaigns for wider access to CR across the UK. Despite the recommendations for exercise-based CR as an integral component of the comprehensive care of patients with CHD, most patients still do not receive it (Bethell 2008). In a recent report from the National Audit for CR (2011), 42% of patients who had a MI, CABG, or a PCI took part in CR across England, Wales and Northern Ireland in 2009-2010. This is an increase of one percentage point on the previous year and four percentage points on 2007-2008. Some regions improved significantly more than others and the participation rate for Northern Ireland as a whole increased from 30% in 2008-2009 to 40% in 2009-2010. Recent audit work undertaken in Scotland suggests that the corresponding figures for Scotland in 2010-2011 vary from 58 % of those eligible attending for assessment, to 39% of those eligible completing a programme of CR. The referral rate in Scotland has also been reviewed and it would appear that an estimated 65% of eligible patients having an initiating event of either MI, CABG or PCI were referred for CR in 2011. This includes 75% of heart attack patients, 68% of patients undergoing CABG, and 22% of patients undergoing PCI procedures (ISD 2012). However, of more than 21,000 individuals who could benefit from CR, only around 9,000 were referred and only 5,000 completed a CR programme. This reflects the current funding structure for most programmes, where funding was granted for MI/CABG/PCI, but no further funding has been made available for HF, valves and UA. Very few

patients with these diagnoses are able to access CR. This is likely to remain a problem in the future, as any available extra resource will be utilised by individuals with ACSLT, who will now be eligible for CR, due to the change in definition. The impact of this change in definition on CR teams has been large. In the initial data collection, this thesis identified 396 patients with ACSLT in NHS Ayrshire and Arran, who would be eligible for CR under the new definition.

Current healthcare policy is that all the groups above should receive CR. The current evidence base tells us that, although there are areas where further research is necessary, there is evidence of benefit from CR for the individual. However, if the policymakers are to consider further funding for CR, then one question that needs answered is how cost effective is it ? One of the issues in studying cost effectiveness of CR provision in the UK is the wide variety of provision across the country and the different models of care that are used. Costs for the provision of CR in the UK are difficult to access, but there have been a number of cost-effectiveness reviews, over the last decade, that have examined this issue. A Health Technology Assessment by Beswick et al (2004) based a detailed costing on the staffing mix of 30 UK CR programmes with estimates of the overheads, building capital and equipment costs included, using costs for 2000–2001. This suggested an average staffing cost of £354 and a weighted total average cost to the health service of £486 per patient successfully completing the CR programme. If the costs were spread however, over all the patients being seen by CR, the staff costs were £157 and total costs £220. The cost of the programmes increased as the number of different disciplines of staff, who were involved in providing the programme, increased. The costs varied hugely depending on: the intensity of the programme, level of

staffing, location of programme and equipment used. In a study by Jolly et al (2007), the staff costs of providing either a home programme or hospital programme were found to be £198 versus £182. These costs are obviously some time behind current costs of providing a programme. The raw costs to the organisation are however only one part of the equation and it is important to analyse the effectiveness element as well. As part of the NICE guideline for secondary prevention, analysis was undertaken to examine the cost effectiveness of CR, compared to no CR, in unselected patients after MI. Clinical effectiveness data from three meta-analyses (Jolliffe et al 2001, Taylor et al 2004, Clark et al 2005) was used and the results suggested that CR was cost effective when compared with no CR (NICE 2007). The estimated cost was £7860 and £8360 per Quality Adjusted Life Year (QALY) for men and women respectively. This is well below the level usually considered to be affordable in the NHS (NICE 2010). Recent commissioning information suggests that CR is extremely cost effective at £550 per episode (DOH 2010). Staff costs in 2010-2011 within the current CR programme in NHS Ayrshire and Arran were approximately £400, if spread equally over every patient seen.

In summary, if we consider the changes to the evidence base over the last eight years, it could be argued that CR research still faces the same challenges and difficulties that it did in 2004. There is a substantial body of evidence that suggests exercise CR is effective across populations, and sub-groups and different modes of delivery. But, due to the complex nature of CR, there remain many unanswered questions. The evidence base would also appear to suggest that psychological and educational interventions are of some benefit, but that more research is required into the link between psychological

and educational interventions and the impact on attitudes and beliefs. Questions remain about translating the evidence into practice, especially with the under-represented groups such as the elderly, women and those from ethnic minorities.

7.7 Implications for practice

The thesis was funded by NHS Ayrshire and Arran with the express purpose of improving outcomes for patients. This thesis adds to our knowledge by highlighting some of the difficulties in designing a RCT of CR in a specific sub-group of CHD. In the modern NHS, medicine does not always wait for research to keep up and this thesis was made difficult by changes in clinical practice and government policy. These changes meant that care for patients with ACSLT had to be provided, despite the lack of an evidence base. This group of patients have now been classified as having had an MI and will therefore receive a programme of care that reflects this diagnosis.

It could be argued that patients with ACSLT are no longer a novel group and there is no need for further research, as the MI evidence base will suffice. However, this would minimise the experience of these individuals. The impact of this change in diagnostic categories cannot be underestimated. An individual with this diagnosis would have noticed little change in his or her life previous to the definition change. They would have gone back to work within a week and would not carry the label of having had a heart attack. They would likely have described their admission as a little warning and may have made some changes to their health behaviours because of that. Das et al (2006) found however, that at six months, mortality rates for patients with ACSLT, had risen

to the same level as those for patients with clinical MI. They also found significant differences in the treatment of patients with ACSLT, with less prescription of recommended drugs such as beta-blockers, ace-inhibitors and statins, and relatively limited use of interventional strategies. Following the definition change, these individuals would have had a label which would impact on their life in areas such as driving, work, insurance and personal relationships, yet it is likely that they would also have seen an improvement in their medical management and therefore a reduction in risk. If both groups were treated the same, it is possible that a difference in outcome might become apparent between those with troponins greater than 1 and those with ACSLT. This is an area that will require further evaluation.

This change in definition also had wide ranging implications for staff. No data existed previously on this population to give a clear estimate of the numbers of additional referrals that CR programmes would see. However, the numbers who could have been referred, if the new diagnostic criteria had been in place within NHS Ayrshire and Arran, was an additional 396 patients. This would be a 50% increase in referrals to the local CR programme and would inevitably lead to stress in the system. However, in addition, staff would be dealing with a group of patients for whom there is little accurate data on outcome from CR. There is little evidence to support the theory that outcomes for those with ACSLT are the same as for those with the traditional diagnosis of MI following CR. This thesis has attempted to provide a starting point for this evidence base, but more will need to be done to support staff as they tackle this new population within CR. The challenge of providing care to this group remains.

The evaluation of a complex intervention such as CR is difficult and some of the difficulties have been highlighted within the two literature reviews in this thesis. The intervention was designed to provide an individualised package of care and often one of the difficulties in the CR evidence base is the fact that interventions within the studies are not comparable. Research studies often prescribed the length of intervention and exactly what it should include. This then influences the results, so one study might provide six weeks of exercise and another might provide twelve, both could have benefits, but in clinical practice neither study is of use, if the patient can only attend for three weeks before going back to work, or if he has co-morbidities that make the usual exercise programme not suitable. Often a CR package in clinical practice will have different timescales, different constituent parts or will be delivered to a different standard. It is even more difficult to tease out the benefits when the participants themselves determine the package as is the case in menu-based CR. This thesis was designed using usual CR practice and a menu based approach and this was reflected in the individualised packages of care that the participants received. Even in this small group of individuals, there was a wide variety in the types of interventions used. Clinicians responded to the needs of the participants as they arose. Clinicians are dealing with a wide range of people with a wide range of social, physical and psychological backgrounds. There are many issues that can affect a CR pathway, such as changes in a participant's condition, i.e. another clinical event, or deterioration in chest pain. The participant may exercise personal choice over the type of package they wish, or be unwilling to attend exercise classes and express a preference for home programmes. These are common issues in clinical CR practice that

clinicians manage every day. The small number of participants recruited meant that these issues could not be explored in any great depth. This thesis does highlight differences between the research base and current clinical practice and points to a need to find different ways of evaluating menu-based CR.

Recent literature has shown us that in clinical practice CR programmes are currently struggling to reach a wide range of individuals. Approximately 60% of the traditional groups of MI and revascularisation, who should be receiving CR, are not and this does not include a wide range of individuals for whom a CR package could be considered beneficial (Lewin et al 2011). Only 1% of individuals with HF currently attend a CR programme, despite the evidence base for benefit. The difficulties experienced in undertaking this thesis highlight the need to look again about how clinical practice can be supported by research.

This thesis highlighted the issue of uncertainty. The lack of an 'identity' for the illness had an impact on the ACSLT participants who did not receive an intervention. This meant that they struggled to make sense of their condition. The theoretical framework used within this thesis was the CSM and this is in some ways dependent on the illness itself having a recognisable identity. If this is not the case, then the individual can struggle to make sense of their condition and how to manage it. Yet this issue of uncertainty has not been studied within CR in any great depth. This thesis suggests that the assessment of levels of uncertainty in CR patients and the impact this has on adherence would benefit from further investigation.

The exploratory study had a limited number of participants so it is difficult to draw any conclusions from the outcome data that were produced. There were no statistically significant differences, but there was a tendency to benefit across the domains of misconceptions, symptoms, anxiety, depression, and HRQoL. The results found during the exploratory study were similar to recent research carried out in patients across a variety of sub-groups.

The evidence base shows us that even studies, done in the last ten years, continue to find the same evidence as was previously available. The expected mortality and morbidity benefit has not changed from the original meta-analysis in O'Connor et al (1989) to the recent review by Heran et al (2011).

If we accept the premise that CR works, then our priority becomes caring for the individual. The clinical community therefore needs to focus its research efforts on the how, rather than the what. How do we achieve the benefits rather than what are the benefits? How do we focus our resources on those most in need? How can we ensure that those who require limited input are assisted to achieve the same health gain? This needs a radical rethink of both the organisation and the delivery of CR.

Currently CR is monitored by diagnosis and by phase, individuals do not see themselves as a diagnosis or at a stage. If the focus of service provision is truly about individualised packages of care, then the quality of the assessment process needs to become the priority. Currently we have a number of tools that can assess physical and psychological functioning, but it is not routine practice to explore issues such as uncertainty or illness representation as a part of the

assessment process. CR professionals need to understand more of how people make decisions about their care in order to influence those decisions.

7.8 Recommendations for future research

Several implications for future research were identified as part of this thesis. These concern, firstly, the fact that a RCT is no longer possible due to changes in diagnostic categories and treatments, secondly, the impact that CR can have on patients with ACSLT, and the impact of psychological factors, particularly misconceptions and HRQoL on attitudes and beliefs in individuals with ACSLT, thirdly, the need to examine the impact of professional uncertainty on outcomes for patients, particularly those with long term conditions, fourthly, the need to examine uncertainty theory and its relationship to theoretical frameworks such as the CSM, and fifthly, the need for researchers to focus on supporting CR programmes to develop methods for measuring effectiveness.

Firstly, this thesis has found that a RCT of CR in ACSLT is no longer possible due to changes in healthcare provision. Although the exploratory study was small and no statistically significant changes were found in the outcome measures, there was a trend to benefit that mirrors research within other cardiac populations. This group of patients are now routinely offered CR following their admission. However there is still a need to examine this sub-group to ensure that the outcomes they gain from attendance at CR are similar to those with the original definition of MI. This area of practice therefore still warrants further investigation. The MRC framework suggests different ways to assess a complex intervention such as CR and it is possible that a comparative study, looking at the recovery of individuals by troponin levels using both

quantitative and qualitative measures, could provide useful information that would guide service provision.

Secondly, this thesis has provided interesting data on a range of psychological factors, within a small group of participants, and has highlighted areas for further research. The key elements that require further exploration are misconceptions and HRQoL. Misconceptions are an area that has had little attention within the CR literature and the impact of misconceptions within CR populations on attitudes and beliefs is unknown. All the participants in the exploratory study expressed misconceptions at T1 and T3, even if they had attended CR. The methods by which CR programmes identify and address the misconceptions held by their clients requires further exploration. In addition, this thesis provided data on the issues that participants thought important to their QoL. This thesis found that family, health, and social arrangements were determinants of QoL. The results from SEIQoL appeared to suggest that improvements in these domains took place throughout the period of recovery. However, CR has a limited impact on these issues, so how do CR programmes measure their impact in this domain. There has been limited use of SEIQoL within cardiac populations and further research is required to expand our knowledge of the determinants of QoL within these populations.

Thirdly, this thesis has highlighted the experience of the participants with ACSLT and the level of uncertainty they experienced at a time of change within cardiac services. Professional uncertainty and the lack of a consistent message had an impact on the recovery of participants and it would be useful to further explore areas of practice, both within cardiology and other long term conditions

to see the impact that this type of professional uncertainty has on outcome and how this can be better managed within clinical teams.

Fourthly, this thesis has explored the theory of uncertainty, which has been largely ignored within the CR literature. The impact that the theory of uncertainty has on the theoretical frameworks that underpin CR such as the CSM requires further exploration. Understanding the role the theory of uncertainty could play in CR would be a step towards developing effective interventions that address the psychological needs of individuals.

Fifthly, this thesis has highlighted that there is a need to support clinicians, in achieving the desired benefits of a multi-disciplinary programme of care, by developing methods for measuring effectiveness.

7.9 Conclusion

This thesis contains a feasibility study and an exploratory study. The feasibility study aimed to examine the feasibility of a RCT which would test the impact of a menu-based CR programme, on individuals diagnosed with ACSLT, against standard care. This feasibility study included staff views. The exploratory study aimed to explore the impact that ACSLT and CR can have on this client group.

This thesis provides useful information for practice, but its limitations must be acknowledged. The studies were carried out at two hospitals in the west coast of Scotland and the findings may not generalise to areas where clinical practice is different. Due to the difficulties with recruitment and retention, the participants may not have been representative of the population from which they were drawn. All the participants came from a white Scottish ethnic

background. This limits the applicability of the results to other populations. The design of the studies had limitations due to funding and staffing and the qualitative aspect of both studies needed to be expanded.

The feasibility study was successful in testing the protocols and methods and showed that the intervention was acceptable to participants. The strengths of the feasibility study included the acceptability of the CR intervention, commitment from the specialist CR staff to the process, the use of validated tools that were easy to administer and which the participants found acceptable, and the collection of a wide range of data on a group not previously studied. The areas that would require refinement were recruitment and retention. Data was collected on mortality and morbidity and crossover between groups, which could inform any further calculations of sample sizes for a RCT, and would allow any further trial to be adapted in line with these difficulties. However following a change in government policy and clinical practice, it is no longer possible to carry out a RCT on this population. The new MRC framework (MRC 2008) offers opportunities for evaluating CR in ACSLT in a different way.

The exploratory study involved the use of a large number of measures. Many of these are well established measures used widely in the study of CHD. These measures were shown to be acceptable to the participants suggesting that they may be useful in the further study of patients with ACSLT. No statistically significant differences were found between the groups, but a tendency to benefit in favour of the intervention was noted. Although this exploratory study had small numbers and the data has to be treated with a great

deal of caution, it does reflect the evidence found in other studies on the impact of CR within different cardiac populations

The exploratory study noted the impact that uncertainty had on this group of participants and this has implications for health care research and for CR clinical practice in particular. The participants within the exploratory study experienced professional uncertainty around their diagnosis, which had an impact on their recovery. This professional uncertainty may be resolved by a change in the diagnosis to MI. Yet, while there is some research on uncertainty in cardiology, it is largely ignored within the CR literature. The concept of uncertainty will however be important for CR professionals due to the broadening of the definition of MI.

Uncertainty theory does not give us a theoretical framework on which to base a multi-disciplinary intervention, however the exploratory study suggests that the impact of uncertainty needs further exploration, particularly around the impact that it has on frameworks such as CSM and on the design of CR interventions.

Changes to the evidence base over the last eight years needed to be considered. It could be argued that CR research still faces the same challenges and difficulties that it did in 2004. As has been seen from chapter 7:6, there is a substantial body of evidence that suggests exercise CR is effective across populations and sub-groups and different modes of delivery. But, due to the complex nature of CR, there remain many unanswered questions. Questions remain about translating the evidence into practice, especially with the under-

represented groups such as the elderly, women and those from ethnic minorities.

Currently CR is monitored by diagnosis and by phase, but individuals do not see themselves as a diagnosis or at a stage. If the focus of service provision is truly about individualised packages of care, then the quality of the assessment process needs to become the priority. Currently, we have a number of tools that can assess physical and psychological functioning, but it is not routine practice to explore issues such as uncertainty or illness representation as a part of the assessment process.

The experiences of individuals experiencing an ACSLT have largely been unexplored and the exploratory study findings in this regard are important. They are an initial exploration of an important sub-group of patients with CHD and although it would not possible to research further using a RCT, further work is required to explore how CR can best meet the needs of this sub-group.

The findings within this thesis are in line with the substantive literature that suggests that CR has positive benefits for a wide range of individuals from a wide variety of backgrounds, with a wide range of CHD pathology.

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Appendix One: Qualitative tools and analysis

A1:1 Focus group protocol

Phase 1: Before the focus group

1. **Focus groups**.
    - Two focus groups will be arranged to compare and identify themes which emerge from each discussion.
    - Focus groups should run between 60 and 90 minutes.

2. **Participants:**
    - Each focus group will have between six and ten participants. Fewer than six participants may limit the conversation and yield poor data while more than ten can be unwieldy.
    - Staff should work either in cardiology or cardiac rehab and should have been involved in the care of a participant on the study.
    - Secure names and contact information and send invitations.

3. **Generate your questions.**

Based on the purpose and goals of the focus group, the questions to be addressed are:

- Expectations of the research process
- Barriers to participation
- Perceived impact of CR on the participants
- Provision of the CR programme (CR focus group only)

The script

- *Part one:* welcome participants, explain purpose and context, explain what a focus group is, and make introductions. Explain that information is confidential and no names will be used. You will record the proceedings.
- *Part two*: ask your questions; remember to use probes and follow up questions to explore the key concepts more deeply.
- *Part three*: close the focus group – thank participants, give them contact information for further follow up if requested, explain how you will analyze and share the data.

Role of the facilitator

- The facilitator *should be* knowledgeable about the topic at hand
- The facilitator should be able to keep the discussion going, deal tactfully with difficult or outspoken group members, and make sure all participants are heard
- The facilitator should ask the questions and probes, but not participate in the dialogue or correct participants.

Choose the location

- Choose a location which is comfortable, easily accessible, and where participants can see one another.
- Choose a setting which does not bias the information gathered.

- Consider food or snacks.

Phase 2: Conduct the focus group

Bring materials:

- recorder to record proceedings
- Flip chart paper
- Focus group list of participants
- Focus group script
- Name tags
- Watch or clock

Arrive before the participants to set up room, refreshments, etc.

Introduce yourself carry on the focus group according to the script.

Conduct the session:

- Set a positive tone.
- Make sure everyone is heard; draw out quieter group members.
- Probe for more complete answers.
- Monitor your questions and the time closely – it is your job to make sure you are on track.
- Don't argue a point with a participant, even if they are wrong.

- Thank participants and tell them what your next steps are with the information.

Phase 3: Interpreting and reporting the results

Summarize each meeting

- Immediately after the meeting write up a quick summary of impressions.
- Transcribe the recording of the focus group. This should be done as soon as possible after the focus group has been conducted.

Analyze the summaries

- Read the notes and look for themes/trends. Write down any themes which occur more than once.
- Note context and tone
- Interpret the results

A1:2 Interview Protocol

The questions in this guide represent the main issues to be explored. Preferably, each participant will go through the same set of topics, although the order in which these topics are introduced may vary according to the particular participant.

1. Introduction

In this part of the interview I introduce the participant to the interview situation and explain that there is no intention to judge performance or report 'bad' practice within the healthcare system, but purely to understand the experiences that they have had.

2. Main interview

In the main part of the interview my aim is to get information about the participants' experiences of their illness. In this main part I want to ask questions about how well they understand their illness, how adjusted they feel, what their goals are and whether they feel they are accomplishing these or not.

Main cues

- How have you been since your discharge from hospital (to be asked at T2)?
- How have you been since I saw you last (to be asked at T3)?
- What are the next steps for you?
- Do you have an appointment at the hospital?
- What about getting back to work?
- Have you discussed that with the doctor?

3. Is there something else you would like to tell me?

The objective here is to find out if there are some aspects if their experience that the participants think I have left out or they wish to add something to things they have said earlier.

4. Concluding remarks

Thank the participant for the interview.

Ask how they experienced the interview.

Ask if I may contact them again if something comes up.

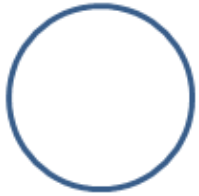
A1.3 A 15-Point Checklist of Criteria for Good Thematic Analysis

Process	No	Criteria
Transcription	1	The data have been transcribed to an appropriate level of detail, and the transcripts have been checked against the tapes for accuracy.
Coding	2	Each data item has been given equal attention in the coding process.
	3	Themes have not been generated from a few vivid examples (an anecdotal approach), but instead the coding process has been thorough, inclusive and Comprehensive.
	4	All relevant extracts for all each theme have been collated.
	5	Themes have been checked against each other and back to the original data set.
	6	Themes are internally coherent, consistent, and distinctive.
Analysis	7	Data have been analysed – interpreted, made sense of - rather than just paraphrased or described.
	8	Analysis and data match each other – the extracts illustrate the analytic claims.
	9	Analysis tells a convincing and well-organised story about the data and topic
	10	A good balance between analytic narrative and illustrative extracts is provided
Overall	11	Enough time has been allocated to complete all phases of the analysis adequately, without rushing a phase or giving it a once-over-lightly.
Written report	12	The assumptions about, and specific approach to, thematic analysis are clearly explicated.
	13	There is a good fit between what you claim you do, and what you show you have done – i.e., described method and reported analysis are consistent.
	14	The language and concepts used in the report are consistent with the epistemological position of the analysis
	15	The researcher is positioned as *active* in the research process; themes do not just "emerge".

A1:4 thematic maps

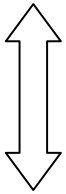
Key to thematic maps

Theme



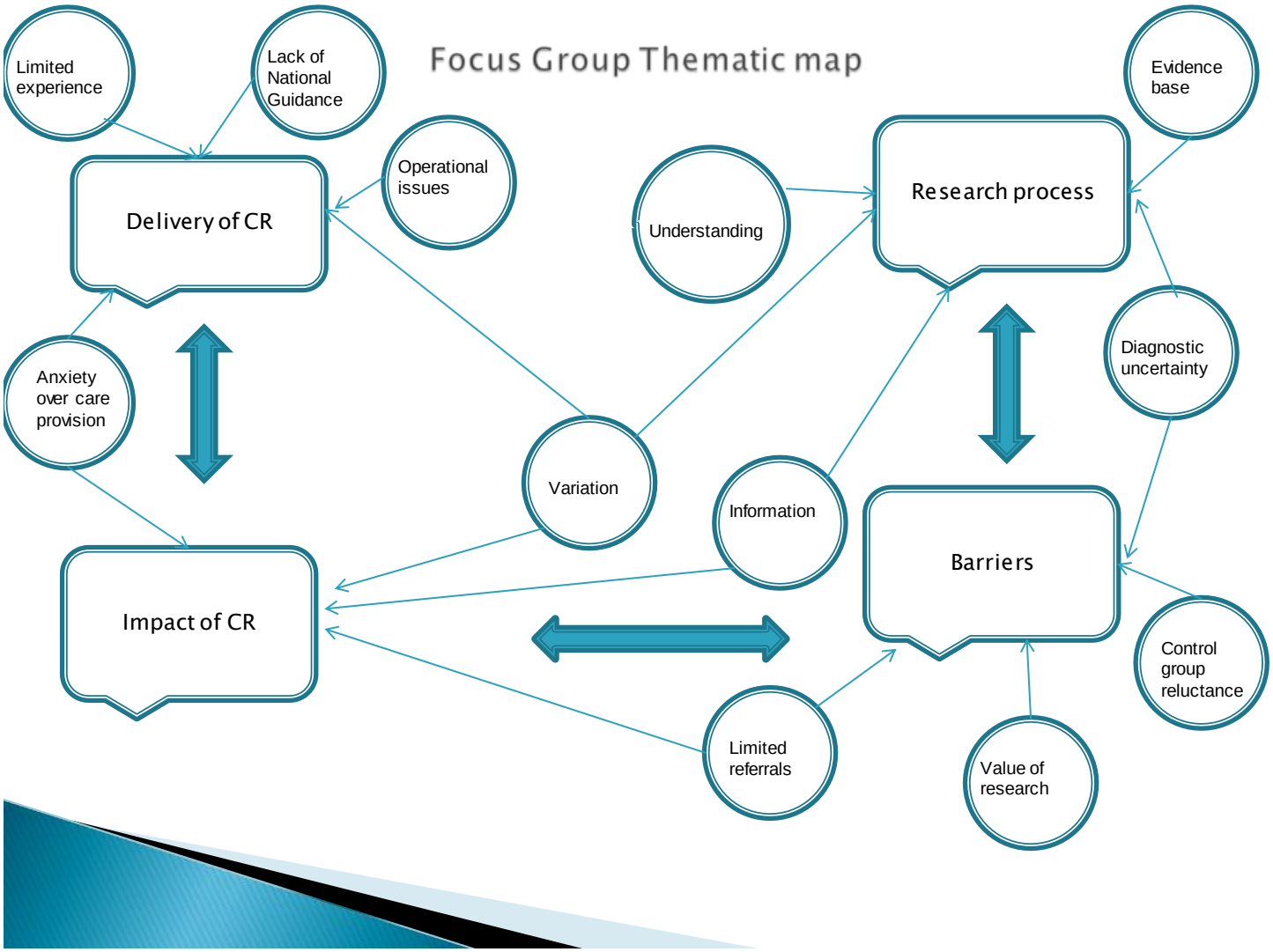
Subtheme

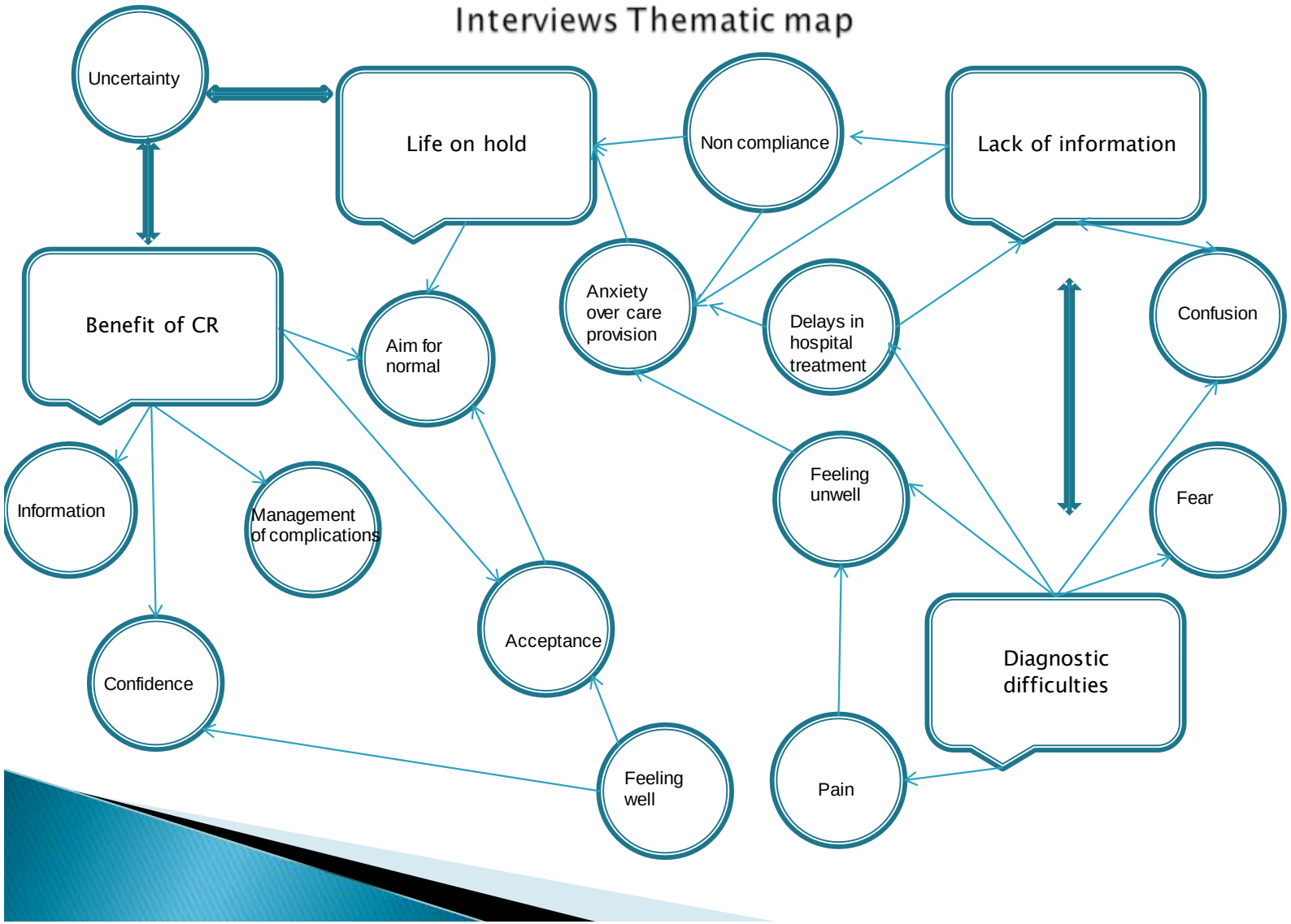
Impact on theme or subtheme



Interdependent themes

Two way impact on themes and subthemes


Focus Group Thematic map
Limited experience
Lack of National Guidance
Operational issues
Delivery of CR
Understanding
Research process
Evidence base
Diagnostic uncertainty
Anxiety over care provision
Variation
Information
Barriers
Impact of CR
Control group reluctance
Limited referrals
Value of research


Interviews Thematic map
Uncertainty
Life on hold
Non compliance
Lack of information
Benefit of CR
Aim for normal
Anxiety over care provision
Delays in hospital treatment
Confusion
Information
Management of complications
Feeling unwell
Fear
Acceptance
Diagnostic difficulties
Confidence
Feeling well
Pain

Appendix Two: Ethics/Research and Development

A2:1 Ethical approval

Ayrshire & Arran Local Research Ethics Committee
NHS Ayrshire & Arran
Eglinton House
Ailsa Hospital
Dalmellington Road
Ayr
KA6 6AB

Telephone: 01292 513628
Facsimile: 01292 513655

9 January 2006

Professor C.A. Niven
Director NMAHP research unit
Department of Nursing and Midwifery
University of Stirling
Stirling
FK9 3LA

Dear Professor Niven

Full title of study: **An exploratory study to examine the effects of a cardiac rehabilitation programe on patients admitted with Acute Coronary Syndrome without Myocardial Infarction**

REC reference number: **05/S0201/66**

Thank you for your letter of 12 December 2005, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information was considered at the meeting of the Committee held on 9 January 2006. A list of the members who were present at the meeting is attached.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Ethical review of research sites

The favourable opinion applies to the research sites listed on the attached form.

Conditions of approval

The favourable opinion is given provided that you comply with the conditions set out in the attached document. You are advised to study the conditions carefully.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Application	1	14 October 2005
Investigator CV	1	14 October 2005
Protocol	1	14 October 2005

Covering Letter		14 October 2005
Summary/Synopsis	1	14 October 2005
Questionnaire	1	14 October 2005
Letter of invitation to participant	1	14 October 2005
GP/Consultant Information Sheets	1	14 October 2005
Participant Information Sheet	1	14 October 2005
Participant Consent Form	1	14 October 2005
Response to Request for Further Information	2	12 December 2005
indemnity	1	14 October 2005
non-validated questionnaire	1	14 October 2005
Supervisor's CV	1	14 October 2005

Research governance approval

The study should not commence at any NHS site until the local Principal Investigator has obtained final research governance approval from the R&D Department for the relevant NHS care organisation.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

05/S0201/66	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project

Yours sincerely

p Susan Dillon

Fr M McManus
Chair

Email: susan.dillon@aaaht.scot.nhs.uk

Enclosures: *List of names and professions of members who were present at the meeting and those who submitted written comments*

Standard approval conditions
Site approval form

UNIVERSITY OF STIRLING

DEPARTMENT OF
NURSING AND MIDWIFERY

Dr Siobhan Sharkey
Chair, Dept Research Ethics Committee

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SS/TI

5 April 2005

Reg No 1122743

Janet A McKay
11 Castle Grove
Kilbirnie
North Ayrshire
KA25 6AW

Dear Janet

An Exploratory Study to Examine the Effects of a Cardiac Rehabilitation Programme on Patients with Acute Coronary Syndrome

Thank you for submitting your proposal, entitled as above, to the Departmental Research Ethics Committee on 4 April 2005. I am pleased to advise you that the committee approved your proposal subject to a note from yourself showing how the points raised below have been addressed.

a) The patient information sheet is lengthy, font size is small and the language is difficult in places. Fraser Boxall and Jean Bell offered to assist in the reworking of the information sheet.
b) The questionnaire – Cardiovascular limitations and symptom profile questionnaire is long, with some questions being sensitive. The researcher should be aware of any stress caused by the length of the questionnaire and identify how this might be addressed during the research.
c) HADS, line 4 has a misspelling.
d) Clarification is required regarding the wording of the patient information sheet as it states that no lifestyle changes are necessary but later on it states that participants will go to rehabilitation.
e) The committee felt that the time frame for people to agree to participate in the study was short and suggested that the research consider the possibility of extending this and allowing for participation after the patient has been discharged.
f) A statement allowing for patients consent for their doctors to be notified of their participation should be added to the Patient consent form. This should also be reflected in the patient information sheet.
g) The researcher needs to be more explicit regarding the available support to participants.
h) The researcher needs to provide more detail regarding accessing patients notes.

Dr Siobhan Sharkey 14/9/2005

Chair

Dept Research ethics committee

University of Stirling

Old Perth road

Inverness

Dear Dr Sharkey,

Following my application to the ethics committee in April I suffered a period of ill health and have had to take three months off my studies. I am only just now returning to my ethics application and would like to answer the queries in your letter of 5th of April.

a) The patient information sheet is currently being rewritten and I will forward the final version for comment
b) I agree that the CLASP questionnaire is long and I would intend to leave it with the participant to allow them time to complete it in privacy. However I would make it clear that any answers would be completely confidential and that if they had any problems completing or understanding the questionnaire, that I would be available to help.
c) HADS misspelling is fixed
d) See new information sheet
e) The application has been altered prior to submitting to NHS Ayrshire and Arran to allow for this to happen
f) Updated patient consent form enclosed, information sheet updated to reflect this
g) Available support to patients is now explicit in the information sheet
h) Patients notes will be accessed in the decision making process to ensure that the inclusion criteria is met. This will be done by staff who currently have access to these notes i.e. ward staff, cardiac rehab staff. In addition information about the clinical pathway of the patient over the course of the study will be required, i.e. blood tests, investigations etc, however permission will be sought from both the clinicians and the patients to access this information. Any data collected will be kept confidential and stored according to guidelines. No information not directly related to the study will be collected.

I hope this is the information that you were looking for and look forward to hearing from you

Janet McKay

Clinical doctorate student

A 2.2 Research and Development approval

Research and Development
Ayr Hospital
Dalmellington Road
AYR
KA6 6AB

Tel: (01292) 614590/614480
Fax: (01292) 288952

NHS Ayrshire & Arran

Mrs Janet McKay
Clinical Co-ordinator
Lister Centre
Crosshouse Hospital
Kilmarnock
KA2 0BE

Date: 12th January 2006
Your Ref:
Our Ref: RM/KLB/R&D 176

Enquiries to: Karen Bell
Extension: 3622
Direct Line: 01292 513622
Email: Karen.bell@aapct.scot.nhs.uk

www.nhs-ayrshire.org

Dear Mrs McKay

An exploratory study to examine the effects of a cardiac rehabilitation program of patients admitted with Acute Coronary Syndrome without Myocardial Infarction

I confirm that the NHS Ayrshire and Arran R&D Management Group have granted Management Approval for the above study to go ahead.

The terms of approval state that the investigator authorised to undertake this study within NHS Ayrshire & Arran is: -

- Mrs Janet McKay, Clinical Co-ordinator, NHS Ayrshire and Arran

With additional investigator: -

- Professor C A Niven, University of Stirling

The sponsors for this study are University of Stirling.

This approval letter is valid until June 2008.

Regular reports of the study require to be submitted. Your first report should be submitted to myself in 6 months time and subsequently at yearly intervals until the work is completed.

In addition approval is granted subject to the following conditions: -

- All research activity must comply with the standards detailed in the Research Governance Framework for Health and Community Care and appropriate statutory legislation.
- If any amendments are to be made to this study protocol and or the Research Team the Researcher must seek Ethical and Management Approval for the changes before they can be implemented.

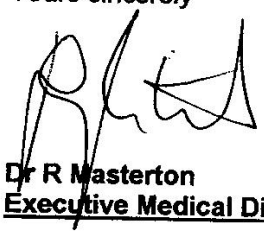
- The Researcher and NHS Ayrshire and Arran must permit and assist with any monitoring, auditing or inspection of the project by the relevant authorities.

- The NHS Ayrshire and Arran Complaints procedure should be accessed if any complaints arise regarding the project and the R&D Department must be informed.

- The outcome and lessons learnt from complaints must be communicated to funders, sponsors and other partners associated with the project.

If I can be of any further assistance please do not hesitate to contact me. On behalf of the committee, I wish you every success with the project.

Yours sincerely



Dr R Masterton
Executive Medical Director

cc Professor C A Niven, Director NMAHP Research Unit, Department of Nursing and Midwifery, University of Stirling, Stirling FK9 3LA

A2.3 Consent form

Centre Number:

Study Number:

Patient Identification Number for this trial:

Title of Project:

An exploratory study to examine the impact of a Cardiac Rehabilitation programme on patients with Acute Coronary Syndrome

N**ame of Researcher:** Janet McKay **Please initial box**

1. I confirm that I have read and understand the information sheet dated .....version 2 for the above study and have had the opportunity to ask questions. ☐

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

3. I understand that sections of any of my medical notes may be looked at by responsible Individuals from NHS Ayrshire and Arran or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records. ☐

4. I agree that my General Practitioner/Cardiologist can be informed of my participation in this study ☐

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

Name of Patient	Date	Signature
Name of Person taking consent (If different from researcher)	Date	Signature
Researcher	Date	Signature

1 for patient; 1 for researcher; 1 to be kept with hospital notes

NHS
Ayrshire & Arran

Invitation
You are being invited to take part in a research study. Before you decide whether to take part it is important for you to understand why the research is being done and what it will involve. Please take the time to read this information carefully and discuss it with others if you wish.

What is the purpose of the study?
We are carrying out research into rehabilitation (a programme of education, support and exercise) for people with heart problems. Currently there is only information on the impact of rehabilitation after a heart attack. We know that it can help people with a heart attack but we don't know if it will be helpful for people like you with chest pain (Acute Coronary Syndrome).

Why are you inviting me?
Your hospital consultant is involved in this study, and we are inviting you because you were admitted to Crosshouse or Ayr hospitals. Approximately 100 people have been invited to take part in the study.

Do I have to take part?
It is up to you decide whether or not to take part. If you do not want to take part, that is fine. If you do decide to take part, but later change your mind, you can withdraw at any time without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive

form part of Janet McKay's doctoral degree. None of the research team will benefit financially from the study.

Who has reviewed this study?
This study has been reviewed by NHS Ayrshire and Arran Ethics Committee and Research and Development group and by the Ethics committee of the Department of Nursing and Midwifery at the University of Stirling.

Can I contact a member of the research team for further information?
If you have received this booklet a member of the research team will automatically contact you. They will be able to provide further information on this trial, answer any of your questions and tell you about the next steps should you decide to take part in the study. If you have any further questions about the study at any stage please feel free to contact:

Janet McKay
Cardiac Rehabilitation
Lister Centre
Crosshouse Hospital
Kilmarnock KA2 0BE
Tele:01563 577175
Janet.mckay@aaaht.scot.nhs.uk

Professor C.A.Niven
Department of Nursing and Midwifery
University of Stirling
Stirling FK73LA
Tele:01786466341

If you wish further independent information about being involved in a research study please contact:
Research Governance office
Department of Clinical Effectiveness
Ayr Hospital
Dalmellington road Ayr Tele:01292610555

You will be given a copy of the information sheet and a signed consent form to keep.
Thank you for agreeing to think about taking part in this study!

What will I have to do if I decide to take part?
If you agree to take part in the study, you will be placed in **study group 1** or **study group 2**. The researcher cannot change the group you will be assigned to. Both groups will be asked at the start of the study to complete a booklet of questions about their health and well-being. This will be repeated at four weeks and six months after discharge when a researcher will visit you at home. A follow-up booklet of questions will be posted to you at home at one year. Your answers will help us measure how things have changed for you over this time. Those in **study group 1** will receive high quality care while in hospital and any further follow-up or investigations that their Consultant Cardiologist deems necessary. Those in **study group 2** will also be seen by the rehabilitation team. **If** the study shows that cardiac rehabilitation helps people with chest pain, those who are allocated to **Study group 1** will be offered access to this programme at a later date.

What are the possible risks and benefits of taking part?
Taking part in the study may not be of direct benefit to you but we hope that the results of the study may improve treatment for other patients like you in future.
Patients who take part in the rehabilitation programme will be monitored closely. This means that underlying problems or any problems, which emerge during the programme, will be picked up quickly. If any such problems arise patients will be referred to their GP or consultant cardiologist.
Exercise can occasionally make chest pain worse in patients with your type of condition. However all patients who agree to take part in the rehabilitation programme will be assessed by highly skilled rehabilitation staff before exercise starts, so that their exercise programme can be tailored to their abilities.

What happens when the research study stops?
The rehabilitation programme will be completed by the end of the study. If it has been shown to be helpful for patients with your condition, it will be offered to all the patients in Study group 1.

What if something goes wrong?
If taking part in this research project harms you, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms should be available to you.

Will the information I provide be kept confidential?
If you give permission we will tell your General Practitioner and the Consultant Cardiologist that you are taking part in this study.
No information about your name and address will be included on the study booklets or forms. Any information that you provide will be stored on computer using only a study number and will be kept secure using passwords. We hope to link your questionnaire answers to relevant information from your NHS medical record, but again the data will be confidential and available to the research team only and will not be linked with your name. When the results of the study are written up, individuals who have taken part will not be identified in any way.

How will the information I provide be used?
The results of this study will help us to understand whether or not rehabilitation can help people with chest pain like yours (Acute Coronary Syndrome). We hope that the results will be published in a number of journals so that others can read and learn from the study. The researcher will make a copy of the overall results available to anyone involved in the research.

Who is doing the study?
An experienced cardiac nurse specialist from NHS Ayrshire and Arran, Janet McKay, is carrying out the research and Prof. Niven and Dr. Shepherd of the Department of Nursing and Midwifery at the University of Stirling will supervise her. The research study will

A2.5 Letter to General Practitioner

Dear Dr

Re:

The above patient has consented to take part in a study looking at the impact of Cardiac Rehabilitation on patients with Acute Coronary Syndrome without Myocardial Infarction. I enclose a copy of the information sheet for this study. Patients can of course withdraw from the study at any point without giving a reason. It is hoped however that this study will provide information that will inform future developments in care for this group of patients. Any medical care provided will of course continue as usual no matter which arm of the study they are placed in. If you require any further information on this study I can be contacted at the address below:

Mrs Janet McKay

Cardiac Rehabilitation, Lister Centre, Crosshouse Hospital

Kilmarnock, KA2 0BE, Tele: 01563 577175

Yours sincerely

Janet McKay Clinical Co-ordinator

Cardiac Managed Clinical Network

NHS Ayrshire and Arran

A2.6 Information sheet for General practitioners and Cardiologists

Study title: An exploratory study to examine the impact of a Cardiac Rehabilitation programme on patients with Acute Coronary Syndrome without myocardial infarction

What is the purpose of the study? For several years in Ayrshire people, who are admitted to hospital with a heart attack, have been able to receive cardiac rehabilitation. This is a programme of education, support and exercise provided by specialist nurses and physiotherapists with the help of doctors and other member of the healthcare team. This has been found to be beneficial for this small group. However this is only a small number of the people admitted to hospital every year with a heart problem. Currently there is very little information about the impact of a programme such as this on other heart problems. We are keen to improve services for all individuals with heart problems and would like to know if Cardiac Rehabilitation would be beneficial to others. For this reason NHS Ayrshire and Arran is supporting a pilot study looking at the impact of Cardiac Rehabilitation on people with Acute Coronary Syndrome without heart attack. The study will last from April 2005 until November 2007.

How do we choose who takes part? They have been chosen for this study because they were admitted to Crosshouse and Ayr hospitals with a diagnosis of Acute Coronary Syndrome. All patients admitted with this diagnosis during the study, who are able to take part, will be approached. We expect to interview 100 patients over the course of the study.

What will happen to them? They will be seen on three occasions over one year, in hospital and at home. They will be asked to complete five short

questionnaires each time and to answer some questions from the researcher on their current health. They will be asked to keep a diary of any chest pain and to measure their activity for a week at two time points using a pedometer. It is anticipated that each interview will last approximately one hour. They will not need to have any blood tests or investigations other than they would normally be expected to receive. They will be allocated to either the usual care group or the intervention arm. If they are allocated to the usual care group, but feel at the end of the study that they would like the opportunity to take part in Cardiac Rehabilitation programme, this will be offered to them provided their cardiologist is in agreement that they are well enough to take part. If they are allocated to the intervention group they will receive information from the Cardiac Rehabilitation team. Cardiac Rehabilitation is a programme of care provided by experienced healthcare professionals, usually a specialist nurse and a physiotherapist. The team will:

- provide information on the diagnosis and its impact on lifestyle
- talk about the risk factors for future health problems
- Provide an individualised programme of exercise to improve activity levels.

They may be asked to participate in an exercise programme twice a week for up to three months. This will be designed according to their abilities and needs. If this is the case, they will be able to claim travel expenses to and from the hospital. The information gathered from this study will be important in helping to design services for people with similar health problems.

Although they have agreed to take part they are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care they receive.

What are the possible disadvantages, side effects and risks? This project does not include drugs or additional investigations and should have no impact on treatments you may wish to provide. We would expect that all individuals recruited to the trial would continue to receive routine medical care. Sometimes during the course of a study like this some health problems such as high blood pressure or high cholesterol levels may be detected. They may wish to discuss these issues with you.

What are the possible disadvantages, side effects and risks of taking part in a Cardiac Rehabilitation programme? Occasionally some people may suffer pain either from bony injury or muscular problems. Occasionally some people may suffer cardiac problems. The risk of a patient taking a cardiac event is calculated at one patient every six years. A senior physiotherapist and an experienced cardiac nurse will assess them and they will tailor the programme to suit their needs and to minimise risk. The consent of a Cardiologist will be needed before they can commence the exercise classes. Sometimes people can become anxious or depressed when they develop a health problem and this may be made worse by a discussion of the problem. The Cardiac Rehabilitation staff will get them the help they need if they develop any of these problems. If the team discover while an individual is attending the classes that they have developed a health problem of which they were

unaware, the team will wish to report this change to yourself and their Cardiologist. Permission will be obtained from the individual for this.

The researcher's responsibility is to collect information on the individual's experiences and recovery from this illness. She will not provide medical advice or support. The information we get from this study may help us to treat future patients with Acute Coronary Syndrome better.

What if new information becomes available? Sometimes during the course of a research project, significant new information becomes available about the treatment that is being studied. If this happens, the researcher will tell the individual about it and discuss with them whether they want to continue in the study. If they decide to withdraw the researcher will make arrangements for their care to continue. If they decide to continue in the study they will be asked to sign an updated consent form. Also, on receiving new information the researcher might consider it to be in their best interests to withdraw them from the study. She will explain the reasons and arrange for their care to continue.

What happens when the research study stops? The provision of Cardiac Rehabilitation to people with Acute Coronary Syndrome is not currently funded within NHS Ayrshire and Arran. So following the completion of the study this service will be withdrawn. The results of this pilot study will be used to decide if a study looking at large numbers of people with Acute Coronary Syndrome across Scotland is possible. This and any follow-up study will provide information on whether Cardiac Rehabilitation for Acute Coronary Syndrome is a useful and safe form of treatment for the NHS to provide. Any results will inform future service developments within the NHS.

What will happen to the results of the research study? The study will last until November 2007 and it will then be submitted to NHS Ayrshire and Arran for comment and for publication to various journals. Meetings will be also be held with various local organisations to disseminate the results. Individuals will not be identified in any report/publication. The researcher will make a copy of the results available to anyone involved in the research. Copies can be obtained from the Cardiac Rehabilitation office in Crosshouse hospital.

Who is organising and funding the research? NHS Ayrshire and Arran CHD Managed Clinical Network supports this research and the researcher will be supervised by the Department of Nursing and Midwifery at the University of Stirling.No one will be paid for this study.

Who has reviewed the study? This study has been reviewed by NHS Ayrshire and Arran Ethics Committee and Research and Development group and by the Ethics committee of the Department of Nursing and Midwifery at the University of Stirling.

What if something goes wrong? If they are harmed by taking part in this research project, there are no special compensation arrangements. If they are harmed due to someone's negligence, then they may have grounds for a legal action but they may have to pay for it. Regardless of this, if they wish to complain, or have any concerns about any aspect of the way they have been approached or treated during the course of this study, the normal National

Health Service complaints mechanisms should be available to them. **Will information be kept confidential?** All information, which is collected, about them during the course of the research will be kept strictly confidential. Any information, which leaves the hospital, will have the individuals name and address removed so that they cannot be recognised from it. Both General practitioners and Cardiologists will be informed of their participation in this study and consent for this will be sought from the individuals concerned.

Further information about this study can be obtained from:

Mrs Janet McKay, Cardiac Rehabilitation

Lister Centre, Crosshouse Hospital, Kilmarnock

KA2 0BE, Tele: 01563 577175

If you have a complaint to make about this study pleases contact:

Professor C.A.Niven

Department of Nursing and Midwifery, University of Stirling

Stirling FK73LA 01786466341

If you wish further independent information about being involved in a research study please contact:

Research Governance office, Department of Clinical Effectiveness

Ayr Hospital, Dalmellington road, Ayr 01292610555

A2.7 Referral protocol

- All patients on admission to the cardiology should be given information on the study
- Suitable patients should be notified to the researcher who will assess suitability for the study
- Once the diagnosis and suitability has been confirmed the patient can be approached for consent to be approached by the researcher
- The researcher and patient will discuss the study and the procedure for obtaining informed consent will be completed
- Following entry to the study the researcher will find a suitable time to complete the baseline assessments
- Thereafter all patients in the treatment arm should be referred to the Cardiac Rehabilitation Liaison Sister (phone Crosshouse ext 2175 or Ayr ext 4177).
- If it is necessary to contact the Cardiac Rehabilitation team for any other reason, they can be contacted on:

  Sister McAskill bleep 3510 Sister Bogle bleep 3350
- Patients will be visited as soon as possible following referral
- During their hospital stay the following subjects will be explained
    - Anatomy and Physiology of the heart
    - Angina and its management
    - Reducing appropriate risk factors
    - Return to normal activities

- Every attempt will be made to see the carer of the client either in hospital or at home

- Referral to appropriate members of the multi-disciplinary team will be made i.e. dietician pharmacist physiotherapist social work

- All patients who are able to leave their home for day time activities normally will be offered an appointment at the Cardiac Clinic within 6 weeks of discharge.
- Any investigations will normally be carried out prior to attendance at the clinic
- Patients who are assessed fit will normally be offered a place at the Cardiac Rehabilitation Classes commencing within 14 days of the clinic
  (see exercise class referral protocol***)***

Appendix Three: Questionnaires

A3.1 York Angina Beliefs Questionnaire v2

THE YORK ANGINA BELIEFS QUESTIONNAIRE

We want to know your views and beliefs about why people get angina and what they should do about it.

It is important that you answer every question. Don't spend too long thinking about your answers - the first thing you thought of is what we want to know.

For each question please ✓ one circle. Please don't leave any out.

	STRONGLY AGREE	AGREE	DISAGREE	STRONGLY DISAGREE	I DON'T HAVE ANY IDEA ABOUT THIS
1. It is not always necessary for people with angina to stop what they are doing when they get angina pain	○	○	○	○	○
2. Angina is a kind of small heart attack	○	○	○	○	○
3. People develop angina because they have too much stress in their lives	○	○	○	○	○
4. There's no need for people with angina to take life easy	○	○	○	○	○
5. People with angina should always avoid things that bring it on	○	○	○	○	○
6. People with angina should exercise	○	○	○	○	○
7. Any sort of excitement is bad for people with angina	○	○	○	○	○
8. Angina is caused by a worn out heart	○	○	○	○	○
9. If people with angina don't rest when they get angina pain it could be fatal	○	○	○	○	○
10. People with angina must stay calm	○	○	○	○	○
11. Rest is not the best treatment for angina	○	○	○	○	○
12. Too much worry causes people to develop angina	○	○	○	○	○
13. Angina pain causes permanent damage to the heart	○	○	○	○	○
14. It's usually safe to argue with people who have angina.	○	○	○	○	○

THANK YOU VERY MUCH FOR YOUR HELP - WE APPRECIATE IT

Here are the answers.

To score the YABQv2: Items 2, 3, 5, 7, 8, 9, 10, 12 & 13 score normally; Strongly agree=4, agree=3, don't have any idea about this=2, disagree=1, strongly disagree=0.

Items 1, 4, 6, 11 & 14 are reverse scored.

1. It is not always necessary for people with angina to stop what they are doing when they get angina pain	Although it may be more comfortable to stop as soon as an attack occurs it is not always strictly necessary. Some people worry that not stopping will cause damage, and need reassuring that if the pain is slight and they want to carry on a reduced pace then that's ok. There are people who work through an attack. Stopping immediately may not always be practical or safe, (if driving or working machinery etc.)
2. Angina is a kind of small heart attack	No it isn't.
3. People develop angina because they have too much stress in their lives	Probably not, the major causes of angina are risk factors like smoking, high blood pressure, diabetes, high cholesterol or a family history. Stress may cause people to adopt risky lifestyles (smoking, fatty diets, lack of exercise etc.) but it is still the risky lifestyle that they need to change. People who believe that the major cause of their developing IHD is stress are less likely to alter their risky lifestyles and have greater morbidity than people who

	acknowledge that their known risk factors need changing.
4. There is no need for people with angina to take life easy	That's right. They should keep up the exercise they do (or increase it slowly if they do none). The main thing is to keep going and build up gradually.
5. People with angina should always avoid things that bring it on	Not necessarily, this could result in the person sitting in the house afraid to do anything. Try taking GTN before hand, or break the task down into small chunks, doing a little at a time and building up activity levels slowly. It is usually possible to give people combinations of drugs that limit the amount of angina. Recent research also suggests that people who suffer from angina attacks may not suffer as much if they subsequently have a heart attack, the angina may provide a sort of protection.
6. People with angina should exercise	It is very advisable for them to exercise, as people who increase their fitness slowly may reduce the amount of angina that they suffer.
7. Any sort of excitement is bad for people with angina	Believing this could severely limit their quality of life. Giving up fun but exciting things could also contribute to depression.
8. Angina is caused by a worn out heart	No.

	Not so. See question 1. However people with angina should be taught how to spot if the pain may be a heart attack and what to do, a great deal of fear is generated because they have not been taught this.
9. If people with angina don't rest when they get angina pain it could be fatal	
10. People with angina must stay calm	Although this **may** lead to a more relaxing life it is not strictly necessary. It could affect quality of life and family life if the striving for calm causes bottling up of problems, by either the angina sufferer or their family.
11. Rest is not the best treatment for angina	Rest causes people to become less fit, and this can cause more angina pain, so rest is a poor treatment for angina.
12. Too much worry causes people to develop angina	No, see question 3.
13. Angina pain causes permanent damage to the heart	No it doesn't.
14. It's usually safe to argue with people who have angina.	Believing that it is not safe can cause problems in relationships, and make the family overprotective.

A3.2 Cardiac Limitation and Symptoms Profile

CARDIOVASCULAR LIMITATIONS AND SYMPTOMS PROFILE

We are trying to find out how people are affected by heart trouble.

Please help us by completing this confidential questionnaire which asks questions about your health and every day activities.

This questionnaire is designed to find out how you have been in the last two weeks.

It is very important that you answer all the questions, unless the questionnaire indicates that you can skip some questions.

Each of the questions has a number of possible answers. Remember to tick only one box for each question. There may be a question where you cannot decide between answers. In this case choose the one that best describes how you have been feeling over the last two weeks.

Angina is a heart pain which is usually felt in the chest, but can also be felt in your arms, throat or jaw. It usually comes on when you exert yourself and goes away if you rest or use nitrolingual spray or tablets.

1 Have you had any angina in the last two weeks?

No ☐ Please go straight to question 7

Yes ☐ Please answer the following questions

2 On average, how often have you had angina in the last two weeks?

No angina at all ☐

Once or twice in the last fortnight ☐

2 to 3 times a week, but not every day ☐

Once a day ☐

2 - 3 times a day ☐

4 or more times a day ☐

3 On average, over the last two weeks, how bad have your episodes of angina been?

Mostly mild ☐

Mostly moderate ☐

Mostly severe ☐

4 Has angina woken you up at night?

- Not at all ☐
- Occasionally ☐
- Often ☐
- Very often ☐

5 With regards your angina, have you had:

- Mostly good days ☐
- Good and bad days ☐
- Only bad days ☐

6 Overall, how bad has your angina been in the last two weeks?

- Mild ☐
- Moderate ☐
- Severe ☐

Shortness of Breath. If you have only been short of breath on very heavy exertion, for example, running upstairs or lifting heavy furniture, please tick "No" and go to question 13.

7 Have you been short of breath in the last two weeks?

No	☐	Please go straight to question 13.
Yes	☐	Please answer the following questions.

8 On average, how often have you been short of breath in the last fortnight?

Once or twice in the last fortnight	☐
2 - 3 times a week, but not every day	☐
Once a day	☐
2 - 3 times a day	☐
4 or more times a day	☐

9 Have you found it difficult to lie flat, without becoming short of breath?

Not at all	☐
A little	☐
A moderate amount	☐
A great deal	☐

10 With regards to your shortness of breath, have you had:

- Mostly good days? ☐
- Good and bad days ☐
- Only bad days? ☐

11 Overall, how bad has your shortness of breath been in the last 2 weeks?

- Mild ☐
- Moderate ☐
- Severe ☐

12 How much has your shortness of breath interfered with your life in the last 2 weeks?

- Not at all ☐
- A little ☐
- A moderate amount ☐
- A great deal ☐

13 Have you had any ankle swelling in the last two weeks?

No	☐	Please go straight to question 17.
Yes	☐	Please answer the following questions.

14 How swollen have your ankles been?

Slightly swollen	☐
Moderately swollen	☐
Very swollen	☐

15 Overall, how bad has your ankle swelling been in the last 2 weeks?

Mild	☐
Moderate	☐
Severe	☐

16 How much has your ankle swelling interfered with your life in the last 2 weeks?

Not at all	☐
A little	☐
A moderate amount	☐
A great deal	☐

17 Have you been tired or lacking in energy over the last 2 weeks?

No ☐ Please go straight to question 21

Yes ☐ Please answer the following questions

18 In general, how tired have you been in the last 2 weeks?

I have felt a little tired ☐

I have felt moderately tired ☐

I have felt very tired ☐

I have felt exhausted ☐

19 How much of the time have you been tired?

Just at the end of the day ☐

For up to a couple of hours most days ☐

For half the day ☐

Most or all of the day ☐

20 How much energy have you had in the last 2 weeks?

A great deal ☐

A moderate amount ☐

Very little ☐

None at all ☐

21 How far have you been able to walk outdoors in the last 2 weeks?

- I've managed up to a mile walking briskly at times ☐
- I've managed up to a mile at a normal pace ☐
- I've managed up to half a mile ☐
- I've managed up to about a quarter of a mile ☐
- I've managed 50 to 200 yards ☐
- I've managed only a few steps ☐
- I've not been able to walk outside at all ☐

22 What speed have you been walking at outside in the last 2 weeks?

- I've walked briskly at times ☐
- At a normal pace for my age ☐
- Only a bit slower than others my age ☐
- Slowly and stopping occasionally ☑
- Very slowly and stopping frequently ☐

23 How well have you been able to climb up stairs in the last 2 weeks?

- I've walked up stairs briskly at times ☐
- At a normal pace for my age ☐
- Slowly without stopping ☐
- Very slowly and stopping once ot twice ☐
- One step at a time stopping frequently ☐

24 How easily have you been able to bend down or stretch for things in the last 2 weeks?

- No problem at all ☐
- Only a little difficulty ☐
- Some difficulty ☐
- Unable to do at all ☐

25 How much have you gone out socially, eg, to the pubs, dancing, bingo, restaurants in the last 2 weeks?

- As much as I wanted to ☐
- A bit less than I would have liked ☐
- Much less than I would have liked ☐
- Not at all, although I wanted to ☐

26 How much have you engaged in active hobbies, eg, swimming, bowling, golf in the last 2 weeks?

- As much as I wanted to ☐
- A bit less than I would have liked ☐
- Much less than I would have liked ☐
- Not at all, although I wanted to ☐

27 How much has your physical condition stopped you from getting out and seeing friends and family in the last 2 weeks?

- Not at all ☐
- A little ☐
- A moderate amount ☐
- A great deal ☐

28 How much light housework have you done, eg washing-up, dusting, tidying around the house in the last 2 weeks?

- As much as I wanted to ☐
- A bit less than I would have liked ☐
- Much less than I would have liked ☐
- None at all, although I wanted to ☐
- I have not done any, but this has nothing to do with my heart problems ☐

29 How much heavy housework have you done in the last 2 weeks, eg hoovering, cleaning windows, floors etc

- As much as I wanted to ☐
- A bit less than I would have liked ☐
- Much less than I would have liked ☐
- None at all, although I wanted to ☐
- I have not done any, but this has nothing to do with my heart problems ☐

30 How much light DIY have you done in the last 2 weeks? (eg mending plugs, touching up paintwork)

- As much as I wanted to ☐
- A bit less than I would have liked ☐
- Much less than I would have liked ☐
- None at all, although I wanted to ☐
- I have not done any, but this has nothing to do with my heart problems ☐

31 How much heavy DIY have you done in the last 2 weeks (eg decorating, carpentry)

- As much as I wanted to ☐
- A bit less than I would have liked ☐
- Much less than I would have liked ☐
- None at all, although I wanted to ☐
- I have not done any, but this has nothing to do with my heart problems ☐

32 Have you been worried about your heart problems in the last 2 weeks?

- Not at all ☐
- A little ☐
- A moderate amount ☐
- A great deal ☐

33 Have you felt dependent on your family in the last 2 weeks?

- Not at all ☐
- A little ☐
- A moderate amount ☐
- A great deal ☐

34 Have you been worried about your family in the last 2 weeks?

- Not at all ☐
- A little ☐
- A moderate amount ☐
- A great deal ☐

35 How often have you had sexual intercourse in the last 2 weeks?

- As much as I wanted to ☐
- A bit less than I would have liked ☐
- Much less than I would have liked ☐
- Not at all, although I wanted to ☐
- I have not been sexually active, but this has nothing to do with my heart problems ☐

36 In the last 2 weeks, have you been afraid of having sex in case it brings on angina or breathlessness

- Not at all ☐
- A little ☐
- A moderate amount ☐
- I have not had sex because of this ☐
- I have not had sex, but this has nothing to do with my heart problems ☐

37 In the last 2 weeks, have you had trouble enjoying sex because of tiredness, breathlessness or angina?

- No trouble at all ☐
- A little ☐
- A moderate amount ☐
- A great deal ☐
- I have not had sex because of this ☐
- I have not had sex, but this has nothing to do with my heart problems ☐

This is the end of the questionnaire.

Thank you for your help.

A3.3 Hospital Anxiety and Depression Scale

Hospital Anxiety and Depression Scale

Emotions play an important part in most illnesses. This questionnaire is designed to help us to know how you feel. Please tell me which of these replies comes closest to how you have been feeling in the past week, regarding the items I am about to read out to you. Don't take too long over your replies: your immediate reaction to each item will probably be more accurate than a long though-out response. Tick only one box in each section.

I feel tense or "wound up":

- Most of the time
- A lot of the time
- Time to time, occasionally
- Not at all

I still enjoy 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
- From time to time but not often
- Only occasionally

I feel cheerful:

- Not at all
- 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 so 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 ever I did
- Rather less than I used to
- Definitely less than I used to
- Hardly at all

I get a sudden feeling of panic:

- Very often indeed
- Quite often
- Not very often
- Not at all

I can enjoy a good book or radio or TV programme:

- Often
- Sometimes
- Not often
- Very seldom

Your Health and Well-Being

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. ***Thank you for completing this survey!***

For each of the following questions, please tick the one box that best describes your answer.

1. **In general, would you say your health is:**

Excellent	Very good	Good	Fair	Poor
☐1	☐2	☐3	☐4	☐5

2. **<u>Compared to one year ago</u>, how would you rate your health in general <u>now</u>?**

Much better now than one year ago	Somewhat better now than one year ago	About the same as one year ago	Somewhat worse now than one year ago	Much worse now than one year ago
☐1	☐2	☐3	☐4	☐5

3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	☐ 1	☐ 2	☐ 3
b Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐ 1	☐ 2	☐ 3
c Lifting or carrying groceries	☐ 1	☐ 2	☐ 3
d Climbing several flights of stairs	☐ 1	☐ 2	☐ 3
e Climbing one flight of stairs	☐ 1	☐ 2	☐ 3
f Bending, kneeling, or stooping	☐ 1	☐ 2	☐ 3
g Walking more than a mile	☐ 1	☐ 2	☐ 3
h Walking several hundred yards	☐ 1	☐ 2	☐ 3
i Walking one hundred yards	☐ 1	☐ 2	☐ 3
j Bathing or dressing yourself	☐ 1	☐ 2	☐ 3

4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Cut down on the amount of time you spent on work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Accomplished less than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c Were limited in the kind of work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d Had difficulty performing the the work or other activities (for example, it took extra effort)	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

5. During the <u>past 4 weeks</u>, how much of the time have you had any of the following problems with your work or other regular daily activities <u>as a result of any emotional problems</u> (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Cut down on the <u>amount of time</u> you spent on work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b <u>Accomplished less</u> than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c Did work or other activities <u>less carefully than usual</u>	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

6. During the <u>past 4 weeks</u>, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours, or groups?

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

7. How much <u>bodily</u> pain have you had during the <u>past 4 weeks</u>?

None	Very mild	Mild	Moderate	Severe	Very severe
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

8. **During the <u>past 4 weeks</u>, how much did <u>pain</u> interfere with your normal work (including both work outside the home and housework)?**

Not at all	A little bit	Moderately	Quite a bit	Extremely
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

9. **These questions are about how you feel and how things have been with you <u>during the past 4 weeks</u>. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time <u>during the past 4 weeks</u>…**

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Did you feel full of life?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Have you been very nervous?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c Have you felt so down in the dumps that nothing could cheer you up?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d Have you felt calm and peaceful?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
e Did you have a lot of energy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
f Have you felt downhearted and low?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
g Did you feel worn out?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
h Have you been happy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
i Did you feel tired?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

10. **During the <u>past 4 weeks</u>, how much of the time has your <u>physical health or emotional problems</u> interfered with your social activities (like visiting with friends, relatives, etc.)?**

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

11. **How TRUE or FALSE is <u>each</u> of the following statements for you?**

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
a. I seem to get ill more easily than other people	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b. I am as healthy as anybody I know	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c. I expect my health to get worse	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d. My health is excellent	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Thank you for completing these questions!

A*3:5 Feasibility Questionnaire*

To be asked by researcher at the end of six month interview

1. Did the information you received before starting the study prepare you for what actually happened in the study?

2. How do you feel about being involved in the study?

3. How did you find filling in the questionnaires?

4. If someone asked you to be involved in another similar study would you consider it?

(If in intervention group)

5. Did you have any problems take part in the Cardiac Rehabilitation programme?
6. Do you have any comments about the study or the Cardiac Rehabilitation programme that you would like to share with us?

A3.6 GRACE Score

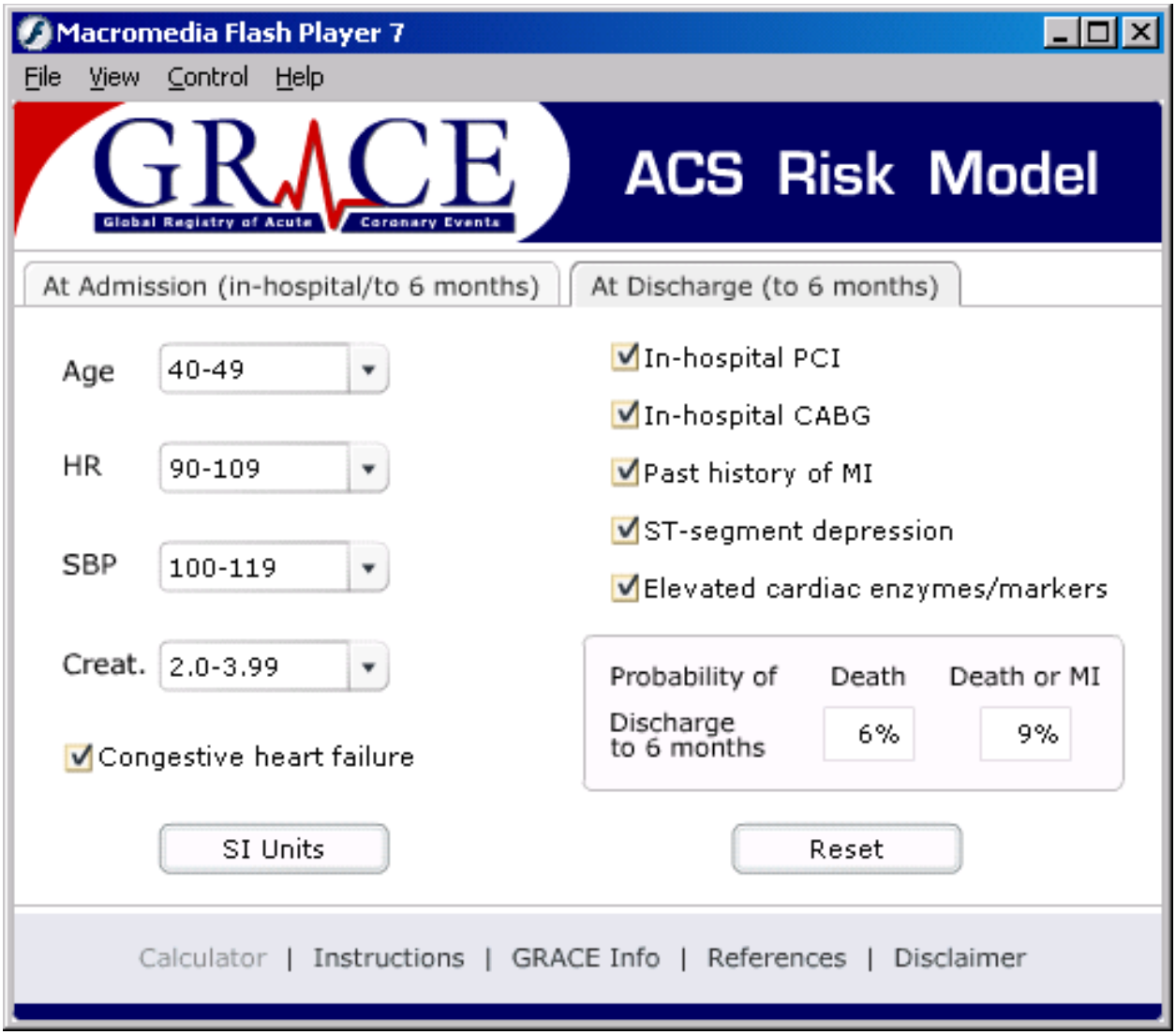


Figure 1. GRACE Prediction Score Card and Nomogram for All-Cause Mortality From Discharge to 6 Months

Risk Calculator for 6-Month Post-Discharge Mortality After Hospitalization for Acute Coronary Syndrome

Record the points for each variable at the bottom left and sum the points to calculate the total risk score. Find the total score on the x-axis of the nomogram plot. The corresponding probability on the y-axis is the estimated probability of all-cause mortality from hospital discharge to 6 months.

Medical History

① Age in Years — Points
- ≤29 0
- 30-39 0
- 40-49 18
- 50-59 36
- 60-69 55
- 70-79 73
- 80-89 91
- ≥90 100

② History of Congestive Heart Failure 24

③ History of Myocardial Infarction 12

Findings at Initial Hospital Presentation

④ Resting Heart Rate, beats/min ..... Points
- ≤49.9 0
- 50-69.9 3
- 70-89.9 9
- 90-109.9 14
- 110-149.9 23
- 150-199.9 35
- ≥200 43

⑤ Systolic Blood Pressure, mm HG
- ≤79.9 24
- 80-99.9 22
- 100-119.9 18
- 120-139.9 14
- 140-159.9 10
- 160-199.9 4
- ≥200 0

⑥ ST-Segment Depression ..11

Findings During Hospitalization

⑦ Initial Serum Creatinine, mg/dL — Points
- 0-0.39 1
- 0.4-0.79 3
- 0.8-1.19 5
- 1.2-1.59 7
- 1.6-1.99 9
- 2-3.99 15
- ≥4 20

⑧ Elevated Cardiac Enzymes 15

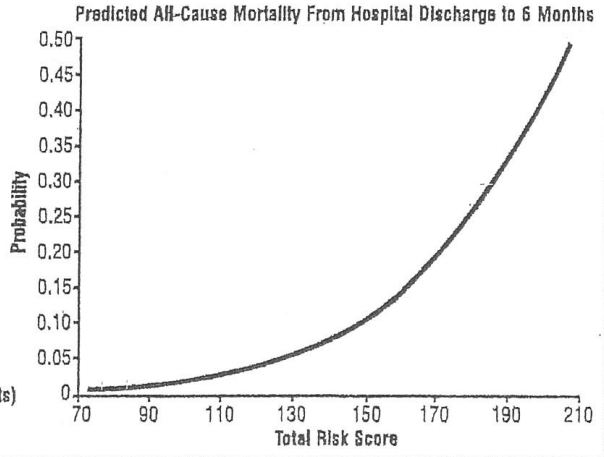
⑨ No In-Hospital Percutaneous Coronary Intervention 14

Points

① _____
② _____
③ _____
④ _____
⑤ _____
⑥ _____
⑦ _____
⑧ _____
⑨ _____

Total Risk Score _____ (Sum of Points)

Mortality Risk _____ (From Plot)



Eagle KA, Lim MJ, Dabbous OH, et al. A validated prediction model for all forms of acute coronary syndrome: estimating the risk of 6-month post-discharge death in an international registry. JAMA 2004; 291:2727-33. © Copyright 2004 American Medical Association.

A3.7 Data collection sheets

Demographics		
Name: Address Postcode:	NHS Number:	Participant number
Date of Birth:	Date of Death:	
GP Address		
Consent obtained	YES/NO	
Group	CONTROL/INTERVENTION	

	Date	Completed
Baseline assessment		YES/NO
Eight week assessment		YES/NO
Nine month assessment		YES/NO
2 year assessment		YES/NO
Withdrawn		reason

Participant number
Gender: Not Known ☐ Male ☐ Female ☐ Unspecified ☐
Marital Status: Single ☐ Married ☐ Permanent partnership ☐ Divorced ☐ Widowed ☐ Unknown ☐
Age on leaving full-time education: **Current Employment status:** Employed full-time ☐ Employed part-time ☐Self-employed full-time ☐ Retired ☐ Self-employed part-time ☐ Unemployed looking for work☐ Gov. training course☐ Looking after family/home☐ Permanently sick/disabled ☐ Temporarily sick or injured ☐ Student ☐ Other reasons ☐ Occupation if employed _____
Ethnic origin: White (British)☐ White (Irish)☐ White (other)☐ Mixed white/Asian ☐ Mixed other ☐ Indian☐ Pakistani ☐ Bangladeshi ☐ Other Asian ☐ Black African☐ Black other ☐ Chinese ☐ Black Caribbean ☐ Mixed white/black Caribbean ☐ Other Ethnic Group ☐ Mixed white/black African☐ Not stated ☐
Site Ayr Hospital ☐ Crosshouse Hospital ☐

Previous Events	
Acute Coronary Syndrome ☐ Bypass Surgery ☐ Angioplasty☐ Cardiac Arrest ☐ Angina ☐ Other Surgery ☐ HF ☐ Pacemaker ☐ ICD☐ Congenital Heart ☐ Transplant ☐ LV Assist Device ☐ Other☐ None ☐	
Weight: kg **Height:** cm	BMI:
Blood Pressure: / mm Hg	Has patient smoked in last 4 weeks: Yes ☐ No ☐ Is patient an ex-smoker ☐ Smokalyser reading _____ How many cigarettes per day _____ How active on a scale of 1-10 are you

Comorbidity
Angina ☐ Arthritis (osteoarthritis) ☐ Cancer ☐ Diabetes ☐ Stroke ☐ Osteoporosis ☐ Chronic bronchitis ☐ Emphysema ☐ Asthma ☐ HBP ☐ Claudication ☐ Rheumatism ☐ Chronic Back Problems ☐ Other Comorbid Complaint ☐
Cholesterol: Total: HDL: LDL: Ratio: Triglycerides: Troponin T
ECG: Exercise test: Echocardiography: Grace score (see attached info)
Previous interventions: Angiography ☐ Angioplasty ☐ Angioplasty with stent ☐ Bypass Surgery ☐ Thallium ☐

Follow-up medical treatment: Medical follow-up ☐ Rehab follow-up ☐ Both ☐ Angiography☐ Angioplasty with stent ☐ Bypass Surgery ☐ Thallium ☐
Drugs:
Aspirin ☐ Other antiplatelet agent ☐ ACE inhibitor ☐ BetaBlocker☐ Statin ☐ Other: ☐
Drugs:
Aspirin ☐ Other antiplatelet agent ☐ ACE inhibitor ☐ Beta Blocker ☐ Statin ☐ Other:

Examinations & Tests eight weeks **Participant no**	
Weight: kg Height: cm	BMI:
Blood Pressure: / mm Hg How active on a scale of 1-10 are you Pedometer reading over a week: Have you had a episode of chest pain over the last week Yes/No If Yes how many times : Is it worse or better than the pain you went into hospital with: Yes/No	Has patient smoked in last 4 weeks: Yes ☐ No ☐ ex-smoker ☐ Smokalyser reading _____ How many cigarettes per day _____

Further cardiac incidents :

Routine attendance at GP☐ Emergency attendance at GP☐ emergency call out of out of hours service ☐

Admission to hospital ☐

Outcomes:_____

Further treatments: Angiography ☐ Angioplasty☐ Angioplasty with stent ☐ Bypass Surgery ☐ Thallium ☐

other ☐

Examinations & Tests (nine months) **Participant no**	
Weight: kg BMI:	Blood Pressure: / mm Hg
How active on a scale of 1-10 are you Pedometer reading over a week: Have you had a episode of chest pain over the last week Yes/No If Yes how many times : Is it worse or better than the pain you went into hospital with: Yes/No	Has patient smoked in last 4 weeks: Yes ☐ No ☐ ex-smoker ☐ Smokalyser reading _____ How many cigarettes per day _____
Cholesterol: Total: HDL: LDL: Ratio: Triglycerides:	

Further cardiac incidents : Routine attendance at GP☐ Emergency attendance at GP☐ emergency call out of out of hours service ☐ Admission to hospital ☐ Outcomes:_____ Further investigations: Angiography ☐ Angioplasty ☐ Angioplasty with stent ☐ Bypass Surgery ☐ Thallium ☐ other ☐
Drugs: Aspirin ☐ Other antiplatelet agent ☐ ACE inhibitor ☐ Beta Blocker ☐ Statin ☐ Other:

Appendix Four: Article

A4.1 Article

Type of article	Research
Journal for submission	Journal of Cardiac Nursing
Title	Anxiety, Depression and Quality of Life in patients with Acute Coronary Syndrome
Authors	Janet McKay, Consultant Nurse Cardiac Care NHS Ayrshire & Arran Dr Ashley Shepherd, Senior Lecturer, University of Stirling Professor Kate Niven, University of Stirling
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Abstract

Cardiac rehabilitation (CR) has been shown to be effective in reducing mortality and morbidity in Coronary Heart Disease (CHD). There is a limited amount of research that evaluates the impact of menu-based CR, in patients with Acute Coronary Syndrome with low Troponin levels (ACSLT).

This feasibility study was a repeated measures case control study of menu-based CR using a range of health assessments. Participants (n=33) were recruited from cardiology wards following an admission with ACSLT. Both groups had an improvement in anxiety and their Health Related Quality of Life (HRQoL). Approximately 29% of the total study population were found to be depressed at baseline. A pattern of change across all the subscales of the SF36v2, was found that requires further investigation.

This study is an initial exploration of the experiences of individuals experiencing ACSLT and further work is required to explore how CR can best improve the psychological well being of individuals with ACSLT.

Key words: acute coronary syndrome, cardiac rehabilitation, anxiety, depression, quality of life

Introduction

Coronary Heart Disease (CHD) is a leading cause of death across the world, with Scottish CHD mortality amongst the highest in the United Kingdom (BHF 2012b). Significant attention has been paid over recent decades to reducing mortality and morbidity from CHD.

Acute Coronary Syndrome (ACS) is a term that has appeared over the last decade within the CHD medical terminology (Fox et al 2004). The diagnosis of ACS is determined by elements of the clinical presentation. These include a history of CHD, electro-cardiographic changes and raised biochemical markers such as Troponin T. Initially in the UK, there were three categories of ACS: ACS with clinical MI, ACS with myocyte necrosis, and ACS with UA (Fox et al 2004). However the Joint European Society of Cardiology/American College of Cardiology (ESC/ACC 2000) defined an MI as any troponin rise and did not accept the need for the category of ACS with myocyte necrosis. This debate led to differences in clinical practice across the UK.

Many people with CHD experience anxiety, depression, emotional and social disturbance, reduced Health Related Quality of Life (HRQoL) and failure to return to work (Petrie and Weinman 1997, Rugulies 2002, Shibeshi 2007). In a recent meta-analysis looking at anxiety as a predictor of medical prognosis after MI, Roest et al (2010) found that post MI anxiety is consistently related to adverse cardiac events. Between 31-45% of patients with CHD including those with stable and UA or MI suffer from clinically significant depressive symptoms (Carney 2008, Thombs 2008). Persistent psychological distress and poor social support are powerful predictors of

outcome following MI, independent of the degree of physical impairment (Hemingway and Marmot 1999).

Cardiac rehabilitation (CR) has been shown to be effective in reducing mortality and morbidity in CHD (Heran et al 2011). Healthcare is moving toward the goal of implementing evidence-based interventions that have been rigorously evaluated and found to be both efficacious and effective (Bowen et al 2009). However the design and evaluation of complex interventions, such as CR, is problematic. There are a large number of diverse components within a CR programme, including the theoretical framework, which, act and interact with one another to achieve a range of outcomes for the individual.

Despite a range of research on populations such as women (Williams et al 2006), ethnic minorities (Banerjee et al 2007), the elderly (Audelin et al 2008, Giallauria el al 2010) and a range of cardiac diagnosis (Davies et al 2004, Todd and Ballantyne 1992), the evidence base for CR remains predominantly male, middle aged and low risk and based on patients following a myocardial infarction (MI) or cardiac revascularisation procedure (Heren et al 2011). There is also a limited amount of research that evaluates menu-based CR.

This study focused on patients with ACS with myocyte necrosis, more commonly described as, ACS with low troponin (ACSLT) (Troponin T<1ng/ml). DAS et al (2006) found significant differences in the treatment of patients with ACSLT compared to MI, with less prescription of recommended drugs such as beta-blockers, ace-Inhibitors and statins. The relatively limited use of interventional strategies and of short term and secondary prevention drugs further suggested that

patients with ACSLT would benefit from early identification and from being treated more aggressively.

Prior to 2007, patients with ACSLT would not have met the referral criteria in place in the majority of CR programmes (Lewin et al 2004). Research has shown that the morbidity and mortality of patients with ACSLT is similar to those diagnosed with MI (SIGN 2007), yet there is limited data on other outcome measures for this population such as anxiety, depression, and HRQoL. There has also been limited research on the impact that menu-based CR might have on outcomes for these individuals.

Aim: The aim of this study was to examine the feasibility of a randomized controlled trial (RCT) which would test the impact of a menu-based CR programme, on individuals diagnosed with ACSLT, against standard care. It also aimed to explore the impact that CR had on this client group.

Research design: This feasibility study employed repeated measures of a range of health assessments in two cohorts of patients who had experienced an admission with ACSLT. The study was conducted in 2007, prior to the change in definition of ACSLT.

Ethical approval

Ethical approval was obtained from the Ethics Committees of the local Health board and the University of Stirling. Written permission to contact patients was received from consultant cardiologists. The study was conducted within the research governance framework of the NHS in Scotland.

Method

Recruitment : A study information sheet was made available to all patients admitted to hospital with an ACSLT. Any patient expressing an interest in the study was directed to speak to the investigator, at which point any queries which the patient had were addressed. Those who agreed to participate were requested to provide informed consent prior to the completion of the five questionnaires.

Sample size: Patients were recruited during their index admission. A consecutive sample of patients (n = 33) was recruited over a 12-month period from the coronary care units of two District General hospitals. One cohort received standard care (n=19) and the remaining patients received a CR intervention (n=14). Recruitment was stopped in November 2007 due to the change in diagnostic criteria noted above. The inclusion criteria were: aged 16 or over, no previous attendance at CR, able to read and speak English, diagnosed as ACSLT. Additionally, anyone with a terminal illness was excluded from the study

Measures: The study included three widely used screening questionnaires standardised for use with physically ill populations: The Hospital Anxiety and Depression Scale (HADS), Schedule for the Evaluation of Quality of life- Direct Weighting (SEIQoL-DW) and the SF36v2, all of which have been validated in cardiac populations (Dempster and Donnolly 2000). The HADS (Zigmund and Snaith 19) is a 14-item measure for symptoms of anxiety and depression, which focuses on non-somatic indicators of anxiety and depression to allow for the identification of such difficulties in physically ill populations. Index score ≥7 is thought to indicate caseness for both the anxiety and depression subscales (Bambauer et al 2005).

SEIQoL-DW is a QoL measure which is derived from the Schedule for the Evaluation of Individual Quality of Life (SEIQoL) (O'Boyle et al. 1993). It is a short form of the original SEIQoL and was validated against the original by Hickey et al (1996). The practicality and brevity of this measure make it useful in clinical situations where QoL is important. It has been shown to have high levels of consistency and validity with older medical patients, stroke, cancer and palliative care patients, and has been found to be acceptable and practical to use with these patient populations (Campbell and Whyte 1999, Waldron et al 1999; O'Boyle and Waldron 1997, Hickey et al. 1996). The measure allows participants to nominate the areas of life which are most important, rate their level of functioning or satisfaction with each, and indicate the relative importance of each to their overall QoL. An overall QoL score can then be calculated.

The SF36v2 has been used in a wide variety of cardiac populations when assessing HRQoL (Lavie and Milani 1995, Mendes de leaon et al 2001). It has been well validated and has proven useful in monitoring general and specific populations, comparing the burden of different diseases, differentiating the health benefits produced by different treatments, and in screening individual patients. This comprehensive short-form with only 36 questions yields an 8-scale health profile as well as measures of HRQoL. The scales of each question are coded summarised and transformed into a scale of 0 (the worst possible QoL) to 100 (the best possible). The SF36v2 also provides a summary of several of the scales to two components.

Demographic and clinical information

A standard demographic form was used to collect self-report data on age, gender, ethnicity, marital status, education, and employment status. Participant health status and diagnosis were obtained via medical notes review.

Cardiac Rehabilitation intervention

The intervention utilised within this study was a menu-based CR programme, as currently provided within NHS Ayrshire &Arran, which utilises the CSM as its theoretical framework (Leventhal et al 2003). Participants in the intervention group were referred to the specialist CR team while in hospital and were followed up for four months. The number and types of interventions provided can be seen in Table 1

Insert Table one

Procedure

Following participant consent, patients completed a compiled booklet including all measures described above and a form to collect demographic information. The questionnaires were completed in the ward prior to discharge (T1) and during an interview at home at nine months (T3).

Insert figure one

Data analysis

Statistical analysis was performed using SPSS for Windows (version 15.0). Descriptive and comparative analysis was carried out to provide background information (e.g. age, employment status, diagnosis, medical history) regarding the sample. Results were then analysed according to treatment group.

Results

Demographic and clinical characteristics

Eight patients were lost to follow-up at 9 months, 2 died, 3 were withdrawn due to ill health and 3 failed to respond to repeated contact by letter. Twenty five patients completed the study. During this period 11 received a package of CR and 14 did not. The small numbers within the study mean that the data can only be viewed as exploratory in nature. The demographic characteristics of the sample for the present study are shown in Table 2, including age, gender, marital status, and deprivation status. All participants in the study were on aspirin and the prescription rates of the three remaining secondary prevention drugs were, statins (92%), beta-blockers (84%) and ace-inhibitors (64%).

[INSERT TABLE 2 HERE]

Anxiety and depression

The HADS measures two key psychological factors, namely anxiety and depression. This study found that means in both groups were greater than 7 (mildly anxious) at T1 and that in the control group they remained greater than 7 (mildly anxious) at T3. Anxiety levels in the intervention group had fallen to within normal ranges at T3. There was little change in mean anxiety levels between T1 and T3 in the control group. However the intervention group had higher levels of mean anxiety at T1 and this had reversed at T3. The relative change between the two time points was -0.08 in the control group and- 2.73 in the intervention group. There was a wide variation in individual scores in the control group between T1 and T3 with half the control group showing a worsening of anxiety levels and half showing improvement, therefore leading to little mean change.

[INSERT FIGURE 2 HERE]

The control group was more depressed at baseline and at T3, but the relative change between T1 and T3 was 0.73 in the control group and 1.4 in the intervention group. It is important to note that within the control group there were four participants who presented with scores greater than 10. This level of depression would be treated as requiring intervention in clinical practice. Of these four participants, two had reduced their score below 11 and the other two continued to score high levels of depression at T3. Within the intervention group there were no individual scores above 10 at T1 and only one at T3. Approximately 29% of the study population had some degree of depression throughout the period of the study

[INSERT TABLE 3 HERE]

Quality of life

Global QoL was measured using the SEIQoL-DW, while HRQoL was measured using the SF36v2. Twenty four participants completed a SEIQoL-DW at T1 and T3. They had to identify five variables that made a difference to their QOL. Of these, nineteen stated that their family was the main contributing variable to their QOL, rising to 21 at T3, with most suggesting that it represented approximately 50% of the total score. Three participants at baseline stated that their health was the main contributor to their QoL, with an additional one stating faith and one work.

The second most important contributor was often defined as health with eleven participants identifying this and three identifying work. The five who had not chosen family as variable one, did choose it as variable two. In many cases the second variable represented around 20-30% of the total score.

The last three variables picked by the participants varied quite a lot but can be summarised as social arrangements. These could be holidays, pets, hobbies or a range of other items which related to entertainment. These often had values of between 5-15% of the total score. Any differences between the groups at T1 and T3 did not reach statistical significance. But both groups had an improvement in their QOL as measured by SEIQoL-DW across the time of the study with the mean change being 5.35 in the control group and 8.47 in the intervention group

SF36v2 has several different components and can be analysed compared to a variety of populations. Two key scales are the physical care summary and mental health care summary scales. A small improvement in QoL is noted in the mental health scale of the SF36v2, with the control group improving slightly more than the

intervention group, however the control group started from a lower baseline on this scale. This may also reflect the results found on the HADS scale, which showed a higher level of depression in the control group at T1. The results, on the physical summary scale show a slightly different picture; here the control group stay the same and the intervention group improve by 8.

There are eight subscales of the SF36v2 and if we consider the control group first we can see a mixed picture of improvement and deterioration. Physical functioning, role physical, and general health seem to deteriorate, and vitality, social functioning and role emotional improve. In the intervention group only general health appears to deteriorate. All other factors appear to improve.

[INSERT FIGURE Three HERE]

Information on norms within different groups are available for the SF3v2 and at T1 the control group was worse than the CHD norms on all factors except role physical and the intervention group was worse than the norm on everything except general health, role emotional and physical functioning. At T3 the control group was below the norm on all factors except bodily pain, role emotional and the physical summary scale and the intervention group was consistently above the norms across all factors.

Discussion

Demographic and clinical characteristics: During this study, the incidence of ill health and death was high (15%), with 9% crossing over from control to intervention group, and an additional 9% lost to follow-up. This combination of events is however recognised in other CR trials. In a Cochrane review of exercise rehabilitation by

Joliffe et al (2004), it was noted that losses to follow up within many trials were high, but often not adequately described. This was also noted in the review of home-based CR versus hospital where losses to follow up varied considerably across all studies (Taylor et al 2010). Within many studies groups were analysed according to initial random allocation. This trial however used a final group design in that the data was analysed by the final outcome for the individual, control or treatment.

Anxiety and Depression

The literature tells us that anxiety and depression are common in various patient groups with CHD (Carney 2008, Roest et al 2010). Whalley et al (2011) in the latest review of psychological interventions in CHD argue that psychological interventions may produce small to moderate reductions in depression and anxiety, and may also reduce cardiac mortality. As part of the CR programme, patients in the intervention group received psychological assessment and intervention where required (see Table 1). The incidence of anxiety and depression noted in the literature is reflected in the study participants, several of whom reported high levels of anxiety and depression. Across the timescale of this study there was a reduction in anxiety in both groups with the tendency to benefit favouring the intervention group.

Quality of life

Family is mentioned by all patients and ranked highly. This pattern of family, health, followed by social activities has also been noted in patients with cancer (Campbell and Whyte 99), and diabetes (Walker and Bradley 02). The results from this study show that both groups had an improvement in their global QoL as measured by

SEIQoL-DW across the time of the study with slightly larger changes in the intervention group.

The use of the SF36v2 is advantageous in allowing comparisons across disease states and populations. Chan et al (2005) examined HRQoL using the SF36v2 in a group of 182 CR participants that included some with ACSLT and found significant differences in SF-36 scores for all eight subscales: physical functioning, limitations due to physical health problems, bodily pain, general health, vitality, social functioning, limitations due to emotional health problems and mental health. The main differences were higher mean scores on all subscales of the SF-36 at the 6-month period, as compared with baseline data for those who received an intervention. Within this study the control group had a mixed picture of improvement and deterioration and in the treatment group, with the exception of general health all factors appear to improve. This study has highlighted a pattern of change across all the subscales of the SF36v2, within a defined subgroup, that requires further investigation.

Cardiac Rehabilitation and ACSLT

This study was a feasibility study of ACSLT and the changed definition of MI meant that patients could no longer ne recruited as they became eligible for CR. However the evidence base for CR is primarily based on trials conducted on MI populations prior to the reclassification of MI and the results of those trials cannot be applied without some reservations to this patient group. This study has highlighted that there is a need for further research on the impact of menu-based CR in this area. Clinicians working within CR require more information on which to base their clinical

practice and the updated MRC framework for researching complex interventions may provide some direction for future research.(MRC 2008).

Limitations: Although the study provides useful information for practice, its limitations must be acknowledged. It was carried out at two district general hospitals in the west coast of Scotland and the findings may not generalise to areas where clinical practice is different. The sample was small and no significant differences were found. The control and intervention groups had substantial drop-outs throughout the course of the study and in addition there were three participants who crossed from the control to intervention group due to further cardiac events.

The study population consisted of a high number of males versus females and the experiences of the women may not have been adequately reflected within the data that was collected, in addition all the participants came from a white Scottish ethnic background. This reflects the local population but limits the applicability of the results to other ethnic populations. Furthermore, it was a requirement of the study that participants could read and understand English, which resulted in the exclusion of people who required interpreters.

Conclusions: The experiences of individuals experiencing an ACSLT have largely been unexplored and the study's findings in this regard are important. They are an initial exploration of an important subgroup of patients with CHD and, further work is required to explore how CR can best meet the needs of this subgroup. These findings are in line with the substantive literature that suggests that CR has positive benefits for a wide range of individuals from a wide variety of backgrounds, with a wide range of CHD pathology (ref). The updated MRC framework (ref) suggests

different ways to assess a complex intervention such as CR and it is possible that a comparative study looking at the recovery of individuals by troponin levels using both quantitative and qualitative measures could provide useful information that would guide service provision.

Recommendations: Further research studies on the experiences of individuals with ACSLT are needed to expand the existing body of knowledge on CR and to ensure that CR services are responsive to the needs of their clients.

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Key Point sentences:

- Cardiac rehabilitation is now a cornerstone in the recovery process for individuals following a cardiac event
- Levels of anxiety and depression have been noted in patients with ACSLT similar to those found in patients with MI
- family, health, followed by social activities are the key domains of QoLfound in this study
- ACSLT is now classified as MI
- the evidence base for CR based on trials conducted on MI populations prior to the reclassification of MI cannot be applied to ACSLT without some reservations

- Further research studies on the experiences of individuals with ACSLT are needed

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Table ***1 CR interventions in the intervention group***

Participant code/Intervention group	219	220	222	223	224	225	106	107	108	109	110
Education (nurse)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Risk factor management (nurse)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Exercise advice (physio)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Medication advice(nurse/pharmacist)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Healthy eating (nurse/dietician)		✓		✓	✓		✓	✓	✓	✓	✓
Specialist smoking cessation advice	✓	✓									
Outpatient programme or Home programme (i)		✓	✓	1/2	✓		✓	1/2	✓		

Table 2 Baseline demographic factors on admission

	Study groups				Overall total		
	Control group		Intervention			tota	s
	%	cou	%	coun	%	Co	
Gender							
M	78.5	11	63.6	7	7	18	n
F	21.5	3	36.4	4	2	7	
Age group							
<50	7.1	1	27.2	3	1	4	n
50-59	42.8	6	36.4	4	4	10	
60-69	28.5	4	18.2	2	2	6	
70-79	7.1	1	9.1	1	8	2	
>79	14.2	2	9.1	1	1	3	
Mean age		61.7		57.2		59.	
Marital status							
Living alone	21.4	3	9.1	1	1	4	n
Married/with partner	78.6	11	91	10	8	21	
Employment status							
Working	28.6	4	45.4	5	3	9	n
On Sick	35.7	5	9.2	1	2	6	
Retired	35.7	5	45.4	5	4	10	
Depcat class							
1-2	14.3	2	18.2	2	1	4	n
3-4	28.6	4	27.3	3	2	7	
5-6	57.1	8	54.5	6	5	14	

Figure 1 Flow chart of withdrawals

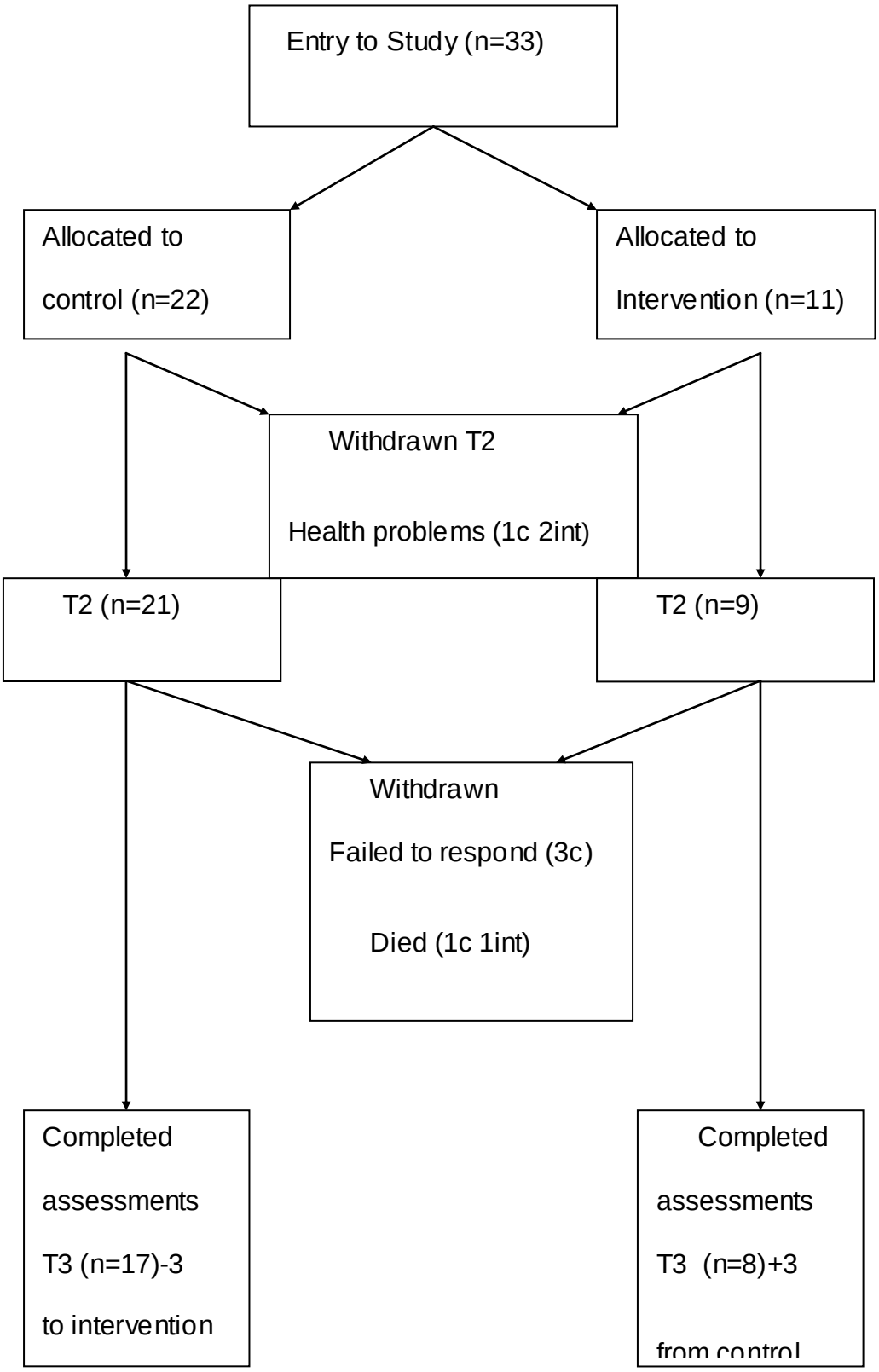


Figure 2: Change in anxiety scores

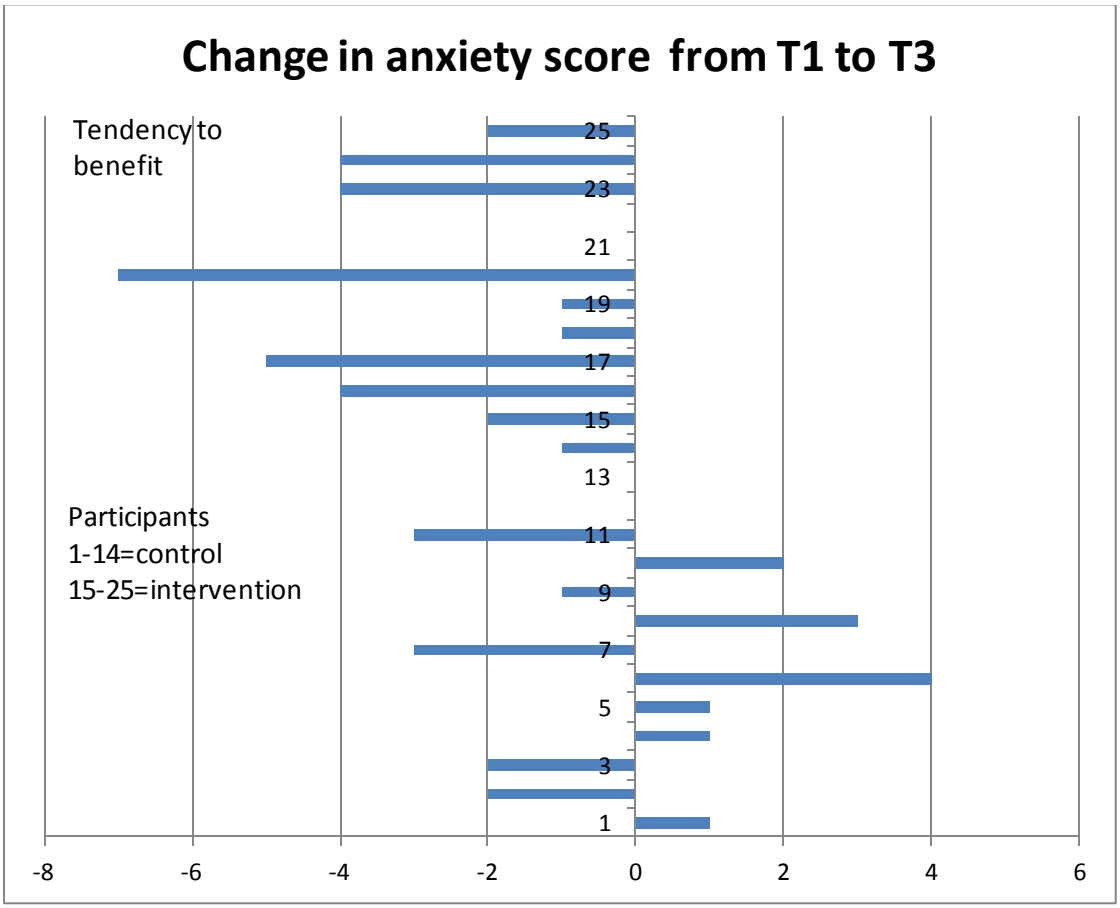
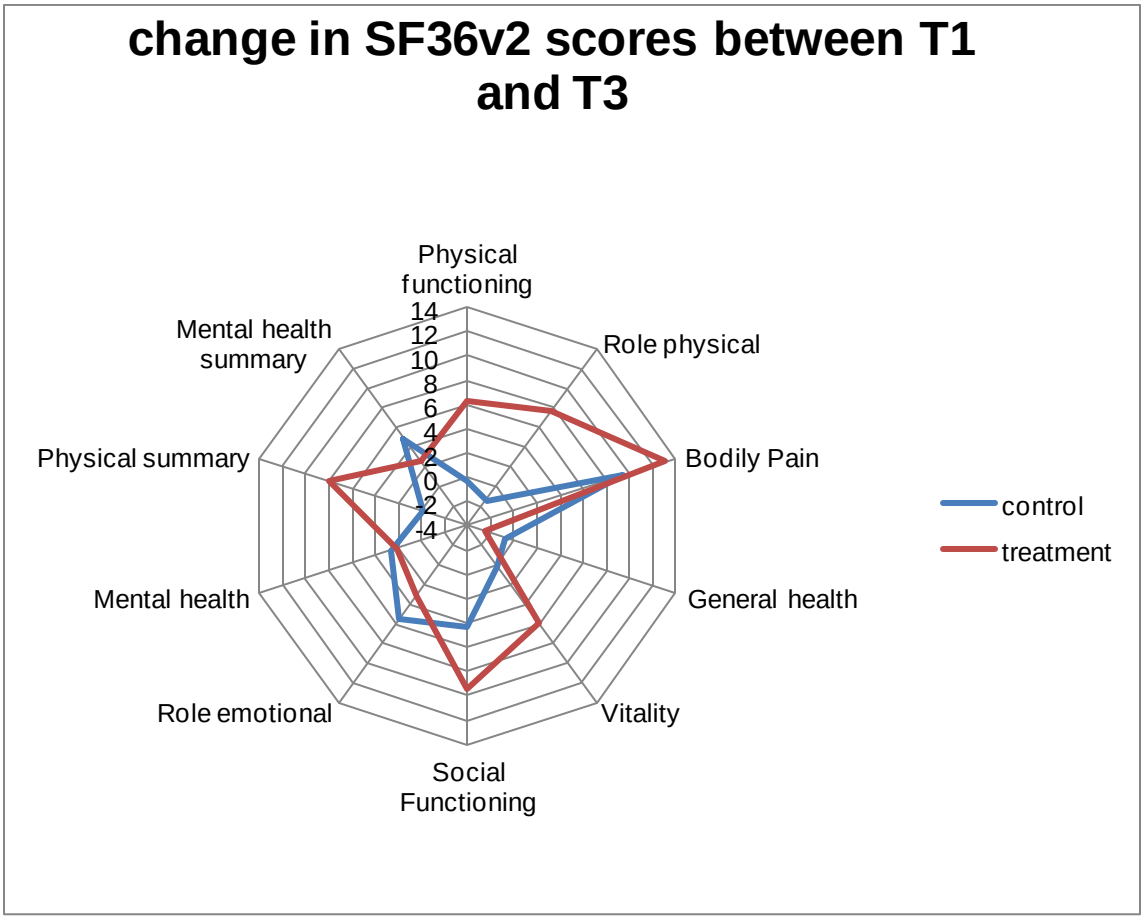


Table *3 Depression Scores by category at T1 and T3*

	control				intervention			
	T1		T3		T1		T3	
	%	cou	%	cou	%	cou	%	cou
0<7	57	8	57	8	82	9	91	10
7-10	14	2	21.5	3	18	2	0	0
>10	29	4	21.5	3	0	0	9	1

Figure 3


change in SF36v2 scores between T1 and T3
Physical functioning
Role physical
Bodily Pain
General health
Vitality
Social Functioning
Role emotional
Mental health
Physical summary
Mental health summary
14
12
10
8
6
4
2
0
-2
-4
control
treatment

A4.2 Guidelines for submission

British Journal of Cardiac Nursing,
Vicqui Stuart-Jones, tel.: 020 7501 6769, email: bjcardn@markallengroup.com

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Additional information

Clinical article
Clinical articles should be between 2000–2500 words. It is therefore suggested that you focus your article on an aspect of a clinical topic in depth rather than trying to cover the whole topic. For example, if you were writing an article on acute coronary syndromes, it would be better to focus on the care of a patient with either non-ST elevation MI or ST elevation MI and then to discuss the treatment in the acute phase. Another article could then explore risk factors or investigations or rehabilitation. A clinical article should include the latest evidence-based guidelines /research relating to the topic.

Care Study
Care studies should be between 1500-2000 words. As the title suggests, articles in this category should focus on the care of an individual with a cardiac related condition, following an episode of care. It would be interesting for the reader if as much information about the patient (ensuring confidentiality) is included as succinctly as possible. A multi disciplinary theme would also be useful.

The article should provide information about the presenting condition of the patient, starting with how he/she presented to the author's clinical area. The article should include the patient's medical and social history, any risk factors for his/her condition, current medications, his/her clinical observations (if possible) and results of any other initial tests (e.g. ECG). There should also be a discussion about the treatment that was given to the patient and how he/she might be followed up. Please see notes about consent above.

If the author chooses to adopt a reflective approach for the care study to identify personal learning gained, it is recommended that a framework is used to guide this process. Some useful references are

Boyd E, Fales A (1983) Reflecting learning: key to learning from experience. *Humanist Psychol* **23**(2): 99–117

Carper B (1978) Fundamental ways of knowing in nursing. *Adv Nurs Sci* **1**(1):13–23

Durgahee T (1976) Promoting reflection in post graduate nursing: a theoretical model. *Nurse*

Educ Today **16**: 419–26

Gibbs, G (1988) *Learning by Doing. A Guide to Teaching and Learning Methods.* Further Education Unit, Oxford Polytechnic, Oxford

Drug Focus
The aim of this section is to provide the nurse giving the medication a sound background knowledge about a specific drug or group/class of drugs, to ensure safe use. It should contain a discussion of the background physiology/pathophysiology, the pharmacology (including pharmacodynamics and pharmacokinetics) of the drug, indications for use, any licensing issues (e.g. only available on a named patient basis) the side effects, contraindications and nursing considerations, particularly with regard to patient information.

Practical Procedures both invasive and non-invasive
A usual word length is around 2000 words. These articles would normally include

- Indications and contraindications for the procedure including the evidence base, any related pathophysiology and any consent issues (e.g. acute setting, unconscious patient etc).
- A description of the procedure including required patient preparation, equipment/environment
- Complications to include common and rare, how to identify that they have occurred and any immediate or follow-up actions required
- Nursing care including patient information

Research articles
Research articles can be primary qualitative or quantitative research or a systematic review. They should be between 3000–4000 words and follow the traditional research structure:

- Introduction / background
- Aim(s)
- Research design
- Methods and methodology
- Results
- Discussion
- Conclusion/recommendations
- Acknowledgement(s)
- References

Background
This should outline what is already known about the subject area, including any previous research studies. The author should demonstrate sound rationale for undertaking the study and their chosen design.

Aim(s) or research questions
What the author hoped to achieve or answer by undertaking their study e.g. gain greater insight in to the experiences of women in primary care coronary heart disease prevention clinics *or* 'What are the experiences of women in coronary heart disease prevention clinics within a primary care setting?'.

Research design
Was qualitative or quantitative approach utilised and why? Outline chosen design and justify this design over other possible designs.

Ethical issues
May link with design and methodology. Please see above under general guidelines.

Methods and methodology
There should be sufficient detail in this section to enable other researchers to replicate your work. Additional headings may help to structure this section e.g. sample, procedure, data collection methods (including information regarding reliability and validation of any tools used in quantitative studies and approaches used to address issues around study rigour in qualitative studies) and analysis.

If submitting a review article please explain the nature of the review e.g. high quality traditional literature reviews, aggregative and interpretive reviews, qualitative, quantitative and mixed method systematic reviews, meta-analyses, meta-summaries and meta-syntheses. Details of the search strategy (databases searched with dates, search terms used, exclusion and inclusion criteria combined with rationales for your choices) should be included).

Results
If pertinent, this section may be subdivided with further headings. Data should not be presented in both text and tables.

Discussion
The author should relate his/her findings to previous research and relevant clinical practice, commencing with any unique findings of their study. This section may also contain information regarding any limitations to the study and therefore findings/generalisability.

Conclusions/recommendations
What do the results contribute to current and future clinical practice? Is further research needed to fully answer the original questions or fulfil the aim(s)? Based on the findings, what do the authors recommend as 'next steps'?

Acknowledgement(s)
These should include any funding bodies/grants that supported the research or contributed to the salaries(s) of any of the authors, acknowledgement of any particular units/wards or individuals who helped ensure the success of the project or assisted with writing it up.

References
As previously detailed.

Practice/service development or innovation (to include clinical audit)
These articles should be between 2000-3000 words and may follow a very similar structure to research articles, depending on the focus. If the project is clinical audit, the authors should include information regarding the audit cycle, recognized practice standards and clinical governance issues.

Career Focus
These should be 1000-1500 words. The aim of these articles is to give the reader an understanding of a particular role and an awareness of the types of roles he/she may be interested in for the future. The author may wish to describe the route he/she followed and the qualifications needed. For more detailed guidance please contact the editor.

Appendix Five Protocols

A5.1 In-Hospital Education programme

- A full explanation of the structure of the heart and the process that causes Acute Coronary Syndrome
- Risk Factors associated with CHD

  Topics such as smoking cessation, diet, lack of exercise, hypertension and diabetes will be discussed if appropriate.
- Assessment of Psychological functioning should take place using the Hospital Anxiety and Depression scale
- Return to Normal

  The patient and their spouse will be advised about topics such as

  Mobility

  Managing chest pain

  Return to work

  Marital relations Drugs

  Driving

  Resuming hobbies

  Sexual activity

Discharge planning

At this time it is important to recognise any issues that might impede the return to normal of the client and their family and referrals are often made to other agencies. This includes

- Fitness assessment by the physiotherapist/occupational therapist
- Information on drugs by pharmacist
- Home help referral to Social Work if appropriate

A5.2 Guidelines for psychological assessment

1. All patients prior to discharge should be assessed using the Hospital Anxiety and Depression scale. This will provide baseline data for future assessment.

2. All patients should be assessed at four weeks as part of the routine review.

3. Any patient with a score greater than 10 should be discussed with the acute rehabilitation team and General Practitioner with regards to future management.

4. Any patient with a score of greater than 7 should be reassessed within a fortnight and if the score remains higher than 7 should be discussed with the acute rehabilitation team and General Practitioner with regards to future management.

5. All patients should have a final assessment prior to discharge from the programme.

6. The HAD scale is only suitable for use with individuals with no prior history of Psychiatric illness.

A5.3 Staff standards for phase three Cardiac Rehabilitation

1. All staff involved with cardiac patients should have Basic Life Support Training.

2. B.L.S. training should be updated annually.

3. At least one member of staff should be trained in A.L.S., able to recognise V.F. and defibrillate.

4. Procedures for cardiac arrest should be rehearsed and recorded.

5. CPR training should be offered to patient's spouses and families.

6. Staff should keep a personal development log to record relevant ongoing learning.

Based on 'Cardiac Rehabilitation – Guidelines and Standards, D.R. Thomson, G.S.

Bowman, A. Hopkins et al © 1997 Royal College of Physicians, London.

A5.4 Phase three exercise class standards

Aims

- To increase patients knowledge about the benefits of exercise.
- To enable patients to exercise symptom free/manage their own symptoms.
- To enable patients to exercise within their own personal limits, safely using any equipment.

Staffing

- Two Cardiac Rehabilitation professionals present at all times during exercise.
- Aim towards a staff: patient ratio of 1: 5 as recommended by B.A.C.R.
- All new patients have a named member of staff to work with them on their first day.

Classes

- Are offered twice weekly at two different sites (Ayrshire Central Hospital and Crosshouse) for equity of local access.
- The class should consist of a low impact aerobic warm up lasting around 15 minutes and including major muscle group stretches.
- This should be followed by a 20 minute conditioning phase – circuit training.
- Patients work up to a target heart rate that is individually set and self monitor using the Borg Scale of Exertion.

- This is followed by a cool down – low intensity activities and muscle stretching of 10 minutes duration.
- Relaxation.
- Individuals record their attendance and pulse response to exercise at every class.
- Patient documents are reviewed monthly for pulse aberrations by the physiotherapist, those patients with problems are then reviewed individually.
- Patients normally can attend for three months.
- Patients are discharged with the option of attending a Phase IV maintenance class if this is appropriate.

The patients G.P. is notified of attendance and any other relevant information.

A5.5 Phase three entry standards – exercise programme

AIM

Screening and risk stratification of patient's prior to recruitment to the exercise component of phase III cardiac rehabilitation.

- All patients should have a signed consent form/letter from their cardiologist, G.P. or surgeon.
- All patients will be assessed by the physiotherapist prior to entry to the class.
- Phase III exclusion criteria – see attached sheet.
- All patients should be given at date for starting class at the six week review clinic.
- All patients should receive written information preparing them for entry into class prior to assessment – see attached sheet.

Monitoring – Possible through documentation audit.

A5.6 Phase three physiotherapy assessment standard

Aim: To identify problems that may influence participation in the class.

Assessment should be written and include

Subjectively:

Presenting condition and investigations

Social history

Drug history

Past medical history – specifically: Asthma/Epilepsy/ Diabetes

Joint Problems/Depression

Objectively: Heart rate/Blood pressure

ETT result

Echocardiogram result

Angina/Orthopnea

Palpitations/ Ankle Swelling

Dizziness

BMI (if appropriate)

HAD scale (if appropriate)

1. All patients should be taught how to monitor their pulse with written advice available.
2. All patients should be familiarised with the Borg Scale.
3. Patients should be given individual advice on any co-morbidity problem that may affect them exercising.
4. All patients should be familiarised with fire exits, changing and toilet facilities.
5. All patient should be familiarised with documentation, clothing.
6. Induction also includes:

   Monitoring during exercise

   The importance of advising staff on changes in symptoms and medication

   Advice re eating prior to class if necessary

Based on CSP Standards for Phase III Cardiac Rehabilitation. June 1999.

A5.7 Exclusion criteria phase three

1. Acute pericarditis, myocarditis.
2. Exercise induced ventricular arrhythmia's.
3. Aortic Stenosis.
4. Acute Febrile illness/viral infection.
5. Uncontrolled resting hypertension > 200/100 mmHg.
6. Severe Cardiomyopathy.
7. Some psychiatric disorders.
8. Thrombophlebitis – if requiring active treatment.
9. Aortic aneurysm.
10. Recent pulmonary embolus.

A5.8 Health & safety

1. There are a minimum of two C.R. health-care professionals present at all times during exercise.
2. The recommended ratio of staff : patients is 1 : 5.
3. All patients are observed during the exercise session.
4. No patient should leave class complaining of any cardiac symptoms.
5. There is a clear emergency protocol.
6. All classes are within close proximity to a telephone and to resuscitation equipment.
7. All resuscitation equipment is checked weekly.
8. All exercise equipment is checked annually.
9. The temperature should ideally be 65 - 72°.
10. Drinking water is always available.

Based on CSP Guidelines for Cardiac Rehab Phase III, Published Jan 2000.

A5.9 Phase three emergency protocols

1. Each class should be attended by a minimum of two members of staff, one of which should possess an A.L.S. qualifications, all others B.L.S. (annually updated).
2. A defibrillator and emergency trolley and telephone should be situated in the immediate vicinity of the class.
3. Emergency equipment should be checked weekly.
4. Cardiac class staff should rehearse and record an arrest situation.
5. Any acute coronary incident should be reported to
   i) cardiac rehab officer
   ii) clinical services manager
   iii) relevant cardiologist

   within one working day and the local R.T.O. within five working days.
6. All staff should be debriefed within five working days.

Phase three roles in an arrest scenario

Aim

To act quickly and safely in treating casualty while keeping other patients calm and clear of causing an obstruction.

Person 1 (C.R. Nurse)

- Stays with patient assessing and treating as appropriate.

Person 2 (C.R. Physio)

- Bring defibrillator
- Bring emergency trolley
- Make crash call (3333 Crosshouse, 2222 Ayrshire Central Hospital)
- Call ambulance ((9)999))
- Return to assist with patient.

Person 3 (Physio Assistant)

- Clear room of all unaffected patients
- Return to casualty if required
- Keep unaffected patients calm
- Direct crash team/paramedics to casualty.