THE UNIVERSITY OF HULL

ILLNESS PERCEPTIONS OF HEART FAILURE PATIENTS WITH AN IMPLANTED DEVICE: RELATIONSHIP TO PSYCHOLOGICAL DISTRESS AND QUALITY OF LIFE

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SARAH KATE EATON

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ABSTRACT

Background:

CRT and CRT-D are implanted cardiac devices used in the heart failure population. To date, there is an absence of research examining psychosocial functioning and non-medical predictors of CRT and CRT-D patient outcomes.

Main Aim:

To utilise Leventhal's self-regulatory model as a framework for examining cognitive and emotional representations in CRT and CRT-D patients. Factors considered were: anxiety, depression, physical and mental quality of life.

Methodology:

A cross sectional questionnaire based analysis of 151 participants split between three cardiac device groups (CRT, CRT-D and ICD). Measures used were, the Illness Perception Questionnaire-Revised (IPQ-R), the Hospital Anxiety and Depression Scale (HADS) and the Short Form 12 Health Survey (SF-12).

Results:

A significant number of patients, across device groups, reported clinically significant anxiety and depression. Physical quality of life was significantly reduced in all device groups. In contrast, mental quality of life was within the average or above average range. Experience of reduced symptoms and a perception of the device as 'in control' were predictive of lower levels of depression. A perceived lack of personal control and unpredictable symptoms, were common to all groups, and was predictive of anxiety and reduced quality of life. Clinical implications and suggestions for future research are discussed.

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CHAPTER ONE

INTRODUCTION

This chapter will begin by providing a brief introduction to the functioning of the heart, and the problems experienced by patients with heart failure. The role of the Cardiovascular Resynchronisation Therapy Device (CRT) and the Cardiovascular Resynchronisation Therapy Defibrillator Device (CRT-D) in the treatment of heart failure patients with electrical conduction abnormalities and life threatening heart rhythms will be outlined. Existing research on psychological distress and quality of life in heart failure patients will then be reviewed. Finally, the concept of illness perceptions and the literature on perceptions in both cardiac and non-cardiac populations will be examined.

1.1 INTRODUCTION TO THE HEART

The heart is essentially two distinct, but anatomically connected muscular pumps (**Figure 1.1**). These are:

1) The Right sided pump – Receives blood from the body (muscles and organs) and pumps blood into the lungs to gather oxygen and remove carbon dioxide.

2) The Left sided pump – Receives oxygen-rich blood from the lungs and pumps it out through the arteries to all parts of the body, including the heart muscle itself.

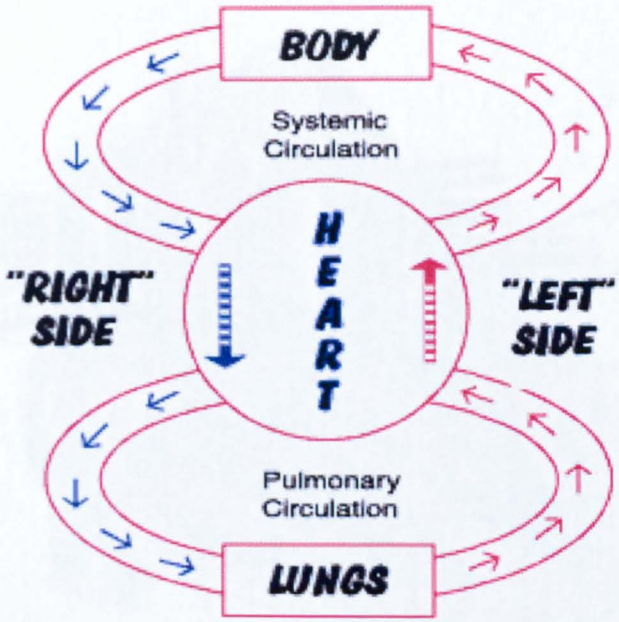


FIGURE 1.1 THE FUNCTIONING SYSTEM OF THE HEART (Heart Failure Online, 2007)

The heart has four chambers, two at the top (the right and left atria) and two at the bottom (the right and left ventricles). Between each atria and ventricle is a valve, which ensures that the blood flows in one direction (the tricuspid valve and mitral valve). Blood enters the heart through the atria and is then pumped via the valves into the ventricles. It is the strong pumping action of the ventricles that pumps the blood away from the heart (**Figure 1.2**).

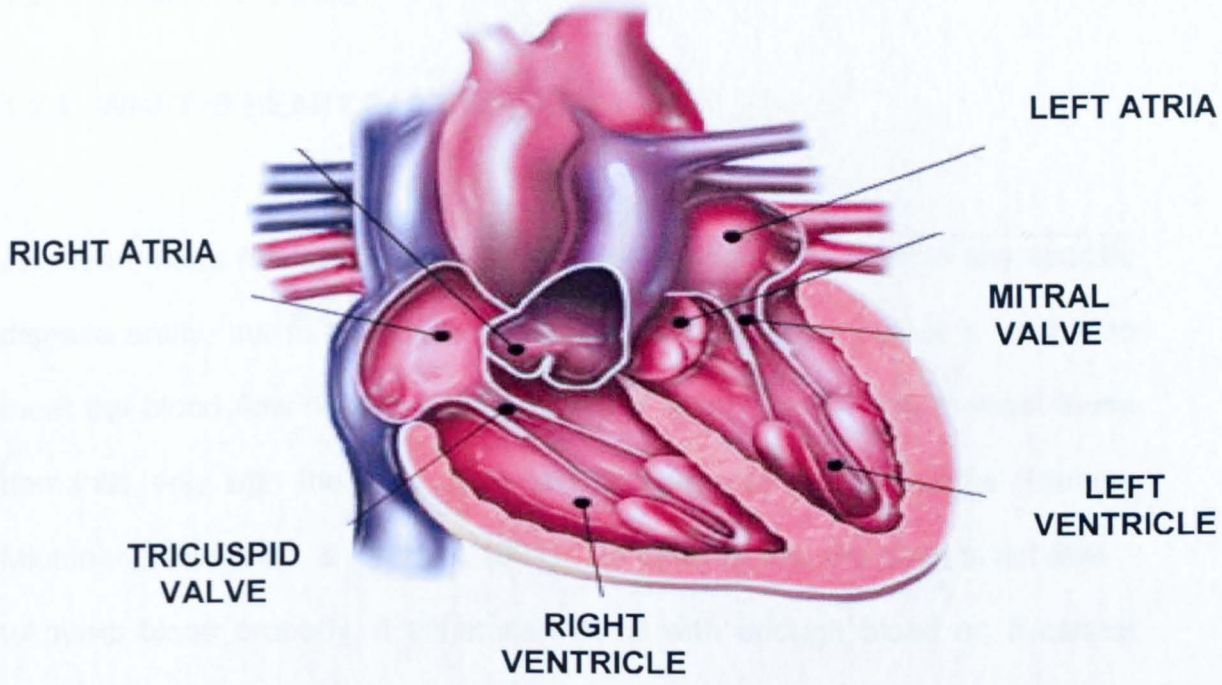


FIGURE 1.2 THE ANATOMY OF THE HEART (Cornell University, 2007)

The heart's pumping action is controlled by a complex electrical system, which sends impulses (beats) through the chambers of the heart causing it to contract and pump blood around the body. This system is very sensitive to the body's needs and constantly adjusts its rate of pumping to the stress or activity demands of the body. Sometimes the electrical system in the heart does not work as well as it should, which can lead to problems with the rhythm of the heart, ultimately impacting on the heart's ability to ensure blood flow throughout the circulatory system. Heart Failure (HF) is the term used when the heart becomes less efficient at pumping blood round the body. HF will now be described in more detail.

1.2 HEART FAILURE

1.2.1 WHAT IS HEART FAILURE?

The term 'heart failure', as a clinical diagnosis, does not refer to any specific disease entity, but to a functional state in which cardiac output is unable to meet the blood flow needs of the peripheral organs, or is able to meet these demands only with the help of certain compensatory mechanisms (Remes, Miettinen, Reunanen, & Pyorala, 1991)[1]. In other words, the heart is not able to pump blood properly; it either cannot fill with enough blood or, it cannot pump with enough force or both.

1.2.2 THE SIZE OF THE PROBLEM

HF is an increasingly common condition and is a major economic burden for healthcare systems in developed nations. Current figures estimate the total direct medical cost of HF each year at just over £625 million. The incidence of HF is about one new case per 1000 population per year and is rising by approximately 10% per year (NICE, 2003). This increases with age and is over 10 cases per 1000 in people aged 85 years and over. Currently prognosis is poor with survival rates worse than those for breast or prostate cancer. The annual mortality for those with HF ranges from 10% to over 50% depending on the severity of the condition (NICE, 2003). HF accounts for approximately 5% of all admissions to hospital and is associated with very high readmission rates

[1] For the purpose of this study heart failure will be referred to as a 'condition'

(NICE, 2003). HF is associated with major consequences for both the individual and the UK economy.

1.2.3 WHAT CAUSES HEART FAILURE?

HF may result from damage to the heart muscle. The damage is most commonly caused by a heart attack, but sometimes it may be caused by drinking too much alcohol, a viral infection, or by a disease of the heart muscle called 'cardiomyopathy'. For some patients the cause of the damage is unknown.

HF can also result from conditions that put an extra workload on the heart. The heart may have coped with this increased workload for many years before HF occurs. Problems that can cause an increased workload include:

- High blood pressure
- Anaemia
- Heart valves that leak or are too narrow
- Thyroid gland disease
- A heart rate that is much too fast, or too slow or irregular

Many patients are not aware that there are functional problems with their heart until the condition becomes more advanced and they begin to experience symptoms. At this stage, HF usually presents with breathlessness, fatigue and fluid retention. However, if left untreated and in extreme cases, the picture is

very similar to advanced cancer – loss of weight, loss of appetite, shortness of breath, weakness, fatigue and jaundice.

1.2.4 HOW IS HEART FAILURE TREATED?

For most patients with HF there is no known cure. However, advances in medical treatment mean that the outlook for many people with HF has improved substantially in recent years. The symptoms of HF usually respond well to drug treatment. Drugs that are commonly used by people with HF include diuretics, ACE inhibitors, digitalis, beta-blockers, anticoagulants and anti-platelet drugs (these drugs are described in more detail in Appendix B). HF cannot always be controlled by medication. There are some forms of surgery that can help certain patients with HF. Such surgery can involve the replacement of heart valves, the insertion of an electronic device or in the most severe cases, replacement of the heart via transplant. This review will focus on HF patients who have received an implanted electronic device. The two devices appropriate to the HF population are the Cardiovascular Resynchronisation Therapy device (CRT) and the Cardiovascular Resynchronisation Therapy Defibrillator device (CRT-D). It is important at this stage to note that a third device group will also be involved in the present study. This third device is known as an Implanted Cardioverter Defibrillator (ICD). Although not all patients who receive an ICD have a clinical diagnosis of HF, the reasons for the inclusion of this group will become apparent following a description of CRT, CRT-D and ICD devices, which are covered in the next sections (i.e. Section 1.2.5 and 1.2.6.).

1.2.5 CARDIOVASCULAR RESYNCHRONISATION THERAPY DEVICE (CRT)

It is estimated that 30%-50% of patients with more advanced HF present with electrical conduction abnormalities that effect both sides of the heart (Aaronson, Schwartz, Chen, Wong, Goin, & Mancini, 1997). This electrical abnormality may result in a delay in the electrical impulse to the heart's two pumping chambers (the right and left ventricles) (see Section 1.1), which can lead to the exacerbation of HF symptoms, as the chambers of the heart do not function in synchrony. This is a problem that cannot be controlled by medication, but may be helped by a CRT device.

The CRT device is equipped with three leads; two leads conduct pacing signals to specific regions in the right side of the heart, usually at positions **A** (the right atria) and **B** (the right ventricle; Figure 1.3); and a third lead at position **C**, entered through the coronary sinus into the left ventricle (Figure 1.3) conducts signals directly into the left ventricle. These three leads in combination deliver electrical impulses (Cardiovascular Resynchronisation Therapy) to both sides of the heart to help synchronise the contraction of the heart's ventricles and improve its efficiency.

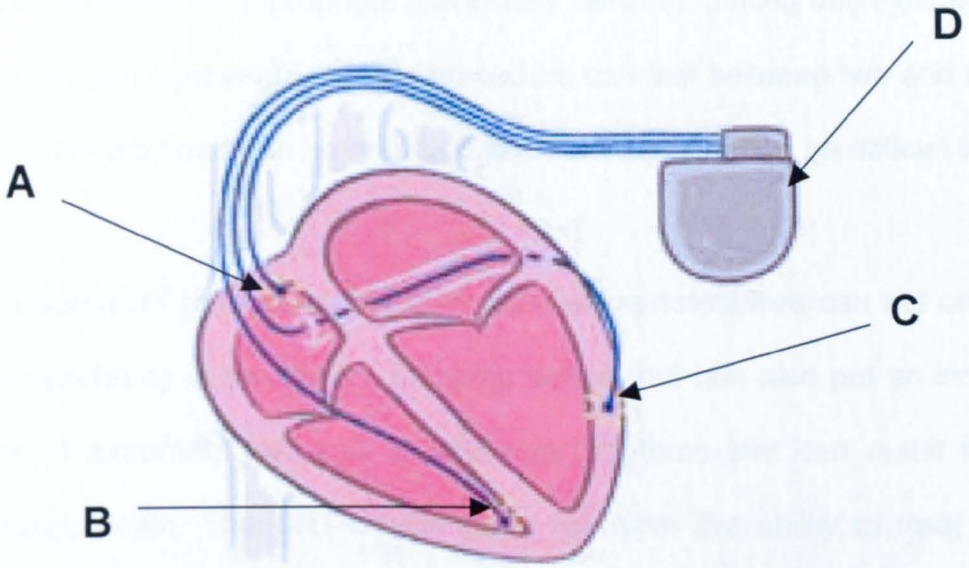


FIGURE 1.3 POSITIONING OF CRT DEVICE LEADS
(Heart and Vascular Institute, 2007)

The CRT device is implanted by means of a surgical procedure, which is conducted under local anaesthetic. An incision is made in the upper chest region to enable insertion of the device and leads. During the procedure two very fine wires are placed into a vein and guided into the upper and lower right chambers of the heart. The lead tips are then attached to the heart muscle. A third wire is guided through the vein to a small vein on the back of the heart called the coronary sinus to pace the left lower chamber. The other ends of the leads are then attached to the pulse generator (Figure1.3, **D**), which is placed under the skin in the upper chest, just below the shoulder[2].

Once the leads are in place they are tested using small amounts of 'current' delivered through the leads and into the heart muscle. This enables the leads

[2] The pulse generator is the sealed metal case that contains the battery and electronic circuitry of the CRT device.

to be checked for appropriate placement, sensing, pacing and synchronising of the left and right ventricle. The procedure can last between two and five hours as in HF the heart can be enlarged and the third lead can be difficult to place.

For some HF patients electrical conduction abnormalities can not only lead to dyssynchrony in the heart's pumping action, but can also put an individual at risk of extremely fast and chaotic heart rhythms that can result in sudden cardiac death. The CRT device does not have the ability to treat the heart when the heart rhythm becomes very chaotic. Medication may decrease the risk of recurring chaotic rhythms but a device known as an Implanted Cardioverter Defibrillator (ICD) can provide patients with an additional "safety net" (Gersh, 2000).

The ICD is a surgically implanted device that automatically detects and treats abnormalities of heart rate and rhythm. The device consists of a battery generator, which is implanted into the patient's chest and two leads which are positioned inside the heart (British Heart Foundation (BHF) 2002). The device continually monitors the patient's heart rate and can deliver defibrillation when chaotic rhythms are detected. Defibrillation is the procedure of stopping and resetting the heart. The ICD can correct chaotic rhythms by delivering up to a 30 Joule 'shock' or multiple 'shocks' (also known as 'firings') to reset the heartbeat and reverse this potentially life threatening event (BHF, 2002). ICD devices have been the focus of much research attention and have been shown to be 99 percent effective in detecting and treating life-threatening heart rhythms (Gersh, 2002). However, for the HF population although the ICD

device does provide protection from sudden cardiac death, it does not address the problem of dyssynchrony and resultant HF symptomatology. As such, the HF device industry has recently introduced models that incorporate a defibrillator function alongside the synchronising (CRT) function required by the HF population (Ng, 2003). Devices with this capability are called Cardiac Resynchronisation Therapy Defibrillators (CRT-D) and are briefly described below.

1.2.6 CARDIOVASCULAR RESYNCHRONISATION THERAPY DEFIBRILLATOR DEVICE (CRT-D)

In the combined device, known as CRT-D, the "CRT" part of the device sends small electrical signals to both ventricles to enable them to contract in synchrony (as described in section 1.2.5). In addition, the "D" part of the device refers to "defibrillation", or the electrical shock(s) (also known as 'firings') the device is capable of delivering to the heart muscle. The defibrillator function acts as a 'reset' device for the heart, jolting it with an electrical shock of up to 30 Joules; to restore the heart beat to a normal rhythm in certain critical circumstances (i.e. when a dangerously rapid rhythm is detected; BHF, 2002). The CRT-D is very similar in appearance to the CRT and ICD device, as is the surgical procedure for implantation. The main difference in the procedure is that the patient is sedated following the leads having been tested and the generator attached (this is also the procedure followed for implantation of an ICD). At this stage, in order to ensure that the device is functioning correctly, the heart is deliberately put into an abnormal rhythm. If the abnormal rhythm is

sensed and the defibrillator delivers a shock then the procedure is completed via the closing of the incision (BHF, 2002).

In summary, CRT devices can be implanted for HF patients to resynchronise the pumping action of the heart and improve associated symptomatology. Some HF patients are also at risk of life threatening heart rhythms that cannot be controlled by CRT. ICD devices are very effective in detecting and treating life-threatening rhythms, but do not ameliorate HF symptoms. For HF patients with dyssynchrony and a risk of life-threatening rhythm, a CRT-D device may be the treatment of choice.

The primary focus of this study regards CRT and CRT-D recipients, as it will become clear in later sections that these patient populations have received limited research attention, particularly from a psychological viewpoint. In contrast, there is a growing body of medical and psychological literature regarding patients with an Implanted Cardioverter Defibrillator (ICD). In light of the fact that ICD patients have received an implanted device to treat a cardiac condition, a device that has the potential to fire and shock the heart (as is the case for CRT-D patients), it is possible that the ICD literature may be very relevant to CRT and particularly CRT-D patients. Rather than rely solely on the ICD literature it was considered scientifically rigorous to recruit a sample of ICD patients for comparative purposes.

The next section will briefly review the CRT and CRT-D medical literature with regards to the physiological and mortality benefits afforded by these devices.

1.2.7 THE EFFECTIVENESS OF CRT & CRT-D FROM A MEDICAL PERSPECTIVE

From a medical perspective CRT has been shown to increase exercise tolerance, improve symptomatic status, and has been suggested to reduce the number of hospital admissions for patients with worsening HF (Cazeau, Leclercq, Lavergne, Walker, Varma, & Linde, et al., 2001; Abraham, Fisher, Smith, Delurgio, Leon, & Loh, et al., 2002). The potential morbidity and mortality benefits afforded by CRT have been more recently supported by a multicentre, international, randomised trial (CARE-HF, 2005). This trial compared the effect of standard medical (drug) therapy alone versus a combination of standard medical therapy and CRT, on the risk of complications and death. Results indicated that patients receiving CRT and medical therapy benefited from a 36% reduction in all cause mortality, and a reduction in heart-related hospitalisation. CARE-HF (2005) purported, based on hazard ratio calculations that, for every nine CRT devices implanted, one death and three hospitalisations for major cardiovascular events were prevented.

With regard to CRT-D devices, there has been far less research attention in this area, due to the device only having been developed within the last seven years (MIRACLE ICD Trial, 2003). The limited research available suggests that in addition to improvements conferred by the CRT component of the device, the defibrillator component further reduces mortality risk (MIRACLE ICD Trial, 2003; COMPANION Study, 2004). By far the largest trial to date, COMPANION (2004), randomised more than 1,600 patients to either medical (drug)

treatment only, CRT or CRT-D device treatment. This study had to be stopped part way through because of a 20% reduction in mortality and admission rates across the groups who had received a CRT or CRT-D device (i.e. it was no longer ethical for a group of patients to only receive drug treatment). The group with the most notable benefit, receiving CRT-D, showed a 40% reduction in mortality, compared with a 24% reduction in mortality in the CRT group (COMPANION, 2004).

While the literature clearly indicates that both CRT and CRT-D are effective life-saving devices and have the potential to improve physiological outcomes, it is naïve to look at medically based outcomes in isolation, for a number of reasons. Firstly, there is evidence that highlights the lack of a direct relationship between an individual's level of functioning (both physical, social, psychological, etc) and the actual degree of physical impairment, as considered from a medical perspective. Furthermore, there is literature to suggest that physicians might be inclined to view patients' health status more positively than patients themselves (Jachuck, Brierley, Jachuck & Willcox, 1982; Gorkin, Norvell, Rosen, Charles, Shumaker & McIntyre, 1993). With both these points in mind it is questionable whether improved physiological outcomes for HF patients, following receipt of a CRT or CRT-D device, will be accompanied by improved functioning from the patients' perspective. The need to examine these issues in this population is further emphasised by the wealth of literature in the HF arena (in patients without devices), which reveals the profound negative effect of HF on patients' physical, social and psychological functioning (see Section 1.3 for an overview of HF literature). As such, this is

clearly a population who already arguably require a great deal of psychological support from nursing and medical teams. A level of support that it is naïve to assume some patients no longer require following receipt of a CRT or CRT-D device (Frodsham, 2005).

The ICD (Implanted Cardioverter Defibrillator device) literature further highlights the importance of examining psychological outcomes in the HF device population. While implantation of a defibrillator does reduce the risk of sudden cardiac death, research in ICD patients has shown that the device can induce new fears and elicit negative psychological reactions in patients (Sears, Todaro, Lewis, Sotile & Conti, 1999). The National Institute of Clinical Excellence acknowledged that 'implantation and activation of an ICD can have an adverse psychological impact' and as such recommended psychological preparation for patients living with an ICD. More recently, the National Service Framework for Coronary Heart Disease (CHD NSF) highlighted that patients who are about to receive an ICD, or have recently done so, are at significantly increased risk of anxiety, depression, and reduced quality of life (Department of Health, 2005). Given the psychological issues identified in the ICD literature and the CHD NSF identifying HF as an area where increased understanding of psychological issues is required it is striking that there is an absence of such research in CRT-D patients.

The rapidly increasing number of individuals being recommended for a device further highlights the importance of examining psychological outcomes in both CRT and CRT-D patients. Currently, for those HF patients with electrical

conduction abnormalities and possibly the additional risk of sudden cardiac death, there is no known cure and limited symptomatic relief via pharmacologic (drug) treatment alone. As such, some researchers in the medical sphere are moving towards consideration of these devices as the routine choice of treatment (Haywood, 2001; Cleland, Daubert, Erdmann, Freemantle, Gras & Kappenberger, et al., 2005). It is important to stress that medical research in the HF device arena, particularly regarding CRT-D devices, is still very much in its infancy. As such, there exists a lack of consistent clarity as to which patients will benefit the most from receiving a device. This has sparked much debate in the medical sphere and is the focus of a great deal of research attention (McAlister, Ezekowitz, Wiebe, Rowe, Spooner, Crumley, et al., 2004; Bristow, Saxon, Boehmer, Krueger, Kass, De Marco, et al., 2004). In line with NICE (2003) guidelines, highlighting the importance of putting patients with HF "at the centre of care", it is considered crucial that psychological outcomes and an appreciation of the patients' perspective receive rightful attention in this debate.

To date, there is a dearth of literature examining the psychosocial perspective of HF patients with a CRT or CRT-D device. The only literature available is from a limited number of studies involving CRT and CRT-D patients in the medical sphere, where quality of life measures have been included, but referred to in a very limited fashion. With regards to CRT patients, the CARE-HF (2005) study incorporated a quality of life measure specifically designed for use with a HF population (Minnesota Living with Heart Failure Questionnaire,

MLWHF)[3]. It was reported that CRT patients recorded significantly improved quality of life scores when followed up two years after receiving a device. Despite the importance of this study incorporating a measure that begins to enable consideration of quality of life from the patients' perspective, there are a number of issues that need to be borne in mind. CARE-HF (2005) was an eminent study involving many highly respected and influential clinicians. It was acknowledged that the benefits afforded by the CRT devices in the study were due, at least in part, to the adherence of patients and investigators to the study protocol (Cleland et al., 2005). The experience of receiving and living with a CRT device, or a CRT-D device, is arguably different for patients not involved in landmark, multicentre, international, randomised trials. Furthermore, CARE-HF (2005), being a medically oriented trial, did not attempt to understand the reasons for patients' reports of high or low quality of life outside of the assumed relationship with physiological and symptomatic improvements. However, given that research supports the lack of relationship between the extent of an individual's level of functioning and actual physical impairment it is of paramount importance that this issue is examined in more depth and forms an important part in the HF device debate.

The MIRACLE ICD Trial (2005) was the only study identified that incorporated a quality of life measure (this measure was the MLWHF questionnaire) when examining the benefit conferred by a CRT-D device for a subset of HF patients. In line with the results of CARE-HF (2005), improvements in quality of

[3] This questionnaire is called The Minnesota Living with Heart Failure Questionnaire (MLWHF). It is a validated, self-administered, disease specific 21-item questionnaire assessing health-related physical, psychological and social impairments (Rector, Tschumperlin, Kubo, Bank, Francis, McDonald, et al., 1995)

life were noted between baseline (pre receipt of device) and six months post implant. However, the MIRACLE (2005) research paper commented, only very briefly, about the apparent improvement in quality of life and did not consider the reasons behind this improvement. Again, the implicit assumption seemed to be made that physiological improvements provided sufficient explanation for changes in quality of life. In addition, despite the research and guidelines highlighting the potentially negative psychological impact of receiving a defibrillator, no attempt was made to examine these factors.

In summary, while the lifesaving and symptomatic benefits of CRT and CRT-D have been well documented, little is known about psychological outcomes or the perspective of the patient as a means of understanding patient functioning in the real world post implantation. This is a distinct gap in the literature, not only in light of the issues highlighted in this section, but particularly in view of NICE (2003) recommendations purporting the need to "put people with heart failure at the centre of care".

The next section will provide an overview of literature in the HF arena that further highlights the importance of considering psychological outcomes in this population.

1.3 THE PSYCHOLOGICAL ASPECTS OF HEART FAILURE

Patients with HF face many difficult issues. Increasingly debilitating physical symptoms such as shortness of breath, weight gain and fatigue; role changes due to reduced physical and perhaps psychological functioning; hospitalisations; forced retirement; financial stress, and disruption of usual sources of social support (Martensson, Dracup, Canary, & Fridlund, 2003). It is not surprising therefore that a number of studies have reported that HF is accompanied by various psychological responses such as anxiety, depression and reduced quality of life (Juenger, Schellberg, Kraemer, Haunstetter, Zugek & Herzog, 2002; Rumsfeld, Havranek, Masoudi, Peterson, Jones, Tooley et al., 2003; Gottlieb, Khatta, Friedmann, Einbinder, Katzen, Baker et al., 2004). These three areas will be described and the literature relating to these issues will be reviewed (see Section 1.3.3).

1.3.1 ANXIETY AND DEPRESSION

Most individuals have periods where they feel sad, lethargic, and uninterested in any activities, even pleasurable ones. Mild depressive symptoms are a normal response to many of life's stresses (Atkinson, Atkinson, Smith, Bem & Nolen-Hoeksema, 2000). Depression becomes a clinical concern when the symptoms become severe enough that they interfere with normal functioning, and when they continue for weeks at a time. Although depression is characterised as a mood disorder, there are actually four sets of symptoms. In addition to emotional (mood) symptoms, there are cognitive, motivational, and

physical symptoms. A person need not have all of these to be diagnosed as depressed, but the more symptoms an individual experiences, and the more intense the symptoms, the more likely the individual could benefit from clinical support.

Depression is arguably the most frequently explored psychosocial topic in cardiac psychology, and more specifically in the area of HF. It has been associated with adverse prognosis (Murberg, Bru, Tveteras, & Aarsland, 1999; Jiang, Alexander, Christopher, Kuchibhatla, Gaulden, & Cuffe, 2001), reduced functional ability (Majani, Pierobon, Giardini, Callegari, Opasich, Cobelli, et al., 1999) and greater use of health care resources (Jiang et al., 2001; Rozzini, Sabatini, Frisoni, & Trabbucchi, 2002).

Anxiety is one of the most prominent and pervasive emotions (Rachman, 1998). It is a state of apprehension, uncertainty, and fear resulting from the anticipation of a realistic or fantasised threatening event or situation, often affecting mood, thought, behaviour and physiological activity. In contrast to depression there is a paucity of literature on anxiety among individuals with HF (MacMahon & Lip, 2002; Haworth, Moniz-Cook, Clark, Wang, Waddington, & Cleland, 2005), despite the fact that the condition frequently presents co-morbidly with depression. It could be hypothesised that the symptoms of depression, in contrast to anxiety, are more categorical and more readily treated with medication and understood within a medical model framework. The predominance of medically driven research in the HF arena may therefore have favoured assessment of a disorder, such as depression, that fits more

clearly within the medical model. Thus explaining the relative dearth of anxiety compared to depression literature in HF.

1.3.2 QUALITY OF LIFE

The concept of quality of life is not yet defined in a uniform way, lacks clarity and even creates confusion (Coelho, Ramos, Prata, Bettencourt, Ferreira & Cerqueira-Gomes, 2005). Guyatt (1993) used the term "health related quality of life" (HRQOL) because many widely valued aspects of life are not generally considered as "health related" such as income, freedom and quality of the environment. As such, HRQOL can be defined as "....the overall effect and outcome of an illness and its treatment on an individual's physical, psychological and social well-being as perceived by that individual" (Guyatt, 1993). Despite the complexity and ambiguity relating to the concept of quality of life, over the past decade, there has been a growth in the use of quality of life measures as an indicator of health outcome. Since 1948, when the World Health Organisation defined health as being not only the absence of disease and infirmity but also the presence of physical, mental and social well-being, quality of life issues have become steadily more important in health care practice and research (Testa & Simonson, 1996). Indeed, 49% of patients, in one qualitative study, were prepared to select therapy that improved quality of life even if the treatment shortened life (Rector, Tschumperlin, Kubo, Bank, Francis, McDonald, et al., 1995). HF is no exception to this, where the goal of treatment is not only to prolong life and relieve symptoms, but also to improve

social and psychological functioning (Dunderdale, Thompson, Miles, Beer, & Furze, 2005).

The literature relating to anxiety, depression and quality of life will now be reviewed.

1.3.3 RESEARCH ON PSYCHOLOGICAL DISTRESS AND QUALITY OF LIFE IN HEART FAILURE PATIENTS

Juenger et al. (2002) used a cross sectional design to assess quality of life of HF patients compared with the general population and other chronic disease groups; and correlated the different aspects of quality of life with relevant somatic (physical/medical) variables. Quality of life was measured by the SF-36, which is a generic health survey designed to assess aspects of health that are not disease, treatment or age specific. The majority of the HF patients (88.2%) were in NYHA functional class II or III[4]. The HF sample was characterised by significantly reduced scores in all aspects of quality of life compared with a healthy reference group, and all indices of quality of life decreased with worsening NYHA functional class. When the HF group were compared to patients with chronic hepatitis C and also patients with major depression, the HF patients in NYHA II were characterised by significantly worse physical health, but better mental health. However, patients with more

[4] The New York Heart Association developed a classification system for HF based on severity of HF symptoms, which is now widely accepted in the medical arena (NYHA, 1994). The classification system was designed as NYHA I, II, III or IV on the basis of patients' limitations in physical activities caused by cardiac symptoms and is used as a prognostic measure regarding the impact of cardiovascular disease. Assignment of classes I to IV increase as functional abilities decrease.

advanced HF (NYHA III) had similar scores to patients with major depression in the mental domain, in addition to already dramatically reduced physical health. Interestingly, Juenger et al. (2002) acknowledged that although the data appeared to indicate that quality of life decreased as NYHA functional class worsened, it was found overall that most of the variability in the quality of life data remained unexplained by the established medical indicators (somatic variables) of the severity of HF. As such, the importance of examining psychological factors, which this study (Juenger et al., 2002) did not consider, is clearly paramount in understanding patients' responses to a condition such as HF.

More recently, Calvert, Freemantle & Cleland (2005) investigated the quality of life of a sample of 813 patients with HF due to left ventricular dysfunction (NYHA class III or IV). The study reported that patients' overall quality of life was significantly impaired and comparable to patients with other severe chronic conditions such as Motor Neurone (Green, Kiebert, Murphy, Mitchell, O'Brien, Burrell, et al., 2003) and Parkinson's disease (Siderowf, Ravina, & Glick, 2002). In line with existing research, 78% of the sample indicated that their heart condition had a negative impact on their usual activities and physical functioning (Hobbs, Kenkre, Roalfe, Davis, Hare, & Davies, 2002; Juenger et al., 2002). However, this study, similarly to Juenger et al., (2002) revealed wide variability in the quality of life of patients, but did not examine what other factors apart from physiological outcomes could have accounted for this. Despite this, the authors (Calvert et al., 2005) suggested that the apparent variability in quality of life highlighted the potential use of routine

quality of life assessments in HF patients to 'identify patient concerns, facilitate communication, and to guide clinical decision-making'. Although measures of quality of life arguably provide an important additional source of information for those in the medical sphere, the suggestion of using only these measures alongside medical outcomes needs to be treated with caution. Quality of life is usually measured as a 'lack' of something, which is interpreted as a negative (i.e. if an individual indicates that they are less active then this is interpreted as indicating a lower 'quality of life'), which may not necessarily be the experience of the patient. There may indeed be other aspects of a person's life or way of being (i.e. an individuals spirituality, degree of social support, coping strategies, feelings of control, etc) that contribute to a person's perception of their quality of life and/or their experience of psychological well-being. Gaining an understanding of the presence and role of such aspects could help clinicians develop a clearer understanding of patient outcomes (i.e. both medical and psychological outcomes). Furthermore, it would be naïve to assume that experience of ill health (i.e. a decline in physical well-being) would automatically lead to an overall reduction in perceived quality of life and psychological well-being. Indeed, over recent years there has been an increasing recognition that stressful events such as illness may not only result in negative outcomes but may also lead to some positive changes in people's lives. For example, individuals may develop coping processes that involve finding meaning in a stressful event, which leads to positive reappraisal and personal growth. An interesting example of this involves a local area ICD patient support group. The patients involved, selected to name the group 'Second Chance' as many perceived that receipt of the ICD device had

provided them with a second chance at life. Seeing things in this way, in spite of potential physical limitations, could be hypothesised to protect or enhance patients' quality of life and psychological well-being; with patients appreciating and choosing to make more of their lives.

Consideration of the aforementioned issues highlights the importance of examining the patient's perspective about other aspects of their lives, as a means better understanding outcome measures such as quality of life. Developing a more in depth understanding of such outcomes, via learning from patients who are 'doing well' as well as from those who are struggling, could help to highlight areas for intervention. To date, as briefly described earlier (Section 1.2.7), quality of life is the only concept outside of medical outcomes that has been examined in HF patients with a CRT or CRT-D device.

Research outside of the HF device arena has consistently shown quality of life to be negatively related to psychological distress (Bennett, 2000). Literature examining psychological distress (i.e. anxiety and depression) in the HF population will now be discussed.

Rumsfeld et al. (2003) conducted a multi-centre prospective study of 460 outpatients with HF with the purpose of assessing the frequency of depressive symptoms in an out-patient HF cohort; the association between depressive symptoms and health status; and the predictive effect of depressive symptoms on short-term changes in HF symptoms, functional status, and quality of life. The study utilised the Medical Outcomes Study Depression Questionnaire and

the Kansas City Cardiomyopathy Questionnaire (quality of life measure). Approximately 30% of the HF cohort had significant depressive symptoms at baseline, which was associated with being younger, having a history of alcohol/substance misuse, being on medication for mood related issues and experience of previous depression requiring treatment. Depressed patients also had markedly worse baseline quality of life health status than non-depressed patients and were shown to be at risk for significant worsening of HF symptoms, physical and social function, and quality of life (based on an average six week follow-up). Rumsfeld et al. (2003) concluded that HF outpatients with depression are not only at risk for worse baseline health status, but also for short-term declines in HF symptoms, functional status, and quality of life.

Along similar lines to the aforementioned study, Gottlieb et al. (2004) examined the prevalence of depression in an outpatient HF population (NYHA II-IV) and its relationship to quality of life. A total of 155 patients were evaluated with the Medical Outcomes Study Depression Questionnaire, the MLWHF and the Beck Depression Inventory. Almost half of the sample (48%) scored as depressed and these patients scored significantly worse than non-depressed patients on all components of quality of life. Patients classified as NYHA functional class III and IV were more likely to score as depressed than class II patients, but class III and IV patients did not differ from each other in frequency of depression. In this study depression was observed more commonly among women (64%) than men (44%) and in younger rather than older patients, which is similar to the findings of the study by Rumsfeld et al.

(2003). Gottlieb et al. (2004) hypothesised that younger patients may have been experiencing a larger disparity between their perceived level of functioning and that of their peers, thus accounting for the higher incidence of depression. In contrast, older HF patients may not perceive such a discrepancy between their own health and the health of others in their age group. These studies are considered to highlight the importance of patient perceptions of their health status rather than patient physiological impairment (from a medical perspective) in determining psychosocial outcomes such as depression and quality of life.

In one of the few studies to investigate anxiety in the HF population (NYHA I-III), Majani et al. (1999) found that patients in NYHA class III reported higher anxiety scores than patients in classes I and II. The study also highlighted that approximately half the sample (predominantly NYHA III) experienced sleep disturbance, financial difficulties, dysfunctional eating behaviours, decreased sexual activity and sexual dysfunction. Despite the findings, Majani et al. (1999) acknowledged that there was only a weak relationship between functional class (i.e. NYHA) and anxiety, and also stated that no other medical variables were found to relate to reported levels of anxiety. Again this study highlights the importance of considering psychological factors as a means of accounting for the variance in patient responses; variance that is clearly not fully explained by medical factors. When considering the generalisability of the aforementioned study results, a number of issues need to be borne in mind. Majani et al. (1999) utilised the Cognitive Behavioural Assessment 2.0 measure to assess anxiety and a number of other variables (i.e. depressive

disorders, obsessive compulsive disorders, fears and phobias). This measure was completed by patients using a computer program at the hospital where they were recruited as in-patients. This not only raises the issue again of in-patient versus outpatient populations, but also highlights the potential for exclusion of patients not confident at utilising computer technology. Indeed exclusion criteria in this study included patients over the age of 70 and those unable to fully complete the measures, who were classified as having a 'low educational level' (Majani et al., 1999).

More recently, Haworth et al. (2005) reported that approximately a fifth (18%) of 100 outpatients with chronic HF and left ventricular systolic dysfunction (NYHA I-IV) had at least one anxiety disorder. The diagnosis of anxiety was associated with significantly worse functional status, a history of mental ill health, and co-morbid physical conditions. Although the prevalence of anxiety was lower than that for depression (29%), Haworth et al. (2005) highlighted that this prevalence rate of anxiety was similar to that of patients recovering from a myocardial infarction (MI; a heart attack), and higher than that reported for healthy community dwelling older adults (Lane, Carroll, Ring, Beevers, & Lip, 2002). This suggests that anxiety is an important issue for this population and clearly warrants further research attention. It also highlights that factors such as previous mental ill health and co-morbid physical conditions could be utilised as predictors for poor psychological adjustment. This could assist in targeting interventions for patients potentially deemed at most risk of anxiety and depression (Haworth et al., 2005).

In summary, existing research is relatively consistent in demonstrating that HF has a significant impact on patients' quality of life, and degree of psychological distress, specifically depression. While some attempts have been made to study the prevalence and impact of anxiety, the generalisability of findings is very limited (Majani et al 1999; Haworth et al, 2005). In light of the fact that anxiety is a condition that frequently presents co-morbidly with depression; has been associated with reduced cardiac output in other cardiac groups (Tavazzi, Zotti, & Mazzuero, 1987); and would arguably be intuitively expected given the poor prognosis associated with the condition (MacMahon et al., 2002), it is clearly an area that warrants further research. To date, the majority of studies in the HF device arena have focused on medical outcomes, with a handful incorporating a quality of life measure. There is an absence of research examining the prevalence of psychological distress in these patient groups and the factors that might be related to such outcomes. Furthermore, the limited quality of life literature in this area has been unable to account for the variability in quality of life based on medical outcomes. There is research to suggest that consideration of patients' perceptions might go some way towards accounting for the variability in quality of life and psychological outcomes, seen in previous studies, that was left unexplained by medical factors alone.

In a bid to begin to address the substantial gap in the literature, this study aims to examine the prevalence of psychological distress in HF patients who have received a CRT or CRT-D device, as well as assessing the quality of life reported by these patients. As indicated by research in the HF arena (Rumsfeld et al., 2003), potential non-medical predictors of these outcome

measures, such as age, previous mental ill heath, co-morbid physical conditions and mood medication, will also be examined. Arguably the most important aspect of this study will entail the examination of patients' perceptions and the importance of these perceptions in accounting for quality of life and psychological distress in HF patients with a CRT or CRT-D device. The concept of patient 'perceptions' will be described in greater depth in Section 1.4. Before moving on to consider perceptions, the next section will provide a brief overview of the ICD literature, to provide a context for HF device patients (i.e. CRT and CRT-D).

1.3.4 RESEARCH ON PSYCHOLOGICAL DISTRESS AND QUALITY OF LIFE IN ICD PATIENTS

It is arguably an intuitive expectation that reduced risk of sudden death would be accompanied by improved psychological responses (i.e. reduced anxiety and depression) and improved quality of life. Although implantation has been shown to relieve much of the fear associated with sudden death and is commonly welcomed by patients, the device has been shown to impose new fears and has its own set of negative consequences (Lewin, Frizelle & Kaye, 2001).

Helga, Griegel, Black & Goulden (1997) utilised a longitudinal design to examine the impact of an ICD on the incidence and severity of anxiety and depression. The study found that a third of the sample reported clinically significant levels of anxiety and depression post implantation. Furthermore,

40% to 63% of these patients continued to have problems for over 12 months. Helga et al. (1997) purported that levels of depression were associated with fears about the device firing, and anxiety was related to avoidance of activity. Similar prevalence rates were found in a later study conducted by Frizelle (2001). From a sample of 91 post-implant ICD patients, 25% recorded anxiety scores within the clinically significant range, with 17% reporting scores in the clinically significant range for depression.

Sears et al. (1999) conducted a review of the ICD literature regarding the psychosocial impact of implantation. The studies examined revealed that approximately 13% to 38% of patients manifested clinically significant levels of anxiety and 24% to 33% experienced clinically significant levels of depression. It was suggested therefore that the prevalence of psychological distress was comparable with other cardiac groups, such as those with HF.

It is somewhat unsurprising that ICD patients experience reduced psychological functioning given that patients experience similar issues to those in other cardiac groups (i.e. hospitalisations, cardiac surgery). However, there is also the added issue of continual anticipation and potential experience of defibrillator firings (i.e. shocks) for ICD patients. The literature regarding the impact of firings on psychological outcomes and quality of life is mixed. Burke, Hallas, Clark-Carter, White and Connelly (2003) conducted a meta-analysis of 20 studies. One part of the analysis was aimed at comparing mood (i.e. anxiety and depression) and quality of life between patients who had and those who had not experienced a device firing. The analysis revealed that there was no

difference in outcomes between the groups. However, in the AVID trial (2001), the occurrence of sporadic ICD shocks was associated with significant impairment in health related quality of life, as measured by the Short Form 12 Health Survey. The study found that the experience of one or more firings was associated with significant declines in both physical functioning and mental well being. In line with this, May, Smith, Murdock and Davis (1995) found, from a sample of 21 consecutive patients undergoing ICD implantation, that the quality of life outcomes (mental and physical) for the ICD patients were significantly worse compared to patients with no ICD. Further analyses revealed that there was no difference in quality of life between patients who had not experienced a defibrillator firing and those in the sample who did not have an ICD. These results indicated that the ICD group who had received shocks were more likely to have significantly worse mental and physical quality of life. Collectively, these data suggest that the experience of shock may contribute to psychological distress and diminished quality of life (May et al., 1995).

The ICD literature highlights that reduced risk of sudden death does not necessarily translate to reduced psychological distress and improved quality of life. The research is mixed regarding the association of device firings and psychosocial outcomes. There is arguably sufficient evidence to warrant examination of these outcomes in the CRT-D and CRT population.

In considering the existing research regarding quality of life and psychological distress, the question is raised of whether negative outcomes are inevitable for

patients diagnosed with HF. It has to be borne in mind that despite a significant proportion of patients experiencing psychopathology and reduced quality of life, the majority of patients do not. This suggests that adverse psychological reactions, unlike physical limitations, are not inevitable for patients with HF. It is therefore important to explore, in addition to variables such as age, previous mental ill health, etc, what might cause certain patients to feel anxious and depressed and why quality of life is adversely affected for some individuals but not others.

In considering this question, it may be useful to make a distinction between the terms 'disease' and 'illness'. The aim is not to provide a definitive answer, but to begin to consider the assumptions upon which these terms are based. According to Radley (2004) *disease* is to do with pathological changes in the body and is diagnosed and treated by a clinician. In contrast, *illness* can be taken to mean the experience of disease, including the feelings related to changes in bodily states and the consequences of having to bear that ailment; illness, therefore, relates to a way of being for the individual concerned (Radley, 2004). With this in mind, if the condition of HF is understood as falling within disease terminology, but patients' responses to this 'disease' are understood from an illness perspective, it is not surprising that patients with HF (i.e. the same or similar disease pathology) respond in very different ways.

Self-regulation theory and the development of self-regulation models, such as the Self-Regulation Model of Illness (SRMI; Leventhal, Hudson & Robitaille, 1997), provide a framework for understanding variability in response to an

illness or health threat. Self-regulation is generally construed as a systematic process involving conscious efforts to modulate thoughts, emotions, and behaviours in order to achieve goals in a changing environment (Zeider, Boekaerts & Pintrich, 2000). It is a dynamic motivational system of setting goals, developing and enacting strategies to achieve those goals, appraising progress, and revising goals and strategies. Within self-regulation theory emotional processes form a crucial element of the motivational system – as direct responses to appraisals of goal-related progress, as experiences to be regulated, and as influences on cognitions and behaviours. It has been argued within Health Psychology that the term 'self-regulation' has been so widely used in recent years that there is speculation as to whether self-regulation models, such as the SRMI (Leventhal et al, 1997), are really that different from other models that try to make sense of health and illness behaviour. Yet, although other models in the area include some combination of cognitive processes, affective factors, and behavioural goals, Cameron & Leventhal (2003) contend that 'it is not a self-regulatory model unless it sufficiently captures the dynamic elements of feedback, motivation and goal pursuit' (p.6). More specifically, models such as the Health Belief Model (Becker, 1974), the Theory of Reasoned Action (Ajzen & Fishbein, 1980) and the more recent Theory of Planned Behviour (Ajzen, 1991) all consider the individual as a rational decision-maker who weighs up his or her attitudes and values when evaluating the overall utility of the behaviour in question. However, these models fail to capture several important aspects of behavioural self-regulation: they do not incorporate emotional processes; they view behavioural decisions as static events rather than as dynamic processes that change over time; and

they fail to delineate feedback processes for appraising progress toward or away from goal states. It is these type of 'details' that self-regulation research suggests are critically important for understanding the behaviour of biological systems, including the efforts of human beings, such as HF patients, to protect and maintain health and to avoid and control illness (Leventhal, Brissette & Leventhal, 2003). The researcher perceived that the SRMI (Leventhal et al, 1997) provided a framework and specific variables that began to specify some of these critical 'details'. The next section will provide an overview of this theoretical model as a basis for understanding the psychosocial responses of HF patients who have received a CRT or CRT-D device.

1.4 THE SELF-REGULATION MODEL OF ILLNESS (SRMI)

Illness representation is the central construct of the SRMI. Illness representation can be described as an individual's perception of the meaning and significance of a disease or health threat. It is considered to be a mental schema or organised set of beliefs regarding how a condition usually functions and it is proposed to play an important role in regulating a person's behavioural and emotional reaction to illness. Leventhal et al. (1997) suggested that people organise these beliefs based on the symptoms which they attribute to the illness (*"identity"*), beliefs about causes of the illness (*"cause"*), beliefs about the curability or controllability of the illness (*"cure/control"*), perceived consequences of the illness in everyday life (*"consequences"*), and expected duration of the illness (*"time-line"*).

According to the SRMI, illness representation comes into play as soon as patients experience their initial symptoms, and typically changes with disease progression, emergent symptoms and treatment responses. It is proposed that the generation of illness representation is motivated by a need to establish the personal meaning of ill health. In other words, individuals strive to 'make sense' of ill health. This motivation is based on the assumption that ill health is experienced as a 'threat' to an individual's normal 'healthy' way of being, a state of being that individuals will make efforts to protect and maintain (Bennett, 2000; Leventhal, Brissette & Leventhal, 2003).

Leventhal et al. (1997) propose that when an individual is diagnosed with an illness such as HF, parallel cognitive and emotional representations of the *health threat* (i.e. the diagnosis) are generated, which inform individuals how to *cope* with their predicament (i.e. address any illness consequences or attendant issues with problem-focused coping) and respond to the emotional reactions to the health threat with emotion-focused strategies. The outcomes of the coping procedures are then appraised for effectiveness and may result in the modification and updating of the illness representation (Leventhal, Nerenz & Steele, 1984). This study focuses on the cognitive and emotional representations of HF patients with an implanted device rather than on the coping procedures that may ensue.

It is important at this stage to highlight that aside from 'Illness Representation' a plethora of terms have been used in the literature to describe this construct/organised set of beliefs: illness perceptions, illness cognitions, illness

beliefs and illness schemata are a sample of the more common terms. Scharloo & Kaptein (1997) judge the aforementioned terms to be synonyms of illness representation. For the purposes of this research the term 'illness perceptions' will be used to refer to these types of beliefs.

Examination of patient illness perceptions (IPs) was very recently recommended in the British Association for Cardiac Rehabilitation (BACR) national guidelines as a relevant approach for developing psychological support that meets the needs of individual patients (Coats, McGee, Stokes & Thompson, 2007)[5]. This recommendation was driven by the assumption that patients' responses (i.e. physiological, behavioural, psychological) to ill health were determined by their beliefs and expectations. Despite these guidelines, psychosocial factors and IPs appear to have been very poorly assessed in the HF device population to date. This study aims to add to the HF device literature by examining patients' IPs alongside other psychosocial variables (i.e. anxiety, depression and quality of life). Furthermore, the intention is to explore the predictive power of different dimensions of patients' illness perceptions (see section 1.5) with regards to self-reported psychological variables such as anxiety, depression and quality of life. This is with a view to offering health care professionals a basis from which to address the individual needs of patients. The next section will provide a review of the IP literature.

[5] Cardiac Rehabilitation: a structured program of education and activity guided toward lifestyle modification, increasing functional capabilities and peer support.

1.5 REVIEW OF THE ILLNESS PERCEPTION LITERATURE

"There is nothing either good or bad, but thinking makes it so." (Shakespeare, Hamlet, Act 2 Scene 2)

Cognitive illness perceptions were traditionally elicited through semi-structured or open-ended interviews but more recently self-report questionnaires have been developed. One such commonly used and psychometrically sound measure is the Illness Perception Questionnaire (IPQ, Weinman, Petrie, Moss-Morris, Horne, 1996), which was developed on the basis of the SRMI. The IPQ has shown the ability to differentiate between illness conditions, revealing logical differences (and similarities) on the component's dimensions (i.e. identity, cause, cure/control, consequences, timeline) in a manner reflecting the nature of the disease under study (Hirani, Pugsley & Newman, 2006). For example, Weinman et al. (1996) demonstrated that rheumatoid arthritis patients had higher scores on the identity (i.e. reported more symptoms) and timeline subscales than chronic pain patients, reflecting the characteristics of the condition. A key revision of the IPQ, the Illness Perception Questionnaire-Revised (IPQ-R, Moss-Morris, Weinman, Petrie, Horne, Cameron & Buick, 2002) refined and expanded the number of subscales of the original IPQ[6]. The IPQ-R consists of a list of symptoms to reflect the identity of the illness (identity subscale 1); 18 causal items (causal subscale 2); and 40 belief statements regarding the perceived duration of the illness (timeline subscale 3); the expected effects and outcome of the illness (consequences subscale 4); the degree of personal control (personal control subscale 5); the perceived efficacy of the treatment (device control subscale 6); the extent of

[6] The reasons for the revision of the IPQ and more detailed information about the IPQ-R and its use in the present study are covered in Section 2.3.2.

understanding about the illness/symptoms (illness coherence subscale 7); the cyclical nature of the illness (timeline cyclical subscale 8); and the emotional impact of the illness (emotional representation subscale 9). Unless otherwise indicated, the studies that will be discussed in the following section have utilised the IPQ or IPQ-R as a means of examining individuals' IPs.

It is important to note that Leventhal, Leventhal & Contrada (1998) proposed that the IP subscales are interrelated and as such function as groups of beliefs instead of single cognitions. It is also acknowledged that dependent on the illness being investigated and the context of the investigation, the relative importance of each component (i.e. subscale) may vary (Hirani et al., 2006). Due to the lack of research in this area regarding HF device patients, all the IP components are of interest and will be examined using the IPQ-R. It is hoped that the current research will go some way towards identifying the components that are most pertinent for these patient groups. This will hopefully highlight the issues requiring attention/the potential areas for intervention by health professionals and also aid the focus of future research in this area.

The next section will provide a review of the IP literature from both cardiac and non-cardiac populations, particularly given the dearth of research regarding IPs and HF patients. The literature in the next section has been considered under the following headings: Chronicity, Consequences, Controllability, Illness Coherence and Cause[7].

[7] Despite the headings, all areas examined by the IPQ-R have been considered. Given the potential associations between certain components the same components may have been discussed in more than one section.

1.5.1 CHRONICITY

It is essential to note that an individual's IPs may not be accurate according to medical standards, but it is these perceptions which have been shown to influence patients' responses, and attempts to manage illness (Ridder, 2004). With this in mind, it is of interest to consider the 'chronic' label that the medical world assigns to HF[8]. Bearing in mind the earlier distinction highlighting the difference between the medical ('disease') and individual ('illness') perspective, it would appear naïve to assume that HF patients also view their condition as chronic in nature.

Research paints an inconsistent picture as to patients' views regarding the chronicity of their illness and also the impact that this has on patients' psychosocial functioning.

Ekman, Norberg, Lundman (2000) found that about one-fifth of patients who were deemed from a medical perspective to have chronic HF did not consider themselves to be chronically ill. Ekman et al. (2000) attributed this to the absence or reduction in severe symptoms as a result of medication, whereby some individuals then considered themselves 'cured'. As such, if patients' experienced another or a further deterioration in their health (i.e. increased symptoms) they would interpret this as a new acute event.

[8] Although no scientific definition of chronic disease exists, it is widely accepted that such disease states are long-term, progressive in nature and are without the prospect of cure.

A number of studies in both cardiac and other illness populations have shown that patients who have a strong belief that their illness is chronic report higher levels of disability and poorer psychological adaptation to their condition (Heijmans, 1999; Scharloo, Kaptein, Weinman, Hazes, Willems, Bergman, et al, 1998).

In a recent study examining the relationship between depression and IPs among patients who had experienced an acute coronary event, lower levels of depression were associated with the perception of an acute rather than a chronic time course (Grace, Krepostman, Brooks, Arthur, Scholey, Suskin, et al, 2005)[9]. As such, Grace et al. (2005) proposed that patients' efforts to minimise the perceived course of their illness might have been warranted and functional in reducing or protecting patients from experiencing elevated depression. Despite this proposal, the authors felt it should be treated with caution. The proposal was related to the work of Baumeister (1989), who proposed an optimal state of psychological functioning whereby a slight-to-moderate distortion of the self and the world is most adaptive. Large positive distortions are dangerous and vulnerable to disconfirmation, whereas accurate perceptions may lead to depression and maladjustment (Baumeister, 1989).

This hypothesis is related to other research that has claimed that the risk of maladaptive outcomes (both behavioural and psychological) increases when the appraisal of chronicity of illness is not consistent with (medical) reality. In line with this Horne and Weinman (2002) explored IPs in a population of

[9] The patients enrolled in the study had received a confirmed diagnosis of MI, unstable angina, congestive heart failure, or had undergone a percutaneous coronary intervention, or a coronary bypass graft surgery.

asthma sufferers. It was found that those whose symptoms were deemed to be cyclical (i.e. either not present or not as severe all the time) were less likely to perceive their condition as chronic and in turn were significantly more likely to fail to use preventative medication. This was proposed to be associated with a belief that the medication was unnecessary when symptoms were not present. Similar to Ekman et al's research this raises an interesting question about the relationship between the number/severity of symptoms patients experience and their perceptions about the chronicity of a particular illness. Given the literature regarding the physiological and medical benefits that HF patients experience following receipt of a cardiac device it would be of interest to examine the impact that this has on perceptions of chronicity, and more importantly the potential impact it has on psychosocial outcomes.

In contrast to Ekman et al's. (2000) findings, Cherrington, Lawson & Clark (2006) explored the IPs of persons diagnosed with systolic HF, and a significant number of participants (n=22) perceived that their illness would last a long time. The authors interpreted this as revealing that patients had an understanding that their condition was 'chronic' in nature. This finding was viewed in a positive light as it was judged to reflect that patients understood their condition, as it fitted with the accepted medical view. Cherrington et al. (2006) proposed that this argument was further supported by a significant number of participants endorsing the view that they had a coherent understanding of their heart condition.

Cherrington et al's. (2006) 'positive' finding has been supported in other patient populations. Meyer, Leventhal & Gutmann (1985) examined IPs in patients

with hypertension and purported that if patients were able to accept that their condition was chronic they were more likely to participate in, and sustain their treatment regime. This is in line with another study examining IPs and quality of life in haemodialysis patients, which showed that increased perception of disease chronicity was positively and significantly associated with better personal control and physical functioning (Covic, Seica, Gusbeth-Tatomir, Gavrilovici & Goldsmith, 2004).

Lau-Walker (2004) found that patients who had recently been diagnosed with myocardial infarction (i.e. heart attack) and accepted that their condition was chronic, were likely to exhibit high exercise and diet self-efficacy. In line with other research the author suggested that this had important implications for nursing intervention, whereby if patients could be helped to accept that their heart condition was long term, this might increase adherence to rehabilitation programmes as well as engagement in recuperative health behaviours (i.e. medication, physical exercise, dietary changes, etc).

When considering this body of research literature, particularly those from cardiac populations (Lau-Walker, 2004; Cherrington et al., 2006) it is important to bear the following limitations in mind. Caution needs to be taken when considering literature on MI patients in relation to an out-patient HF group with cardiac devices, as often participants in MI studies have been in-patients at the time of recruitment, as was the case in the study by Lau-Walker (2004). There is research to suggest that there are distinct differences between in-patient and out-patient populations. This is relatively intuitive given that a stay in hospital is usually associated with an acute event of some description, which

would be expected to give rise to a different psychological and behavioural pattern of response and management. With regards to the Cherrington at al. (2006) study the generalisability of the findings is limited due to the small sample size (n=22) and also the fact that participants were significantly younger than average HF patients (i.e. mean age 51 versus 65). In addition, the study did not examine the relationship between illness representations and any outcome measures such as psychological distress, quality of life, activity tolerance, or hospital readmission, for example, which are factors that have been associated with patients' emotional and behavioural responses to ill health.

In summary, with regards to whether or not HF patients with a CRT or CRT-D device view their condition as chronic and what impact this has is unclear. There is research to suggest that HF patients are aware of the medically chronic nature of their condition and that this has positive implications for secondary preventative health behaviour. However, there is also literature that highlights a certain subset of patients whose perception of illness is in contrast to that proposed from a medical viewpoint. This appears to be related to the experience and severity of symptoms, a reduction or absence of which may be associated with reduced psychological distress. There is no existing literature that examines these issues in CRT or CRT-D patient populations.

As well as the presence and severity of symptoms being related to perceived chronicity of illness, there is also research to indicate that symptoms are related to individuals' beliefs about the consequences of their illness. The next

section will consider patients' perceptions regarding the consequences of their condition and the relationship with psychosocial outcomes.

1.5.2 CONSEQUENCES

Weinman et al. (1996) proposed that the number of symptoms ascribed to an illness was highly correlated with the belief that the illness was a serious condition (i.e. it had serious consequences). In fact there is research to suggest that beliefs about consequences may be more important predictors of both behavioural responses to illness and psychological adjustment than beliefs about chronicity (Scharloo et al, 1999).

Scharloo et al. (1999) conducted a longitudinal study of patients with rheumatoid arthritis and found that even when severity of illness was controlled for patients, perception of adverse consequences of the illness were associated with more visits to the outpatient clinic, more tiredness and higher levels of anxiety. This finding has also been reflected in research involving populations of both psoriasis and multiple sclerosis patients, whereby beliefs about the serious consequences of illness were associated with poorer psychological adjustment (Cameron & Moss-Morris 2004).

Studies have shown that patients' perceptions of the consequences induced by illness play an important part in determining whether patients return to work after a myocardial infarction (Petrie, Weinman, Sharpe & Buckley, 1996; French, Lewin, Watson & Thompson, 2005). Petrie et al., (1996) found that

patients who thought that their illness would last a short time and have less serious consequences returned to work earlier. A more recent prospective study, showed that IPs measured within 24 hours of a patient being admitted to hospital following a myocardial infarction were predictive of patients' physical, emotional and social quality of life measured six months later (French et al., 2005). The Consequences subscale was shown to be the strongest predictor of quality of life (i.e. patients reporting the most negative consequences within 24 hours of being admitted to hospital, reported the most reduced quality of life six months later). The results of this study were used as the basis for explaining why an in-hospital intervention that had successfully changed (post-myocardial infarction) patients' perceptions did not influence the uptake of rehabilitation but led to earlier return to work and a lower level of symptom reporting (Petrie, Cameron, Ellis, Buick & Weinman, 2002).

Although myocardial infarction is a potential contributory factor in the development of HF, the studies of IPs in myocardial infarction patients are not directly applicable to patients with HF (see Section 1.5.1), particularly given that the majority of studies have utilised in-patient populations soon after a cardiac event. Furthermore, French et al., (2005) did not include the identity (symptoms) part of the IPQ, which has been shown in a number of studies to be associated with both perceived chronicity and consequences. In addition, the study employed the original version of the IPQ, which has now been superseded by the IPQ-R, which could potentially provide important additional information (i.e. that regarding perceptions about personal control, treatment control, the extent to which illness/symptoms are regarded as puzzling, the

degree of unpredictability and the emotional impact associated with the illness).

Cherrington et al. (2006) identified that HF patients considered their condition to have serious consequences for all aspects of their lives, which was associated with lower levels of perceived personal control (i.e. HF patients who associated serious consequences with their heart condition were less likely to perceive that they had any control over their condition. It could be hypothesised that these patients would be less likely to engage in secondary preventative behaviours)[10]. Interestingly, in the same study the authors also found an association between consequences and perceived treatment control. As such, patients who believed that their illness had more serious consequences were more likely to perceive that their treatment could control their illness and as such were more inclined to adhere to treatment regimes.

In summary, of particular interest is the consistent finding from many of the reviewed studies that, patients' beliefs about the severity of their illness had a greater association with outcome than clinical measures of illness severity. This pattern reinforces the idea that patients' perceptions play an instrumental role in determining both psychological and medical outcomes. Given the prevailing reliance on medical outcomes for HF patients, particularly those who have received a cardiac device, there is a critical need for research examining illness from the patient perspective and, ultimately, consideration given to psychological issues in service planning and treatment delivery.

[10] Secondary preventative behaviours such as changes to diet, exercise, giving up smoking, etc.

The next section will review literature regarding patients' perceptions of control, from both a personal and a treatment perspective.

1.5.3 CONTROLLABILITY

Research has shown that people are motivated to maintain control over their environment and that perceiving such control is beneficial (Helgeson, 1992). In fact when individuals are deprived of control, depression and negative affect have been shown to result (Seligman, 1975; Wortman & Brehm, 1975). According to Thompson (1981), the beneficial effects of control are not limited to actual control attempts but may include control perceptions. For example, even though heart disease patients have limited opportunity for control, Michela and Wood (1986) found that patients spontaneously generated perceptions of control. The onset of illness, particularly that perceived to be chronic in nature, has been described as a victimisation experience (Janoff-Bulman & Frieze, 1983). According to Janoff-Bulman et al. (1983) victimisation involves the shattering of basic assumptions about the world, one of which is the assumption of invulnerability. Adjustment to victimisation involves restoration of such world assumptions. Regaining a sense of control over the event can restore feelings of invulnerability. Perceiving control over future events allows one to believe that victimisation is manageable or will not be repeated (Taylor, 1983). Chronic illness is a situation, however, over which an individual does not have complete control, but, because there are aspects of chronic illness that are controllable, perceived control may still be adaptive and

positively affect both physical and psychological health. This is particularly true for cardiac patients for whom positive health behaviours (i.e. stopping smoking, changing diet, starting exercise and adhering to medication regimes) have been shown to play an important role in limiting the progression of illness and improving psychosocial outcomes.

Cherrington et al. (2006) found that HF patients who believed that they had a low level of control over their condition, from a personal and treatment control perspective, were more likely to report that the condition had a greater negative emotional impact (measured via the emotional representation component of the IPQ-R). Furthermore, the authors suggested that these patients were less likely to engage in positive health behaviours. This has certainly been shown to be true for patients who have experienced a myocardial infarction (Cooper, Lloyd, Weinman & Jackson, 1999; Petrie, Weinman, Sharpe & Buckley, 1996). Prospective studies have revealed that myocardial infarction patients' attendance at cardiac rehabilitation programmes is strongly related to the perception that their heart condition can be cured or controlled (i.e. patients who perceived a high level of personal control were found to be more likely to attend and engage in rehabilitation; Cooper et al., 1999; Petrie et al., 1996). These findings have been further supported by research utilising an interpretative phenomenological methodology, in a small number (n=6) of myocardial infarction patients (Wyer et al., 2001). The authors found that attendees at cardiac rehabilitation perceived themselves as in control of their own recovery and viewed the rehabilitation programme as a way of taking responsibility for their health (Wyer et al., 2001). The limitations

regarding the study by Cherrington et al. (2006) and also research related to myocardial infarction patients has been described in Section 1.5.1 and 1.5.2.

Consideration of this body of literature raises the question of whether the concept of 'control' is further complicated in patients who have received a cardiac device. It is conceivable that this type of 'permanent' treatment, the functioning of which a patient may perceive, somewhat realistically, that they have no control over, may potentially reduce or remove perceived personal control. This may be in contrast to the experience of solely taking oral medications (as was the case in the Cherrington et al's., 2006 study), over which an individual can exert personal control through deciding whether or not to take a particular medication or altering the quantity that is consumed. To date, there is no published literature that has explored patients' perceptions of personal and treatment (i.e. device) control or the relationship between these perceptions and psychosocial outcomes. In line with other research it is possible that patients with a device might perceive that they have little or no control over their illness, which may be associated with poor psychosocial outcome(s). Alternatively, even if individuals consider that they have limited personal control, it is conceivable that the perception of the device as 'in control' may mean that psychosocial morbidity is not negatively affected. This hypothesis is supported by the ICD literature, which reports patients' feelings of reassurance and security following receipt of a device (Lewin et al., 2001).

Patients' perceptions of control, whether this be related to personal control or control afforded by an individual's treatment clearly play an instrumental role in

engagement in positive health behaviours. Such engagement is particularly important for cardiac patients, as research has shown changes in health behaviour to be related to improved physical and psychological outcomes. A concept that could go some way towards shaping an individual's perception of control is related to the 'cause' that a person attributes to their underlying condition. The concept of 'cause' will be reviewed in the next section.

1.5.4 CAUSE

The concept of 'control' has been associated with the cause(s) that an individual attributes to their condition. Attempts to identify a cause(s) for an illness is considered to be motivated by efforts to make sense of the illness experience (as discussed in Section 1.5.3). Cameron et al. (2004) also notes that identifying a cause(s) may provide individuals with a sense of predictability and control over their illness.

Michela et al. (1986) propose that people commonly attribute their illnesses to the following factors: hereditary, the actions of others, the environment, fate or chance, or their own character or actions.

In a prospective study of myocardial infarction patients French et al. (2005) found that three causal attribution items: stress, other people's behaviour, and state of mind, were inversely related to health quality of life variables, and this was particularly true for 'stress'. Thus, individuals who attributed their illness to

the aforementioned categories experienced poorer emotional, physical and social quality of life.

Grace et al. (2005) reported that patients who had experienced an acute coronary event perceived dietary habits, heredity, and stress as the greatest cause of their heart condition. Furthermore, increased depressive symptomatology was significantly related to greater endorsement of stress or worry, mental attitude, family problems, emotional state, personality, and overwork as causal factors. This was somewhat supported in an earlier study examining IPs in a chronic fatigue population (Edwards, Suresh, Lynch, Clarkson & Stanley, 2001). The authors found that chronic fatigue patients who attributed the cause of their condition to 'psychological' factors experienced significantly higher levels of anxiety and depression[11].

With regard to HF patients Cherrington et al. (2006) considered the results relating to cause to be inconclusive. The authors reported that HF patients did not attribute their condition to either fate or immunity, and were 'noncommittal' regarding psychological attributions and risk factors as causes. It could be hypothesised that these study results reflect that HF patients are less motivated to formulate causal attributions for their condition. The reasoning for this could be related to a study conducted in a population of diabetes patients (Sissons Joshi, 1995). This study reported that patients were disinclined to identify causes of their condition, as they did not perceive that it was important or helpful to do so.

[11] Edwards et al., 2001, referred to 'psychological' causal factors as those where patients believed CFS was a result of their own behaviour or state of mind

To date there is an absence of research examining causal perceptions in cardiac device patients. However, existing literature appears to highlight the potentially detrimental impact of certain causal beliefs; beliefs that may be based on misconceptions, which could be addressed by health professionals. For example, it is a common misconception in cardiac patients that stress plays a causal role in the development of a patient's heart condition. This can lead patients to reduce their activity levels in a bid to avoid further 'stress' that they perceive could exacerbate their condition. In actual fact reduced activity is more detrimental both physically and psychologically (BHF, 2002). However, patients can interpret any further decline as confirmation that they were correct to reduce their activity, which may lead to further activity restriction. This is clearly an important area of research and has the potential to inform intervention strategies for these patient populations.

In relation to 'cause', consideration of patients' misconceptions raises the questions of how coherent patients' understanding is regarding their condition and the symptoms that they experience. The next section will examine the concept of illness coherence.

1.5.5 ILLNESS COHERENCE (UNDERSTANDING)

The concept of illness coherence is unclear because of the difficulties in defining what is meant by 'understanding' and also then identifying a measure that will appropriately capture this concept. Moss-Morris et al. (IPQ-R, 2002) define perceived understanding (i.e. illness coherence) as the extent to which

patients find their illness/symptoms puzzling. Utilising the IPQ-R, Petrie et al. (2002) found evidence that post myocardial infarction patients who reported perceptions that their condition and symptoms were puzzling, were less likely to attend cardiac rehabilitation. The authors hypothesised that patients who did not have a coherent perceived understanding of their illness were less likely to comprehend the reasoning behind being asked to exercise and to alter their diet, and as such would be less inclined to attend or engage in rehabilitative behaviours (Petrie et al., 2002). This is a pertinent issue for cardiac device patients as positive health behaviour has been shown to play an important role in improving physical and psychological outcomes (as discussed in Section 1.5.3 and 1.5.4). It is possible that cardiac device patients who perceive their illness and symptoms as puzzling might be less inclined to engage in secondary preventative behaviours, which inadvertently leads to a reduction in physical and psychosocial outcomes.

1.5.6 SUMMARY

In summary, further research into IPs in the HF device population is believed to be not only theoretically relevant and interesting, but it also appears to be instrumental in defining targets for interventions via attempts to change IPs. It is possible that intervention strategies could utilise a cognitive behavioural framework as this approach 'captures' individuals thoughts (i.e. illness perceptions). Kaptein (2000) argues that by ignoring IPs (i.e. how the patient has made sense of their illness) health care professionals can impede medical care and any attempts to educate or rehabilitate patients.

There are a growing number of people living with HF due to improvements in medical care and an ageing population. CRT and CRT-D can provide treatment for HF patients whose condition cannot be addressed by medication alone. To date, there is a dearth of literature examining psychosocial outcomes for these patients. Given the significant levels of distress and reduced quality of life experienced by HF patients and, the psychosocial issues highlighted in the ICD literature, it is crucial that these areas are addressed for CRT and CRT-D patients. The SRMI (Leventhal et al., 1997) and, more specifically the concept of IPs, provide a basis from which device patients' psychosocial responses can begin to be understood. Furthermore, it is possible that IPs can be 'captured' and worked with utilising a cognitive behavioural theory framework, as a means of improving patient outcomes.

CHAPTER TWO

2.1 RATIONALE FOR CURRENT STUDY

HF is an increasingly common condition, which is associated with major consequences for both the individual and the UK economy. The symptoms of HF usually respond well to medication, however this is not always the case. In HF patients with electrical conduction abnormalities the CRT device has been found to be effective in ameliorating symptoms (Cazeau et al., 2001; CARE-HF, 2005). Despite this important benefit the CRT device does not provide protection for HF patients who are also at risk of life threatening heart rhythms. The ICD device has been shown to be 99 percent effective in the treatment of life threatening rhythms, but it does not address the issue of symptoms in the HF population. As such, the CRT-D device has been more recently developed, which incorporates a defibrillator function alongside the synchronising function required by those with HF.

To date CRT and CRT-D research has focused on medical outcomes with very limited consideration of psychosocial outcomes (CARE-HF, 2005; Young et al., 2002; COMPANION Study, 2004). The existing HF and ICD literature highlight the importance of examining such outcomes. HF research suggests that a high proportion of patients may experience clinically significant anxiety and depression and reduced quality of life (Juenger et al., 2002; Calvert et al., 2005). In addition, the ICD literature demonstrates that implantation of an ICD

may have adverse psychological consequences (Lewin et al., 2001; Helga et al., 1997; Sears et al., 1999).

A small number of studies have examined quality of life in CRT and CRT-D recipients and have reported significant improvements following implantation (CARE-HF, 2005; MIRACLE ICD Trial, 2005). However, a great deal of variability in quality of life has been found which cannot be accounted for by medical factors. Potential predictors of psychological distress and quality of life have received limited exploration in the HF literature. Age, previous mental ill health, co-morbid physical conditions and mood medication are among those factors that have been associated with psychological morbidity and reduced quality of life (Rumsfeld et al., 2003).

The way in which a patient perceives and subsequently makes sense of their condition has also been shown to play an important role in determining how patients respond both physically and psychologically to ill health (Grace et al., 2005; Scharloo et al., 1999; French et al., 2005; Cherrington et al., 2006). Indeed there is research to suggest that patient (cognitive and emotional) representations of their health status can be more important than absolute physiological impairment in determining psychosocial outcomes. In the current study, the Self-Regulation Model of Illness (SRMI, Leventhal et al., 1997) provides the basis and structure for starting to examine the meaning and associated implications of having a cardiac condition that has required surgical intervention, in the form of a CRT, CRT-D or an ICD device.

Since the development of a psychometrically sound measure based on the SRMI (i.e. the Illness Perception Questionnaire), there has been an increase in research in this area. However, the research regarding cardiac patients is very difficult to generalise to patients with a cardiac device as the majority of studies utilised in-patient populations; patients tended to be recruited following a myocardial infarction or another acute coronary event; and research examining HF patients were based on small sample sizes (Cherrington et al., 2006; Grace et al., 2005; Lau-Walker, 2004). Hence, research examining illness perceptions in HF device patients is warranted to start to gain an insight into the sense that patients make of their condition and the relationship between perceptions, psychological distress and quality of life. Such research could have important practical implications for cardiac rehabilitation and patient counselling in terms of helping patients to cope with their illness by modifying and restructuring their personal models of illness. Such modification and restructuring could be achieved utilising a cognitive behavioural framework (advocated by the BACR; Coats et al, 2007), which 'captures' and works with individuals IPs.

2.2 AIMS

The current study aims to examine the prevalence of psychological distress (anxiety and depression) and quality of life in CRT, CRT-D and ICD patients. The study also aims to investigate the illness perceptions of patients in these three device groups and the relationship of perceptions to psychological distress and quality of life. Finally, the study aims to investigate whether illness

perceptions could be used to predict anxiety, depression and quality of life in device patients.

Although the current study is based on an investigation into an area where there is a dearth of previous psychological research it was deemed appropriate to utilise a purely quantitative design. This design would allow for the examination of the prevalence of psychological distress, the level of quality of life and the investigation of patients' illness perceptions using a psychometrically sound and increasingly popular measure. It was believed that this study could potentially highlight areas that are most pertinent for these patient groups (e.g. patients may perceive that they have very limited personal control, which is associated with increased psychological distress), and thus provide the focus for future, more in depth qualitative studies. Also, this study was interested in comparing the device groups, which was made possible by the quantitative design. Finally, it was hoped that quantitative data might have more 'pulling power' when it came to the dissemination of results into the medical sphere, at the end of the study. Such data might help medics to understand the potential and importance of both psychologically driven research, and provide a clearer rationale for the use of qualitative studies in the area.

2.3 IMPETUS FOR STUDY

The study is the first to examine psychological distress and illness perceptions in CRT and CRT-D recipients. The research is considered important for a number of reasons:

- It will contribute to the research base for HF patients
- Given the lack of clear relationship between physiological and quality of life outcome measures, utilised in CRT and CRT-D patients, it may go some way towards accounting for variability
- It will aid in the identification of misconceptions that may have adverse psychological consequences and thus help focus interventions aimed at preventing distress and enhancing quality of life in these patient populations
- A longer-term aim is that the identification of patients who are experiencing adverse psychological consequences, or who are deemed to be at risk of such consequences, will enable appropriate interventions to be put in place. Timely interventions that would aim to save the health service financial and professional resources; as psychological issues could be addressed before potentially becoming entrenched, causing undue distress, disability and cost to the UK economy
- Due to the relative infancy of the CRT and CRT-D devices the medical indicators used for identifying which patients will benefit from receipt of a device are not always clear. As such, it is occasionally left to the professional judgement of the clinician as to whether recommendation

for a device is made. In order to get a clearer idea of which patients 'do well' with which device, medically orientated studies have compared the device groups on medical outcomes. In the present study it was deemed of interest to compare the groups based on psychological outcomes, to add another element to the current debate about which patients might benefit from implantation of a CRT or CRT-D device

- Finally, it will adhere to NICE (2003) guidelines highlighting the importance of patients with HF being "at the centre of care"

2.4 RESEARCH QUESTIONS

1) What is the prevalence of psychological distress experienced by patients who have received a CRT, CRT-D or an ICD device?
2) What is the quality of life experienced by patients who have received a CRT, CRT-D or an ICD device?
3) What are the illness perceptions of patients who have received a CRT, CRT-D or an ICD device?
4) What is the relationship between patients' illness perceptions and psychological distress?
5) What is the relationship between patients' illness perceptions and quality of life?
6) Do illness perceptions predict anxiety, depression and reduced quality of life in device patients?

2.5 EPISTEMOLOGICAL STATEMENT

The critical realist position assumes that there is a real world that has regularities. However, it asserts that the world can never be known with certainty and understanding is always essentially tentative (Barker, Pistrang & Elliott, 2002). From a critical realist standpoint, reality is testable and measurable. In the current study, it is assumed that patient perceptions, psychological distress and quality of life are real constructs that are essentially quantifiable.

The critical realist perspective highlights the importance of research being replicable. This involves researchers being explicit about methods of data collection and clear about how conclusions have been drawn, thus enabling other researchers to evaluate and replicate research (Barker et al., 2002). The present study aims to provide clear accounts of methodological and analytical procedures to ensure that findings can be evaluated and the research replicated.

For these reasons the researcher adopted a critical realist epistemological position for the current study.

CHAPTER THREE

METHODOLOGY

3.1 DESIGN

The study was non-experimental, correlational and cross sectional in design. Quantitative questionnaire based data was collected at a single time point from patients who had received a CRT, CRT-D or an ICD device between the months of August 2001 and August 2006, at one of two regional implantation centres.

3.2 PARTICIPANTS

Participants were recruited to the study on a volunteer basis from the Cardiology Department of two regional hospitals in the North of England. The original pool of participants comprised 111 CRT, 102 CRT-D and 128 ICD patients (the combined total from patients at the two implantation centres). Participants' details were held on a database within the Cardiology Department at the respective implantation centre and were initially examined by the researcher to identify those who did not fulfil the research criteria[12]. Following this process the potential pool of participants was made up of 97 CRT, 88

[12] There were some concerns that the database systems were not up to date regarding deaths, ex-plants (removal of device), emigration, etc. The researcher checked manual files at the departments to avoid patients or families being contacted inappropriately. Patients whom the hospital did not have any contact details for were also excluded from the research, as this precluded the researcher being able to make contact.

CRT-D and 91 ICD participants who were all invited to take part in the research.

The final sample (those who returned questionnaires) consisted of 53 CRT, 47 CRT-D and 51 ICD recipients, which represent a 60%, 63% and 58% response rate, respectively (see Results Section 4.2 for further sample information).

3.2.1 INCLUSION CRITERIA

Participants were included in the study if:

- They had received a cardiac device (i.e. CRT, CRT-D or ICD) between August 2001 and August 2006
- They were adults over 18 years of age (children require a developmental perspective that is not covered by the present study. Also there is an increased likelihood that their heart condition is congenital which raises issues not covered by this study)
- They provided informed consent to participate

3.2.2 EXCLUSION CRITERIA

Participants were excluded from the study if:

- They were unable to understand English (all questionnaires validated in English language only except for the HADS)
- They had had the device explanted (removed)
- They had Congenital heart failure and/or significant co-morbidities
- The hospital did not hold contact details

- ❖ They were in an unsuitable physical state at point of data collection

3.3 MEASURES

Each of the participants, regardless of device type was administered the same questionnaire pack, via post. However, six participants were met by the researcher and supported in completing the questionnaire pack. The reasons for this fell within three categories:

- ➢ Anxiety regarding ability to understand and complete the questionnaire, but eager to participate (n=3).
- ➢ Difficulties regarding reading or writing (n=2).
- ➢ Problems regarding sight, but eager to participate (n=1).

3.3.1 DEMOGRAPHIC DATA

Data regarding patient age, gender and length of time since implantation of device was attained from the database system at the appropriate implantation centre. Self-reported sociodemographic data included marital status, work status and ethnocultural background. A "yes/no" response item was created to assess whether participants had previously experienced mental ill health (i.e. anxiety or depression). Another two "yes/no" items were created to further assess whether a participant's previous experience of mental ill health (if they had endorsed that item) was related to either their heart condition and/or the device they had received. A "yes/no" response item was created to examine

whether participants were currently taking medication to help with mood. A "yes/no" response item was created to assess whether CRT-D and ICD participants had experienced any device firings. Patients were also provided with space to add any additional comments (see Appendix A for research measures).

In addition to the demographic information and "yes/no" items a number of validated measures were employed in the study. These are described next and can be seen in Appendix A.

Table 3.1 SUMMARY OF FORMAL MEASURES USED IN THE STUDY

MEASURE	TO ASSESS	SCORING
Illness Perception Questionnaire - Revised (IPQ-R)	Nine dimensions of illness perceptions. Dimensions divided in to three sections	Section one – 8 items related to dimension 'Identity'. Score 0-8. Section two – 40 statements each scored 1-5 and combined to generate scores for seven separate dimensions. Section three – list of 18 possible causes each scored 1-5 dependent upon level of agreement.
Hospital Anxiety and Depression Scale (HADS)	Anxiety Depression	7 items pertaining to anxiety and 7 items pertaining to depression, each scores 0-3
Short Form – 12 Health Survey (SF-12)	Eight dimensions of health significantly effected by medical conditions	12 items that can be reduced to 2 summary scores – Physical component summary score (PCS) and Mental component summary score (MCS). Norm based scoring - interpretation of group average according to the place in the distribution of scores for a general population (i.e. mean is 50)

3.3.2 ILLNESS PERCEPTION QUESTIONNAIRE – REVISED (IPQ-R) (MOSS-MORRIS ET AL., 2002)

The IPQ-R is a widely used theoretically derived quantitative measure of the six components of illness representations in Leventhal's Self-Regulatory Model (i.e. identity, cause, cure/control, consequences and timeline) (Leventhal et al., 1980). The original IPQ, which had four components, was developed to investigate only the cognitive components of patients' representations, and this was deemed to limit its capacity to describe patients' responses to illness (Moss-Morris et al., 2002). In 1983, Lau and Hartman adapted the measure, with the introduction of a fifth dimension, about the cure and controllability of the condition. These five components were used to assess illness identity, cause, time-line, consequences and control/cure. The content of the original control/cure component from the IPQ was viewed by Horne (1997) as confounding sets of beliefs, so these beliefs were therefore operated separately as the personal control and treatment control scales (Hagger & Orbell, 2005). Moss-Morris et al. (2002) then conducted further revisions, as it was believed that there was a need to deal with a number of psychometric problems with two sub-scales, and to include additional sub-scales, assessing cyclical timeline perceptions, illness coherence, and emotional representations. This revised version was named the Illness Perceptions Questionnaire-Revised (IPQ-R) and was used in the present study. The nine subscales of the revised IPQ are: (1) identity – the symptoms the patient associates with the illness; (2) timeline – the perceived duration of the illness; (3) consequences – expected effects and outcome; (4) personal control – how

one controls or recovers from the illness; (5) treatment control – the perceived efficacy of treatment; (6) illness coherence – the extent to which patients find their illness/symptoms puzzling; (7) timeline cyclical – how cyclical the patient perceives the illness; (8) emotional representations – emotional impact of the illness; and (9) cause – personal ideas about disease aetiology. Moss-Morris et al. (2002) noted that adaptation of the questionnaire was possible (i.e. the wording of the questionnaire was adapted in the present study to examine perceptions related to patients' 'heart condition'. See Section 3.5.2 for analysis of reliability).

The IPQ-R is divided into three sections. In the first section, identity is measured by assessing the number of symptoms that the patient endorses as being caused by their heart condition from a list of eight symptoms. Subsequently, scores on this sub-scale can range from one to eight. The second part of the IPQ-R consists of 40 statements with which patients are asked to indicate their level of agreement on a five-point scale ranging from *strongly agree* to *strongly disagree*. The scores on these individual items range from one to five and are used to generate scores for the seven illness perception scales. The third part of the IPQ-R is the causal attributions checklist. It provides a list of 18 possible causes of patients' heart condition and patients are asked to rate their agreement with each item as a cause for their own illness. Respondents are specifically instructed to respond according to their own perceptions, which may be different from what their doctor or others could have told them. Finally, patients are asked to note the most important factor, which they believed has caused their heart condition.

Reliability and Validity

Moss-Morris et al. (2002) reported Cronbach alphas for each of the sub-scales that ranged from 0.79 for the timeline cyclical dimension to 0.89 for the timeline acute/chronic dimension. As such, all the sub-scales appeared to demonstrate good internal reliability. The dimensions of the IPQ-R generally showed good stability over a short time period (three weeks) with correlations ranging from 0.46 to 0.88. Personal control was the only dimension to show a correlation less than 0.5. Over a six-month period the retest reliability was examined and the IPQ-R was found to have acceptable consistency. The IPQ-R also demonstrated sound discriminant, known group and predictive validity (Moss-Morris et al., 2002). Data from the principal components analysis provides experimental support for the theoretically driven dimensions of patients' illness perceptions (Moss-Morris et al., 2002).

3.3.3 HOSPITAL ANXIETY AND DEPRESSION SCALE – HADS (ZIGMOND & SNAITH, 1983)

The HADS is a self-report measure, which is used widely as a screening instrument for anxiety and depression. It does not contain questions pertaining to somatic complaints, making it less likely to be confounded by the direct effects of medical conditions. The HADS consists of 14 items divided into two subscales for anxiety (seven items) and depression (seven items). On each item, respondents are required to select the most applicable statement relating to their current functioning. The responses are scored on a scale of 0 to 3, giving a potential global scoring range of 0 to 21 for each subscale. The

authors' recommended classifications of anxiety and depression are displayed in Table 3.2.

TABLE 3.2 CLASSIFICATIONS OF ANXIETY AND DEPRESSION SCORES ON THE HADS (ZIGMOND & SNAITH, 1983)

SCORE RANGE	CLASSIFICATION
0 - 7	Normal
8 – 10*	Mild/Possible Clinical disorder
11 – 14*	Moderate/Probable Clinical Disorder
15 – 21*	Severe/Probable Clinical Disorder

* Clinically significant range

Reliability and Validity

Hermann (1997) reviewed the HADS and reported it to be a reliable and valid measure, sensitive to change in the affective states of anxiety and depression. Herrman (1997) reported Cronbach alphas 0.8 for anxiety and 0.81 for depression indicating high sub-scale internal consistencies. A high correlation was also reported for test-retest reliability ($r > 0.8$ after two weeks) and therefore, the HADS was described as sufficiently stable to withstand situational influences but also sensitive enough to respond to mood changes over time.

Tests for validity showed factorial validity with a two-factor solution. However, discriminant validity of the HADS appeared more questionable. Herrmann (1997) discovered high correlations between the anxiety and depression subscales for most of the patient groups and concluded that these high correlations reflected a real coincidence of anxious and depressed symptomology rather than shortcomings of the HAD scale.

3.3.4 SHORT FORM – 12 HEALTH SURVEY (SF-12; WARE, KOSINSKI & KELLER, 1996)

Information assessing Health Related Quality of Life was obtained using the Short Form - 12 Health Survey (SF-12). The SF-12 is a generic measure of health status, which is relevant across age, disease, and treatment groups. The survey was designed for self-administration, reducing the burden of data collection for health care providers. Most patients can complete the SF-12 in less than 3 minutes without assistance. The survey encompasses 12 questions covering eight dimensions of health significantly affected by a medical condition: physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional, and mental health. The eight-scale profile is commonly reduced to two widely validated summary scores physical component summary (PCS) and mental component summary (MCS) to describe the patient's personal perception of their physical and mental health. The SF-12 was designed as an alternative to the longer SF-36, and provides an accurate reproduction of summary measures.

Scores are calculated following a norm-based scoring algorithm, utilizing a mean of 50 and standard deviation (SD) of 10. The norm-based scoring system allows for interpretation of group average according to the place in the distribution of scores for a general population. The scores greater than 50 represent above average health status. On the other hand, people with a score of 40 function at a level lower than 84% of the population (one standard deviation) and people with a score less than 30 function at a level lower than approximately 98% of the population (two standard deviations). The decrease in PCS will reflect limitation in self-care, physical, social, and role activities as well as severe bodily pain and frequent tiredness. The diminished MCS scores indicate the presence of psychological distress, and the limitation in usual social and role activities due to emotional problems.

The Minnesota Living with Heart Failure Questionnaire (MLHFQ, 1995) has been used in other studies and is a specific quality of life measure for heart failure patients. It was not utilised in the present study for a number of reasons. Firstly, the wording of the questionnaire assumes that patients consider themselves to have heart failure, and in line with the illness perception literature, this was not an assumption the present study wanted to make. Secondly, the researcher wanted to look at outcomes between CRT, CRT-D and ICD patients and the MLHFQ was not necessarily appropriate for all patients in the ICD group. Finally, the MLHFQ is a 21-item questionnaire and 18 of the items were considered addressed by measures used in the present study (i.e. the IPQ-R, HADS and the SF-12).

Reliability and Validity

The SF-12 was developed as an abbreviated form of the SF-36, one of the most widely used generic health status instruments to assess health related quality of life. Regression methods were used to select and score 12 items from the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36, 1992) to reproduce the Physical Component Summary and Mental Component Summary scales in the general population (n=2,333). The resulting 12-item short-form (SF-12) achieved multiple R squares of 0.911 and 0.918 in predictions of the SF-36 Physical Component Summary and SF-36 Mental Component Summary scores, respectively. Scoring algorithms from the general population used to score 12-item versions of the two components (Physical Components Summary and Mental Component Summary) achieved R squares of 0.905 with the SF-36 Physical Component Summary and 0.938 with SF-36 Mental Component Summary when cross-validated in the Medical Outcomes Study. Test-retest (2-week) correlations of 0.89 and 0.76 were observed for the 12-item Physical Component Summary and the 12-item Mental Component Summary, respectively. Twenty cross-sectional and longitudinal tests of empirical validity previously published for the 36-item short-form scales and summary measures were replicated for the 12-item Physical Component Summary and the 12-item Mental Component Summary, including comparisons between patient groups known to differ or to change in terms of the presence and seriousness of physical and mental conditions, acute symptoms, age and aging, self-reported 1-year changes in health, and recovery for depression. In 14 validity tests involving physical criteria, relative validity estimates for the 12-item Physical Component Summary ranged from

0.43 to 0.93 (median=0.67) in comparison with the best 36-item short-form scale. Relative validity estimates for the 12-item Mental Component Summary in 6 tests involving mental criteria ranged from 0.60 to 107 (median=0.97) in relation to the best 36-item short-form scale. Average scores for the 2 summary measures, and those for most scales in the 8-scale profile based on the 12-item short-form, closely mirrored those for the 36-item short-form, although standard errors were nearly always larger for the 12-item short-form (Ware et al., 1996).

3.4 PROCEDURE

Ethical approval for the study was obtained from the Local Research Ethics Committee. The letter of ethical approval and the main ethical considerations for the study are outlined in Appendix C. Approval and Honorary contracts were also obtained from the relevant NHS trusts, to allow the researcher to access patient information from the Cardiology Outpatient Departments at both implantation centres (see Appendix C).

Once ethical approval was received, the researcher sent out on average ten letters of invitation per week (over a seven month period), to CRT, CRT-D and ICD patients implanted between August 2001 and August 2006 inclusive. All patients invited to participate were given written details of what their involvement would entail. It was explained in the letter that patients would be contacted by telephone in a week's time, in order to establish their interest in participating. If patients agreed to take part, the researcher sent the questionnaire pack via post with a pre-paid envelope, for return of the

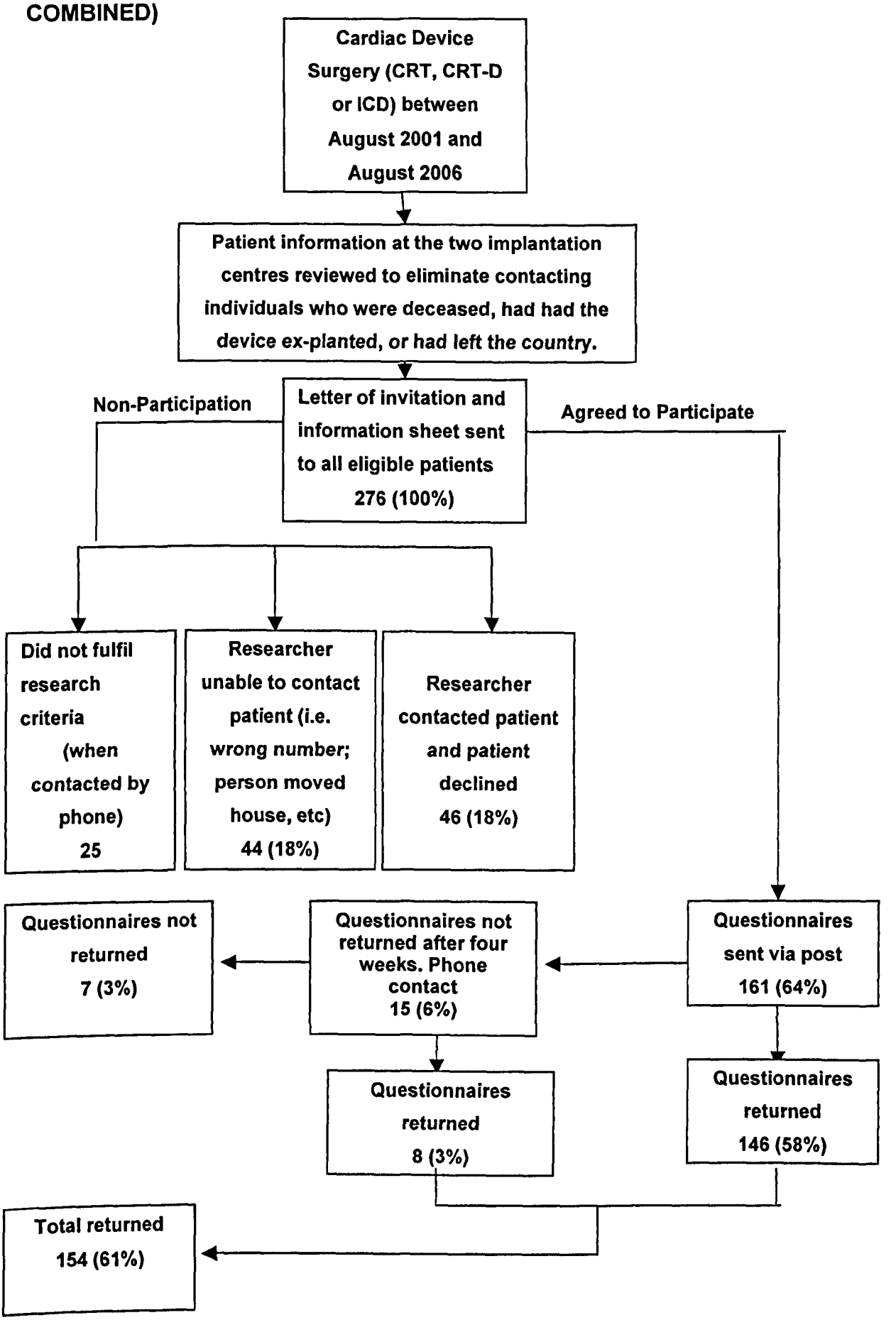
questionnaire on completion. The questionnaire pack included a cover letter encouraging participants to contact the researcher with any further questions relating to the questionnaires or the study itself, or to discuss any concerns (See Appendix D). Patients were informed that returning the completed questionnaires indicated their consent to participate (See Figure 3.1).

If any participant had not returned the questionnaire pack within four weeks of it being sent in the post, the researcher contacted the relevant Cardiology department to confirm the patients continued survival. The researcher then contacted the patient by telephone to enquire whether they had received the questionnaires and whether they still wished to participate. Overall, 15 individuals were contacted in this way, which led to the return of eight (5% of the total response rate) additional questionnaire packets.

All patients' GPs were informed via letter of their consent to participate in the research (Appendix D). In addition, if clinically significant levels of anxiety or depression were reported, patients were contacted and, if they agreed, their GP was informed (see Appendix D for an example letter).

Every participant who returned a questionnaire was sent a letter thanking them for their participation; reminding them of the researcher's contact details; and also reminding them that they would be receiving a summary of the study results at the end of July 2007 (see Appendix D).

FIGURE 3.1 FLOW DIAGRAM OF PROCEDURE (ALL DEVICE GROUPS COMBINED)



3.5 DATA ANALYSIS

3.5.1 POWER CALCULATION

One of the main research questions for the study involved testing for relationships between the outcome variables of illness perceptions, psychological distress and quality of life. The study sought to identify moderate associations between the outcome variables and so a correlation of 0.4 was selected. To detect a correlation of 0.4 with 80 percent power, a sample size of 46 participants in each of the three groups (i.e. CRT, CRT-D and ICD) was required (Hintze, 2001). Although, in line with research question six, it was anticipated that it would be necessary to utilise general linear modelling to control for several predictors simultaneously it was impossible to perform an accurate sample size calculation, as the researcher could not quantify expected differences precisely due to the absence of research in CRT, and CRT-D device patients. As such, it was considered judicious to base the sample size on something more concrete, it was therefore based on a correlation of 0.4 in each device group.

3.5.2 RELIABILITY ANALYSIS

Internal consistency was calculated for the IPQ-R (as it was adapted for patients with a heart condition and a device) using Cronbach's alpha[13]. The

[13] Internal consistency is the extent to which the items constituting the separate subscales of the IPQ-R measure much the same thing (Howitt & Cramer, 2000). The items on each subscale were consecutively entered into a reliability analysis in SPSS to assess the intercorrlation between items on each subscale.

internal consistency was found to be better for some of the IPQ-R sub-scales than for others. The sub-scales, which showed very good levels of internal consistency included: Timeline (alpha = .82), Timeline Cyclical (alpha = .87), Illness Coherence (alpha = .91) and Emotional Representation (alpha = .91). The sub-scales that showed a good level of internal consistency included: Consequences (alpha = .70) and Personal Control (alpha = .79). As all the sub-scales showed either good or very good internal consistency, they were included in the analysis.

3.5.3 QUANTATIVE ANALYSIS

Data were analysed using the Statistical Package for the Social Sciences for Windows Version 14 (SPSS-14). The research questions and the analyses used can be seen in Table 3.3 (see Section 4.1 for detailed rationale of use of statistical tests).

TABLE 3.3 RESEARCH QUESTIONS AND ANALYSIS

RESEARCH QUESTION	TYPE OF ANALYSIS
1. What is the prevalence of psychological distress in patients who have received a CRT, CRT-D or an ICD device?	Descriptives and frequencies were used. Confidence intervals for prevalence of clinically significant cases in the general population were calculated using a standard asymptotic method.
2. What is the quality of life experienced by patients who have received a CRT, CRT-D or an ICD device?	Descriptives and frequencies were used.
3. What are the illness perceptions of patients who have received a CRT, CRT-D or an ICD device?	Descriptives and frequencies were used.
4. What is the relationship between patients' illness perceptions and psychological distress?	Correlational analyses were conducted to examine the relationships between the outcome variables. Scatter plots were examined for each pair of correlated variables and relationships were generally linear. This indicated use of Pearson's correlation coefficients.
5. What is the relationship between patients' illness perceptions and quality of life?	Correlational analyses were conducted to examine the relationships between the outcome variables. Scatter plots were examined for each pair of correlated variables showing relationships were generally linear. This indicated use of Pearson's correlation coefficients.
6. Do illness perceptions predict anxiety, depression and reduced quality of life in CRT, CRT-D or ICD device patients?	Separate General Linear Models were used to examine the predictive relationship of the IPQ-R subscales on level of anxiety, depression and quality of life. Variables, which acted as co-variates in the analysis were: age, device type, previous history of anxiety/depression, mood medication, length of time since receiving device.

CHAPTER FOUR

RESULTS

This chapter comprises of eight sections: Section 4.1 will outline the rationale for the selection of statistical tests employed throughout the analyses, Section 4.2 presents details of the recruitment process and the representativeness of the sample in relation to non-participants; Sections 4.3 to 4.8 address each of the research questions in turn. Initially descriptive data will be presented for psychological distress, quality of life and illness perceptions, in each of the three device groups. This will be followed by correlational analyses of the relationships between patients' psychological distress, quality of life and illness perceptions in each of the device groups. Finally, regression analyses will be utilised to examine the predictive relationship of participants' illness perceptions with psychological distress and quality of life.

4.1 RATIONALE FOR SELECTION OF STATISTICAL TESTS

4.1.1 TEST OF NORMALITY

Visual inspection of histograms revealed that distributions for some of the outcome variables were skewed. However, looking at histograms is subjective and so an objective statistical test, the Kolmogorov-Smirnov test, was used to decide whether the distributions were normal. This test compares sets of the scores on each of the outcome measures to a normally distributed set of

scores with the same mean and standard deviation. The outcome measures used in the present analyses were found to be statistically non-significant ($p>0.05$) on the Kolmogorov-Smirnov test indicating no evidence against normality for any of the measures in the three device groups. Therefore, the data were considered to be sufficiently normally distributed to enable the use of parametric methods for all statistical analyses.

4.1.2 SELECTION OF STATISTICAL PROCEDURE FOR COMPARISON OF GROUP MEANS

Univariate analysis of variance (ANOVA) was used to compare the three device groups in terms of their mean scores on a number of dependent variables. This is a parametric technique, which requires that scores on the dependent variable are independent and numerical, and the data is from normally distributed populations. Descriptive statistics and histograms showed that these criteria were met.

ANOVA provides information about whether the means of the three device groups are significantly different however; it does not show between which groups the difference lies. Gabriel's pairwise test procedure compares all different combinations of the device groups to identify where the difference lies and is suitable when sample sizes between groups are different as was the case for this study.

4.1.3 SELECTION OF STATISTICAL PROCEDURE FOR CORRELATIONAL ANALYSES

Scatterplots were inspected for each pair of correlated variables indicating that the relationships were generally linear. For this reason and as there was no evidence against normality of the data distributions (determined from histograms and Kolmogorov-Smirnov tests), Pearson's correlation coefficients rather than Spearman's correlation coefficients were calculated for the relationships between all outcome variables.

4.1.4 SELECTION OF STATISTICAL PROCEDURE TO EXAMINE THE PREDICTIVE RELATIONSHIP OF INDEPENDENT VARIABLES ON PSYCHOLOGICAL DISTRESS AND QUALITY OF LIFE

Separate General Linear Modelling Regression Analyses was used to examine the predictive relationship of the Illness Perception Subscales (predictor variables) and five additional co-variates, on psychological distress and quality of life (dependent variables). This model was deemed appropriate as previous testing (using scatterplots, histograms and Kolmogorov-Smirnov tests) indicated that the relationships between the variables were generally linear and the data normally distributed. Furthermore, the predictor variables did not correlate with each other very highly, which could have led to problems with multicollinearity[14].

[14] Multicollinearity refers to a situation in which several predictor variables correlate with each other very highly. This results in difficulties because small sampling fluctuations may result in a particular variable appearing to be a powerful predictor while other variables may appear to be relatively weak predictors (Howitt & Cramer, 2000)

4.2 RECRUITMENT AND PATIENT DEMOGRAPHICS

The study invited a consecutive series of patients to participate who had been implanted with a CRT, CRT-D or an ICD device (either a first device or a replacement due to end of a device or battery lifespan) at one of two regional implantation centres between August 2001 and August 2006. In total, 97 CRT, 88 CRT-D and 91 ICD patients were invited to participate in the research study over the recruitment period (September 2006 – May 2007).

With regards to the 97 CRT patients invited to take part nine did not fulfil the criteria and 33 (38%) were not involved in the research (reasons for non-participation detailed in Table 4.1). It followed that 55 (63%) CRT patients agreed to take part and were subsequently provided with the research questionnaires. Of these participants, 53 returned the measures[15]. This represents a 60% overall response rate.

With regards to the 88 CRT-D patients invited to take part 13 did not fulfil the criteria and 25 (33%) were not involved in the research (reasons for non-participation are detailed in Table 4.1). It followed that 50 (67%) CRT-D patients consented to take part and were sent the research questionnaires. Of these 50 patients, 47 returned the measures[16]. This represents a 63% overall response rate.

[15] Of the two participants who did not return the questionnaires: one patient died and the second, despite two follow-up phone calls, failed to return the questionnaire

[16] The researcher attempted to contact three patients on four occasions and was unable to speak with the participants involved

TABLE 4.1 REASONS FOR NON-PARTICIPATION

REASON FOR NON-PARTICIPATION	NUMBER OF PATIENTS		
	CRT	CRT-D	ICD
Did not fulfil inclusion criteria*	9	13	3
Involved in other research	4	5	2
Not interested	8	2	5
Unable to contact	9	15	20
Other demands/health issues	9	1	3
Research too demanding (considered self too old)	3	2	2

* Numbers not included in overall response rate calculation

Finally, of the 91 ICD patients invited to take part three did not fulfil the inclusion criteria and 32 (36%) were not involved in the research (reasons for non-participation are detailed in Table 4.1). It follows that 56 (64%) agreed to participate and were subsequently sent the research questionnaires. 51 patients returned the measures. Of the five participants who did not return completed measures: one had a stroke, one experienced a family breakdown and three were followed up by telephone, but despite prompting did not return the measures. The overall response rate for the ICD group was 58%.

The next section examines the representativeness of participants in the study by comparing participants with non-participants with regards to age, gender and length of time since receiving a device.

4.2.1 REPRESENTATIVENESS OF SAMPLE

Demographic data (i.e. age, gender and length of time since receiving a device) were obtained from the appropriate regional clinic database for all patients implanted with a CRT, CRT-D or an ICD between August 2001 and August 2006. These data are displayed in Table 4.2.

TABLE 4.2 DEMOGRAPHIC DATA FOR PARTICIPANTS AND NON-PARTICIPANTS

DEMOGRAPHIC VARIABLES	CRT		CRT-D		ICD	
	PPTS*	NON-PPTS**	PPTS*	NON-PPTS**	PPTS*	NON-PPTS**
Age M = Mean R = Range (S.D.)	M = 70 R = 49-84 (8.3)	M = 70 R = 46-91 (11.3)	M = 67 R = 40-82 (8.6)	M = 67 R = 47-80 (8.0)	M = 65 R = 32-79 (10.5)	M = 61 R = 22-87 (18.2)
Gender M = Male F = Female	M = 39 F = 14	M = 40 F = 4	M = 42 F = 5	M = 35 F = 1	M = 40 F = 11	M = 21 F = 14
Length of time since receiving a device (months) (S.D.)	25 (12.2)	24 (12.3)	26 (15.7)	25 (16.5)	44 (17.5)	44 (14.7)

* PPTS = Participants
** NON-PPTS = Non-Participants

With regards to CRT patients, the participants group was comprised of a higher percentage of female patients than the non-participant group (26% versus 9%, respectively). In relation to age, independent samples t-tests

revealed that CRT participants did not differ significantly from non-participants in terms of age (t=0.3, df=95, p=0.74) or in the length of time since receiving a CRT device (t=-0.3, df=95, p=0.71) (See Appendix E, Table 1 a-d). Therefore, apart from the gender variable, the sample was considered to be representative of all CRT patients implanted with a device at the implantation centres.

The group of CRT-D participants was made up of a marginally lower percentage of male patients than the non-participant group (89% versus 97%, respectively). Independent samples t-tests revealed that CRT-D participants did not differ significantly from those not taking part in terms of age (t=-.082, df=81, p=0.94) or in the length of time since receiving a CRT-D device (t=0.3, df=81, p=0.78) (See Appendix E, Table 2 a- d). Overall, in terms of these basic demographic variables, the sample was considered to be representative of all CRT-D patients implanted with a device at the implantation centres.

Finally, the non-participant ICD group was comprised of a higher percentage of females than the participants group (40% verses 22%, respectively). However, the reverse was true for male participants compared to non participants (78% verses 60%, respectively). With regards to age, independent samples t-tests showed that there was not a significant difference in terms of age between participants and non-participants (t=1.4, df=85, p=0.18). However, non-participant ICD patients tended to be younger than those who chose to participate. In terms of the length of time since receiving an ICD device, participants did not differ significantly from non-participants (t=0.6, df=85,

p=0.57) (See Appendix E, Table 3 a-d). Therefore, apart from the gender variable, the sample was considered to be representative of all ICD patients implanted with a device at the implantation centres.

The next part of this section focuses on examining more detailed demographic information. Firstly, gender, ethnicity, marital status and employment information will be described. This will be followed by a description of participant responses to questions regarding additional health problems, history of mental ill health and medication (related to mood).

4.2.2 DEMOGRAPHICS OF SAMPLE

The mean age of the CRT patients (n=53) was 70 (S.D.=8.3) years with a range of 49-84 years. With regards to ethnicity nearly all participants were white (98%) with only one female (2%) originating from a different ethnic background. A significant proportion of the participants were male (74%). The majority of the participants were married (81%), and retired (85%). The average length of time since receiving a device was 25 (S.D.=12.2) months (see Table 4.3).

The mean age of CRT-D patients (n=47) was 67 (S.D.=8.6) years, and the range of ages was 40-82 years. All participants were classified as white (100%), and the majority were male (89%). The majority of participants reported being married (64%), although a fifth (21%) noted being separated/divorced or widowed. A high number of participants were retired

(72%), however there were a greater number (17%) in full-time employment, compared to the CRT group. The average length of time since receiving a device was 26 (S.D.=15.7) months (see Table 4.3).

Finally, the mean age of the ICD group (n=51) was 65 (S.D.=10.5) years, and the range of ages was 32-79 years. A significant proportion of the participants were male (78%). The majority of participants were married (73%) and all were of white ethnic origin (100%). Over half of participants were retired (67%), however, similar to the CRT-D group almost a fifth (18%) of patients were in full-time employment. The average length of time since receiving a device was 44 (S.D.=17.5) months (see Table 4.3).

TABLE 4.3 PATIENT DEMOGRAPHICS BY DEVICE GROUP (1)

	DEVICE GROUP		
	CRT N = 53	**CRT-D N = 47**	**ICD N = 51**
GENDER M = Male F = Female	M = 39 (74%) F = 14 (26%)	M = 42 (89%) F = 5 (11%)	M = 40 (78%) F = 11 (22%)
ETHNICITY W = White O = Other	W = 52 (98%) O = 1 (2%)	W = 47 (100%)	W = 51 (100%)
MARITAL STATUS S = Single M = Married S/D = Separated or divorced W = Widowed C = Cohabiting	S = 2 (4%) M = 43 (81%) S/D = 6 (11%) W = 2 (4%) C = 0 (0%)	S = 7 (15%) M = 30 (64%) S/D = 5 (11%) W = 5 (11%) C = 0 (0%)	S = 6 (12%) M = 37 (73%) S/D = 4 (8%) W = 3 (6%) C = 1 (2%)
EMPLOYMENT R = Retired FT = Full time PT = Part-time UE=Unemployed SL = Sick leave	R = 45 (85%) FT = 3 (6%) PT = 1 (2%) UE = 3 (6%) SL = 1 (2%)	R = 34 (72%) FT = 8 (17%) PT = 1 (2%) UE = 2 (4%) SL = 1 (2%)	R = 34 (67%) FT = 9 (18%) PT = 4 (8%) UE = 4 (8%) SL = 0 (0%)
LENGTH OF TIME SINCE RECEIVING A DEVICE (MONTHS) (S.D.)	25 (12.2)	26 (15.7)	44 (17.5)

As a result of the apparent difference in the means between groups regarding length of time since receiving a device the data were further analysed using an unrelated one-way analysis of variance (ANOVA). This revealed that the device groups differed significantly in the length of time since they had received their device ($F = 25.21$, $df = 2, 148$, $p < 0.001$). It was considered statistically rigorous to utilize *Gabriel's* procedure, which adjusts for multiple comparisons, to examine the mean scores in more detail (Appendix E, Table 4 a&b)[17]. This procedure revealed that there was a significant difference between the mean score of the CRT and ICD group and also between the CRT-D and ICD group. As such, the ICD participants appeared to have had a device for significantly longer than the other two groups. The same statistical process was utilized when examining the difference in the mean age of the device groups. ANOVA revealed that the groups differed significantly in relation to age ($F = 3.30$, $df = 2, 148$, $p = 0.039$). *Gabriel's* procedure indicated that the significant difference was between the mean age of CRT and ICD participants, whereby, CRT participants were significantly older than those in the ICD group, but not those in the CRT-D group (Appendix E, Table 5 a&b).

[17] Gabriel's pair wise test procedure was designed to cope with situations in which sample sizes are different, as was the case for this study.

TABLE 4.4 PATIENT DEMOGRAPHICS BY DEVICE GROUP (2)

	DEVICE GROUP		
	CRT N = 53	**CRT-D N = 47**	**ICD N = 51**
OTHER HEALTH PROBLEMS Y = Yes N = No	Y = 36 (68%) N = 13 (25%)	Y = 25 (53%) N = 20 (43%)	Y = 27 (53%) N = 24 (47%)
MENTAL ILL HEALTH HISTORY Y = Yes N = No	Y = 28 (53%) N = 25 (47%)	Y = 22 (47%) N = 25 (53%)	Y = 29 (57%) N = 22 (43%)
MOOD MEDICATION Y = Yes N = No	Y = 14 (26%) N = 39 (74%)	Y = 5 (11%) N = 42 (89%)	Y = 6 (12%) N = 45 (88%)
MENTAL ILL HEALTH HISTORY RELATED TO HEART CONDITION* Y = Yes N = No	Y = 18(64%) N = 10 (36%)	Y = 17 (77%) N = 5 (23%)	Y = 24 (83%) N = 5 (17%)
MENTAL ILL HEALTH HISTORY RELATED TO DEVICE* Y = Yes N = No	Y = 2 (7%) N = 26 (93%)	Y = 3 (14%) N = 19 (86%)	Y = 4 (14%) N = 25 (86%)

* Based on n = 28 CRT, n = 22 CRT-D and n = 29 ICD as questions only completed by patients who responded 'yes' to the initial mental ill health history question.

Table 4.4 highlights that almost three quarters (68%) of CRT participants noted having other health problems beside their heart condition. This was also the case for about half of the CRT-D and ICD participants (53% of both groups).

Table 4.4 also shows that in response to the question "Have you ever suffered from any problems such as anxiety or depression?" just over half of CRT (53%) and ICD (57%) participants gave positive answers. In contrast, just under half (47%) of CRT-D participants reported suffering from such problems. Participants who had reported experiencing anxiety/depression were also asked to indicate whether they related these problems to their heart condition and/or the device they had received. Of the 28 CRT participants who had experienced anxiety/depression, over half (64%) associated this with their heart condition, with only two (7%) also relating this to their device. Almost three quarters (77%) of the CRT-D participants related their experience of anxiety/depression to their heart condition, two of whom also associated such problems with their device. Only one CRT-D patient attributed such problems to the device and not their heart condition. The majority (83%) of ICD participants associated their experience of anxiety/depression with their heart condition. Four (14%) from this group also attributed their problems to the receipt of their device (see Table 4.4).

In response to the question "Are you currently taking any medication to help with mood?" just over a quarter (26%) of CRT patients acknowledged that they were taking such medication. In comparison, lower numbers of CRT-D (11%)

and ICD (12%) participants reported that they were not taking any such medication (see Table 4.4).

Section 3.3 (Methodology) stated that some participants received help from the researcher in completing the questionnaires. A series of univariate ANOVAs revealed that there were no significant differences on any of the outcome variables between participants who were or were not helped. Another series of univariate ANOVAs also revealed that there were no significant differences on any of the outcome variables between participants from the two implantation centres and as such the groups were combined.

Before moving on to address the research questions, the last part of this section will briefly examine the number of participants in the CRT-D and ICD groups who had experienced device firings. Furthermore, the potential effect of these firings on the main outcome measures will be assessed.

4.2.3 PREVALENCE AND EFFECT OF DEVICE FIRINGS

CRT-D and ICD patients were asked to indicate if they had experienced any device firings since implantation. Eight (17%) CRT-D and 20 (39%) ICD participants had experienced their device firing. A series of univariate ANOVAs revealed that the device groups did not significantly differ from one another with regards to psychological distress and quality of life and as such the two device groups were combined to examine the effect of device firing on distress and quality of life outcomes. All results were non-significant, indicating that the experience of device firing has no effect on psychological distress or quality of

life for these patients. This was also the case regarding the majority of the subscales on the IPQ-R. The exceptions were the subscales timeline cyclical and consequences. There appeared to be a significant effect of device firing on timeline cyclical for CRT-D participants ($F = 4.520$, $df = 1, 94$, $p = 0.036$, see Appendix E, Table 6 a&b), which indicated that the experience of device firing related to a participant's heart condition being viewed as more unpredictable. There was also a trend towards significance for the effect of device firing on perception of consequences for the CRT-D group ($F = 3.282$, $df = 1, 91$, $p = 0.073$) (Appendix E, Table 7 a&b). Participants who had experienced a device firing appeared to report more negative consequences associated with their heart condition.

The next section addresses each of the research questions in turn.

4.3 RESEARCH QUESTION ONE:

WHAT IS THE PREVALENCE OF PSYCHOLOGICAL DISTRESS IN PATIENTS WHO HAVE RECEIVED A CRT, CRT-D OR AN ICD DEVICE?

Firstly, the prevalence of anxiety reported by participants will be discussed and secondly, the prevalence of depression will be described.

4.3.1 ANXIETY

The number and percentage of patients' anxiety scores falling within each of the HADS classifications are displayed in Table 3.5. The table also illustrates the 95% confidence intervals for the prevalence of anxiety. The confidence

intervals for anxiety were calculated using a standard asymptotic method (Howitt & Cramer, 2000)[18].

[18] This is a standard method used for calculating confidence intervals for prevalence, by hand. The calculation is:

$$\text{Prevalence} \pm 1.96 \sqrt{\frac{\text{prevalence (1 – prevalence)}}{N}}$$

TABLE 4.5 NUMBER AND PERCENTAGE OF PATIENTS' ANXIETY SCORES ON THE HADS

	DEVICE GROUP		
	CRT Frequency N = 53	CRT-D Frequency N = 47	ICD Frequency N = 51
MEAN (S.D.)	6 (4.6)	5 (4.1)	6 (4.2)
NORMAL (0-7)	36 (68%)	36 (77%)	33 (65%)
MILD (8-10)	9 (17%)	4 (9%)	9 (18%)
MODERATE (11-14)	6 (11%)	5 (11%)	5 (10%)
SEVERE (15-21)	2 (4%)	2 (4%)	3 (6%)
CLINCALLY SIGNIFICANT CASES (RATIO)	17 (32%) (1:3)	11 (24%) (1:4)	17 (34%) (1:3)
95% CONFIDENCE INTERVAL (%)	(19.5%, 44.7%)	(11.8%, 36.2%)	(21.0%, 47.0%)

The majority of participants in all device groups recorded scores that fell within the normal range for anxiety (68%, 77% and 65%). With regards to the

classification of mild anxiety almost a fifth of CRT and ICD participants' scores were within this range (17% and 18%, respectively). Only four (9%) CRT-D patients recorded scores in the mild range. Around 10% of participants in each device group reported experiencing moderate levels of anxiety (11%, 11% and 10%). The numbers were again similar between the groups regarding the reporting of scores classified as within the severe range (4%, 4% and 6%). 17 participants in the CRT and ICD device groups were considered 'clinically significant cases' (32%, 34%), and 11 (24%) CRT-D patients reported anxiety in the clinically significant range[19]. The mean score for each group were classified within the normal range.

The data were analysed using a univariate ANOVA. It was found that there was not a significant effect of device type on the dependent variable anxiety ($F=0.312$, $df=2, 147$, $p>0.05$). Therefore, level of anxiety did not appear to differ significantly between the device groups.

4.3.2 DEPRESSION

The number and percentage of patients' depression scores falling within each of the HADS classifications are displayed in Table 4.6. The table also illustrates the 95% confidence intervals for the prevalence of depression. The confidence intervals for depression were calculated using a standard asymptotic method (Howitt & Cramer, 2000).

[19] Scores falling within the mild, moderate and severe ranges are considered clinically significant

TABLE 4.6 NUMBER AND PERCENTAGE OF PATIENTS' DEPRESSION SCORES ON THE HADS

	DEVICE GROUP		
	CRT Frequency N = 53	**CRT-D Frequency N = 47**	**ICD Frequency N = 51**
MEAN (S.D.)	5 (4.3)	5 (2.9)	5 (3.7)
NORMAL (0-7)	40 (76%)	40 (85%)	41 (80%)
MILD (8-10)	8 (15%)	5 (11%)	5 (10%)
MODERATE (11-14)	2 (4%)	2 (4%)	2 (4%)
SEVERE (15-21)	3 (6%)	0 (0%)	2 (4%)
CLINCALLY SIGNIFICANT CASES (RATIO)	13 (25%) (1:4)	7 (15%) (1:6)	9 (18%) (1:5)
95% CONFIDENCE INTERVAL (%)	(13.3%, 36.7%)	(4.8%, 25.2%)	(7.5%, 28.5%)

The majority of participants in the three device groups reported levels of depression that were classified within the normal range (76%, 85% and 80%),

or the mild range (15%, 11%, 10%). Two participants in each device group recorded scores that were classified as moderate depression (4%, 4% and 4%). There were no CRT-D participant scores that fell within the severe range, however two ICD and three CRT participants reported experiencing depression in the severe range (4% and 6%, respectively). Overall, 13 (25%) CRT patients, nine (18%) ICD patients and seven (15%) CRT-D patients reported scores in the clinically significant range. The mean score for each group were classified within the normal range.

The data were analysed using a univariate ANOVA. It was found that there was not a significant effect of the independent variable device type on the dependent variable depression ($F=0.602$, $df=2, 147$, $p>0.05$). Therefore, level of depression did not differ significantly between the device groups.

A significant proportion of patients, irrespective of device type, experienced clinically significant anxiety. This translates to one third of CRT and ICD patients and one quarter of CRT-D patients. The numbers of cases of clinically significant depression were lower across all device groups. However, prevalence rates were still clinically important with one in four CRT patients, one in five ICD patients and one in six CRT-D patients reporting clinically significant depression. Results suggest that CRT-D patients experience lower prevalence of anxiety and depression than CRT and ICD patients, but this does not reach statistical significance.

4.4 RESEARCH QUESTION TWO:

WHAT IS THE QUALITY OF LIFE EXPERIENCED BY PATIENTS WHO HAVE RECEIVED A CRT, CRT-D OR AN ICD DEVICE?

The SF-12 is able to produce two summary scores - a physical component summary (PCS) and a mental component summary (MCS). Initially, the PCS section of the SF-12 will be described, following which the MCS section will be discussed.

4.4.1 PHYSICAL QUALITY OF LIFE

Table 4.7 illustrates the physical quality of life recorded by participants[20]. A lower PCS reflects limitation in self-care, physical, social and role activities as well as severe bodily pain and frequent tiredness.

[20] The four categories (i.e. above average, average, lower than average and extremely low) were collapsed into two categories. The results were considered more usefully interpretable if a distinction was made between average/above average quality of life and lower/extremely low quality of life. This approach was utilised for both physical and mental quality of life.

TABLE 4.7 PHYSICAL QUALITY OF LIFE SCORES (SF-12)

	DEVICE GROUP		
	CRT N = 53	**CRT-D N = 47**	**ICD N = 51**
MEAN SCORE (S.D.)	33 (10.7)	35 (10.9)	38 (10.9)
AVERAGE / ABOVE AVERAGE PHYSICAL HEALTH 40>	13 (25%)	15 (32%)	19 (37%)
LOWER THAN AVERAGE / EXTREMELY LOW PHYSICAL HEALTH <29-39	40 (75%)	32 (68%)	32 (63%)

Three quarters (75%) of CRT participants scored their physical quality of life within the below average range, which is lower than 84% of the general population[21]. Around two thirds (68% and 63%) of CRT-D and ICD patients also rated their physical quality of life in this range. Only a quarter (25%) of CRT participants recorded scores that fell within the average or above average range. There were more CRT-D (32%) and particularly ICD (37%) participants whose physical quality of life was in the average or above average range. The average score for all patients fell within the lower than average range.

[21] 84% of the general population are estimated to report scores within the average range

A univariate ANOVA revealed that the effect of the independent variable, device type, on the dependent variable physical quality of life was nearing significance (F=2.999, df=2, 147, p=0.053). Physical quality of life appeared to differ most between CRT and ICD patients, this was statistically assessed, adjusting for multiple comparisons, using the *Gabriel* procedure (see Appendix E, Table 8 a&b). The results indicated that there was a significant difference (P = 0.046) in physical quality of life scores between CRT and ICD participants. The CRT group were estimated to report physical quality of life five points lower than the ICD group.

4.4.2 MENTAL QUALITY OF LIFE

Table 4.8 illustrates the mental quality of life reported by participants. A lower MCS indicates psychological distress, and limitation in usual social and role activities due to emotional problems.

TABLE 4.8 MENTAL QUALITY OF LIFE SCORES (SF-12)

	DEVICE GROUP		
	CRT N = 53	**CRT-D N = 47**	**ICD N = 51**
MEAN SCORE (S.D.)	52 (11.2)	52 (10.7)	50 (11.4)
AVERAGE / ABOVE AVERAGE MENTAL HEALTH 40>	43 (81%)	40 (85%)	38 (75%)
LOWER THAN AVERAGE / EXTREMELY LOW MENTAL HEALTH <29-39	10 (19%)	7 (15%)	13 (25%)

At least three quarters of participants in each of the device groups reported mental quality of life scores that fell within the average or above average range (81%, 85% and 75%). A quarter (25%) of ICD participants recorded mental quality of life in the lower than average range, which is lower than an estimated 84% of the general population. Ten (19%) CRT and seven (15%) CRT-D participants also recorded scores that fell within the lower than average range. The average score for all device groups fell within the average or above average range.

The data was analysed using a univariate ANOVA. It was found that mental quality of life did not differ significantly between device groups ($F=0.708$, $df=2, 147$, $p>0.05$).

The majority of patients in all device groups reported physical quality of life scores in the lower than average or extremely low range. CRT patients experienced the poorest physical quality of life, and the ICD group experienced the least reduced physical quality of life. In contrast, the majority of patients reported mental quality of life in the average or above average range. Although analyses revealed no significant difference between device groups, the ICD group reported the poorest mental quality of life and the CRT-D group the highest mental quality of life.

4.5 RESEARCH QUESTION THREE:

WHAT ARE THE ILLNESS PERCEPTIONS OF PATIENTS WHO HAVE RECEIVED A CRT, CRT-D OR AN ICD DEVICE?

Firstly, the subscales of the IPQ-R (Symptoms (Identity), Timeline Acute/Chronic, Timeline Cyclical, Consequences, Personal Control, Treatment Control (defined as device control), Illness Coherence, Emotional Representation) will be discussed and secondly, the causal dimension of the IPQ-R will be described.

❖ **SYMPTOMS**

The mean score of the symptoms subscale for all device groups fell within the moderate range (4, 4 and 4). The maximum score achievable was eight and the majority of participants reported experiencing four main symptoms that they associated with their heart condition (see Table 4.9).

❖ **TIMELINE ACUTE/CHRONIC**

The mean scores on the Timeline subscale fell within the high end of the scale range (27, 28 and 26). This indicated that the majority of participants viewed their heart condition as chronic. The ICD participants were the most varied in their responses, with scores ranging from 13 to 30. In contrast, all the CRT-D group scores fell within the higher end of the scale (21-30) (see Table 4.9).

❖ **TIMELINE CYCLICAL**

The means in the three groups were identical (11, 11, 11). These scores indicated moderate beliefs about the cyclical nature of a participant's heart condition/symptoms. The CRT-D group reported the most scores at the higher end of the range, indicating that some CRT-D participants viewed their condition/symptoms as more cyclical than those in the CRT and ICD groups (see Table 4.9).

❖ **CONSEQUENCES**

The mean scores for the three device groups fell within the moderate to high end of the consequences subscale (30, 31, 27). This indicates that participants perceived their heart condition to be associated with a relatively high level of

negative consequences. The range of scores in all groups extended to the maximum score of 40, indicating extremely negative consequences (see Table 4.9).

❖ PERSONAL CONTROL

The mean score for all device groups fell just above the mid point (18, 17, 16). This shows that participants perceived that they had just less than a moderate level of control over their heart condition. Scores on this subscale ranged to the maximum score of 30, which indicates that some participants' perceived that they have absolutely no control over their condition (see Table 4.9).

TABLE 4.9 SUMMARIES OF RESULTS OF THE IPQ-R SUB-SCALES

SUBSCALE	DEVICE (N)	MEAN (S.D.)	MIN-MAX	MAX POSSIBLE SCORE
Symptoms	CRT (53)	4 (2.1)	0-8	8
	CRT-D (47)	4 (2.2)	0-8	
	ICD (51)	4 (1.9)	0-8	
Timeline acute/chronic	CRT (52)	27 (3.8)	17-30	30
	CRT-D (46)	28 (2.7)	21-30	
	ICD (50)	26 (4.3)	13-30	
Timeline Cyclical	CRT (53)	11 (3.7)	4-17	20
	CRT-D (47)	11 (4.7)	4-20	
	ICD (51)	11 (3.5)	4-16	
Consequences	CRT (52)	30 (6.0)	13-40	40
	CRT-D (46)	30 (5.9)	15-40	
	ICD (49)	27 (6.2)	8-40	
Personal Control	CRT (52)	18 (4.5)	9-28	30
	CRT-D (45)	17 (5.9)	8-30	
	ICD (51)	16 (4.8)	8-30	
Device Control	CRT (52)	15 (3.2)	8-23	25
	CRT-D (45)	14 (4.7)	5-23	
	ICD (51)	14 (3.0)	7-25	
Illness Coherence	CRT (53)	11 (4.0)	5-20	25
	CRT-D (47)	10 (3.9)	5-20	
	ICD (51)	11 (4.0)	5-23	
Emotional Representation	CRT (53)	16 (6.7)	6-30	30
	CRT-D (45)	15 (6.0)	6-28	
	ICD (51)	16 (5.6)	6-30	

❖ DEVICE CONTROL

The mean scores across device groups were almost identical (15, 14, 14). This indicated that participants' perceived their device had just less than a moderate level of control over their heart condition. The ICD group scores ranged to the top end of the scale, whereby some participants perceived that the device had absolutely no control over their heart condition. Although CRT and CRT-D scores did not range up to the maximum, the highest scores still fell within the top end of the scale (see Table 4.9).

❖ ILLNESS COHERENCE

The mean score for all device groups fell within the moderate range (11, 10, 11). This indicates that patients' perceived that they had a relatively good understanding of their heart condition (see Table 4.9).

❖ EMOTIONAL REPRESENTATION

The mean scores fell within the moderate range (16, 15, 16). This indicates that participants felt moderately emotional with regards to their heart condition. Some participants, particularly those in the CRT and ICD groups, reported scores at the maximum end of the scale, which implies that some associate extremely negative emotions with their heart condition (see Table 4.9).

The potential differences between the device groups with regards to the subscales of the IPQ-R will now be examined. The data were analysed using a series of univariate ANOVAs. Due to limitation of space, only significant findings will be reported.

It was found that the effect of device type on IPQ-R Timeline was nearing significance (F=2.994, df=2, 145, p=0.053). The mean for the CRT-D group (M=28, S.D.=2.7) appeared to indicate an increased perception of chronicity compared with the CRT group (M=27, S.D.=3.8), and particularly the ICD group (M=26, S.D.=4.3). In order to examine the significance of the differences between the three means the *Gabriel* procedure was used (see Appendix E, Table 9 a&b). The results indicated that there was a significant difference (P = 0.046) in the mean IPQ-R Timeline scores between CRT-D and ICD participants. The CRT-D group was estimated to score almost two points higher than the ICD group. Thus, the CRT-D participants perceived their condition to be slightly more chronic than the ICD group.

Device type was found to have a significant effect on the IPQ-R subscale consequences (F=4.540, df = 2, 144, p=0.012). The mean for the CRT-D group (M=30, S.D.=5.9) and the CRT group (M=30, S.D.=5.9) was higher than that for the ICD participants (M=27, S.D.=6.2). The Gabriel procedure was utilised to test the significance of the differences between the groups (see Appendix E, Table 10, Table a&b). The test showed that there was a significant difference (P=0.013) between the mean scores of the CRT-D and ICD group. The CRT-D group were estimated to score just over three points more than the ICD group. This indicates that the CRT-D group perceived their condition to have slighter more negative consequences for their lives then ICD participants.

Overall, the device groups were very similar regarding patients' responses on the IPQ-R subscales. Patients reported a moderate number of symptoms; a view of their heart condition as chronic; moderate beliefs about the cyclical nature of their condition; perceptions of a moderate degree of personal and device control; a relatively good understanding of their heart condition, and a negative view of their health status. Although not statistically significant, CRT and CRT-D patients associated their heart condition with slightly more severe consequences than ICD patients. Also CRT-D patients perceived their condition as slightly more chronic than ICD patients.

The causal dimension of the IPQ-R will now be examined. This dimension will be considered separately for each device group.

4.5.1 CAUSAL DIMENSION OF IPQ-R[22]

Table 4.10, 4.11 and 4.12 illustrate the top five factors selected by CRT, CRT-D and ICD patients with regards to what they perceive caused their heart condition[23].

The five most frequently chosen causal factors by CRT patients, from highest to lowest, included: smoking (n=20), hereditary (n=19), overwork (n=19), ageing (n=18), and stress or worry (n=17) (see Table 4.10).

[22] The top five causal factors for each patient group are shown in this section. A full list of causal factors for each group are shown in Appendix F, Tables a, b & c).
[23] Patients were able to agree, disagree or not be sure (i.e. neutral) about the causal role of all factors. Patients were able to agree with as many causal factors as they wished, which is why percentages are not included in this section.

TABLE 4.10 FREQUENCY OF CRT PARTICIPANTS' PERCEPTIONS OF CAUSE

CAUSAL FACTOR	AGREE	NEUTRAL	DISAGREE
Smoking	20	3	30
Hereditary	19	7	27
Overwork	19	11	23
Ageing	18	11	24
Stress or worry	17	10	26

The five most frequently chosen causal factors by CRT-D patients, from highest to lowest, included: smoking (n=24), a participants own behaviour, (n=22), stress or worry (n=21), diet or eating habits (n=20) and hereditary (n=19) (see Table 4.11).

TABLE 4.11 FREQUENCY OF CRT-D PARTICIPANTS' PERCEPTIONS OF CAUSE

CAUSAL FACTOR	AGREE	NEUTRAL	DISAGREE
Smoking	24	2	21
My own behaviour	22	6	19
Stress or worry	21	3	23
Diet or eating habits	20	5	22
Hereditary	19	6	22

The five most frequently chosen causal factors by ICD patients, from highest to lowest, included: hereditary (n=25), chance or bad luck (n=23), diet or eating habits (n=21), smoking, (n=21) participants, and stress and worry (n=20) (see Table 4.12).

TABLE 4.12 FREQUENCY OF ICD PARTICIPANTS' PERCEPTIONS OF CAUSE

CAUSAL FACTOR	AGREE	NEUTRAL	DISAGREE
Hereditary	25	4	22
Chance or bad luck	23	2	26
Diet or eating habits	21	8	22
Smoking	21	2	28
Stress or worry	20	7	24

Patients were also requested to suggest what they perceived to be the number one causal factor for their heart condition. The top three Number One causes for each device group are shown in Table 4.13[24].

TABLE 4.13 NUMBER ONE CAUSAL FACTOR

DEVICE TYPE	RANK	CAUSAL FACTOR	FREQUENCY (%)
CRT (n=53)	**1**	Hereditary	11 (20.8)
	2	A Germ	11 (20.8)
	3	Smoking	9 (17.0)
CRT-D (n=47)	**1**	Hereditary	10 (21.3)
	2	Smoking	8 (17.0)
	3	Stress	7 (14.9)
ICD (n=51)	**1**	Hereditary	14 (27.5)
	2	Smoking	11 (21.6)
	3	Chance/bad luck	6 (11.8)

Heredity and smoking were important causal factors for a high percentage of patients across device groups. CRT and ICD patients also attributed their heart

[24] A full list of the number one causal factors identified by each of the device groups is displayed in Appendix F, Tables d, e & f)

condition to factors beyond their control (i.e. non-modifiable factors) such as a germ or chance/bad luck. In contrast, CRT-D patients were more inclined to attribute their condition to a modifiable cause such as stress.

4.6 RESEARCH QUESTION FOUR:

WHAT IS THE RELATIONSHIP BETWEEN PATIENTS' ILLNESS PERCEPTIONS AND PSYCHOLOGICAL DISTRESS?

The relationships between the subscales of the IPQ-R and anxiety and depression scores (as measured by the HADS) were investigated. In line with the sample size calculation, forty-six participants were successfully recruited to each device group, allowing for the detection of a 0.4 correlation with 90 percent power (Hintze, 2001).

Pearson's correlation coefficients were calculated to investigate whether the relationships between the subscales of the IPQ-R and level of anxiety and depression were statistically significant for each of the device groups. The results of the analyses are displayed in Table 4.14, 4.15 and 4.16. Due to limitation of space only significant relationships are reported.

TABLE 4.14 PEARSON'S CORRELATION COEFFICIENTS FOR CRT PATIENTS' ILLNESS PERCEPTIONS AND PSYCHOLOGICAL DISTRESS

	IPQ-R Symptoms	IPQ-R Timeline cyclical	IPQ-R Consequences	IPQ-R Emotional Representation
HAD Anxiety	r=0.460(**)	r=0.482(**)	r=0.626(**)	r=0.689(**)
HAD Depression	r=0.444(**)	r=0.357(**)	r=0.558(**)	r=0.593(**)

** Correlation is significant at the 0.01 level (2-tailed)

Pearson's correlational analyses indicated significant positive relationships between IPQ-R symptoms; timeline cyclical; consequences, and emotional representation with levels of anxiety and depression. Those patients who experienced most symptoms, in a cyclical manner and associated these with negative consequences and negative emotions, reported higher levels of anxiety and depression.

TABLE 4.15 PEARSON'S CORRELATION COEFFICIENTS FOR CRT-D PATIENTS' ILLNESS PERCEPTIONS AND PSYCHOLOGICAL DISTRESS

	IPQ-R Timeline cyclical	IPQ-R Consequences	IPQ-R Device Control	IPQ-R Illness Coherence	IPQ-R Emotional Representation
HAD Anxiety	r=0.458(**)			r=0.485(**)	r=0.783(**)
HAD Depression	r=0.433(**)	r=0.422(**)	r=0.338(*)		r=0.324(*)

** Correlation is significant at the 0.01 level (2-tailed)
* Correlation is significant at the 0.05 level (2-tailed)

With regards to the CRT-D participants, the analyses showed significant positive relationships between the IPQ-R subscales timeline cyclical, illness coherence, and emotional representation with levels of anxiety. Those CRT-D patients who experienced their heart condition/symptoms as cyclical, who had limited understanding of their heart condition and who felt more negatively about their health status reported greater anxiety. The coefficients also indicated significant positive relationships between the IPQ-R subscales timeline cyclical, consequences, device control, and emotional representation with levels of depression. Participants, who experienced their heart condition/symptoms as cyclical, associated it with negative consequences and negative emotions, and also perceived their CRT-D device to have limited control over their condition, reported higher levels of depression.

TABLE 4.16 PEARSON'S CORRELATION COEFFICIENTS FOR ICD PATIENTS' ILLNESS PERCEPTIONS AND PSYCHOLOGICAL DISTRESS

	IPQ-R Symptoms	IPQ-R Timeline cyclical	IPQ-R Conseq.	IPQ-R Device Control	IPQ-R Illness Coher.	IPQ-R Emotional Represent.
HAD Anxiety	r=0.531(**)	r=0.583(**)	r=0.380(**)	r=0.289(*)	r=0.444(**)	r=0.702(**)
HAD Depression	r=0.634(**)	r=0.431(**)	r=0.385(**)	r=0.357(*)	r=0.375(**)	r=0.583(**)

**** Correlation is significant at the 0.01 level (2-tailed)**
*** Correlation is significant at the 0.05 level (2-tailed)**

Regarding the ICD group, Pearson's correlational analyses indicated significant positive relationships between the IPQ-R subscales symptoms; timeline cyclical; consequences; device control; illness coherence, and

emotional representation. ICD participants reporting increased symptoms; the experience of their heart condition/symptoms as cyclical; a perception of their condition as associated with negative consequences and emotions; a belief that their device had limited control, and also a perceived lack/limited understanding of their condition, reported a higher level of anxiety and depression.

In summary, there is a significant relationship for all device groups between emotional representation and psychological distress. However, there appeared to be a stronger correlation for anxiety than depression across the device groups. Psychological distress was also significantly correlated for all groups with perceptions about the cyclical nature of a patient's heart condition/symptoms. CRT and ICD patients' perceptions of symptoms and consequences were related to psychological distress. Finally, CRT-D and ICD patients' perceptions of device control and understanding of their diagnosis was related to psychological distress.

The next part of this section reviews the relationship between the IPQ-R subscales and quality of life (SF-12).

4.7 RESEARCH QUESTION FIVE:

WHAT IS THE RELATIONSHIP BETWEEN PATIENTS' ILLNESS PERCEPTIONS AND QUALITY OF LIFE?

Pearson's correlation coefficients were conducted to investigate relationships between the subscales of the IPQ-R and physical and mental quality of life for

each of the device groups. The results of the analyses are displayed in Table 4.17, 4.18 and 4.19. Due to limitation of space only significant relationships are reported.

TABLE 4.17 PEARSON'S CORRELATION COEFFICIENTS FOR CRT PATIENTS' ILLNESS PERCEPTIONS AND QUALITY OF LIFE

	IPQ-R Symptoms	IPQ-R Timeline cyclical	IPQ-R Conseq.	IPQ-R Personal Control	IPQ-R Device Control	IPQ-R Emotional Represent.
SF-12 Physical Quality of Life	r=-0.532(**)	r=-0.331(*)	r=-0.543(**)	r=-0.279(*)	r=-0.299(*)	r=-0.281(*)
SF-12 Mental Quality of Life	r=-0.363(**)	r=-0.415(**)	r=-0.561(**)			r=-0.685(**)

**** Correlation is significant at the 0.01 level (2-tailed)**
*** Correlation is significant at the 0.05 level (2-tailed)**

Pearson's correlation analyses revealed significant negative relationships between IPQ-R subscales symptoms; timeline cyclical; consequences; personal control; device control; and emotional representation, and physical quality of life. CRT participants reporting increased symptoms; a perception of their heart condition/symptoms as cyclical; a perception of negative consequences and emotions associated with their heart condition; a perceived lack of personal control, and also a belief that their device had limited control over their condition, reported poorer physical quality of life. This was also the case for CRT participants' mental quality of life, however, perceptions of

control, both personal and related to the device, were not significantly related to mental quality of life.

TABLE 4.18 PEARSON'S CORRELATION COEFFICIENTS FOR CRT-D PATIENTS' ILLNESS PERCEPTIONS AND QUALITY OF LIFE

	IPQ-R Symptoms	IPQ-R Timeline	IPQ-R Timeline cyclical	IPQ-R Conseq.	IPQ-R Device Control	IPQ-R Illness Coher.	IPQ-R Emotional Represent.
SF-12 Physical Quality of Life	r=-0.573 (**)	r=-0.360 (*)	r=-0.470 (**)	r=-0.625 (**)	r=-0.334 (*)		
SF-12 Mental Quality of Life			r=-0.410 (**)			r=-0.312 (*)	r=-0.672 (**)

**** Correlation is significant at the 0.01 level (2-tailed)**
*** Correlation is significant at the 0.05 level (2-tailed)**

For the CRT-D group, Pearson's correlational analyses indicated a significant negative relationship between the IPQ-R subscales symptoms; timeline; timeline cyclical; consequences; device control; illness coherence, and emotional representation, and physical quality of life. CRT-D participants who experienced increased symptoms; perceived their heart condition to be chronic; experienced their condition/symptoms as cyclical in nature; felt the condition was associated with more negative consequences; perceived the device to have less control over their condition; had a less clear understanding of their condition; and felt more negatively about their heart condition, reported poorer physical quality of life. The analyses also revealed significant negative relationships between IPQ-R timeline cyclical; illness coherence; and emotional representation, with mental quality of life. Participants who reported that their condition/symptoms were cyclical; had a less clear understanding of

their condition; and felt more negatively about their heart condition reported experiencing a poorer mental quality of life.

TABLE 4.19 PEARSON'S CORRELATION COEFFICIENTS FOR ICD PATIENTS' ILLNESS PERCEPTIONS AND QUALITY OF LIFE

	IPQ-R Symptoms	IPQ-R Timeline cyclical	IPQ-R Conseq.	IPQ-R Illness Coher.	IPQ-R Emotional Represent.
SF-12 Physical Quality of Life	r=-0.608 (**)	r=-0.386 (**)	r=-0.496 (**)		
SF-12 Mental Quality of Life	r=-0.490 (**)	r=-0.545 (**)		r=-0.392 (**)	r=-0.577 (**)

**** Correlation is significant at the 0.01 level (2-tailed)**
*** Correlation is significant at the 0.05 level (2-tailed)**

Pearson's correlational analyses indicated for the ICD group a significant negative relationship between IPQ-R symptoms, timeline cyclical, and consequences with physical quality of life. Participants reporting a higher number of symptoms; a more cyclical experience of their heart condition/symptoms and associated negative consequences, reported poorer physical quality of life. The analyses also revealed that IPQ-R symptoms; timeline cyclical; illness coherence, and emotional representation were related to mental quality of life in ICD patients. The results indicated that participants who experienced an increased number of symptoms; perceived their condition/symptoms to be cyclical; felt they had a less clear understanding of

their condition; and felt more negatively about their heart condition, reported poorer mental quality of life.

In summary, a number of the IPQ-R subscales were found to be related to patients' physical and mental quality of life. There was a high degree of overlap between device groups and also between the IPQ-R scales related to both physical and mental quality of life. Overall, a greater number of IPQ-R subscales were related to physical quality of life than mental quality of life.

Although correlation coefficients can be useful in revealing what relationships might exist between variables (i.e. the subscales of the IPQ-R, levels of psychological distress and quality of life), it does not provide information about the predictive power of variables. Furthermore, correlation does not allow for consideration of additional variables simultaneously (i.e. demographic factors) that might also have an effect on the variable of interest (e.g. psychological distress and quality of life). Regressional analyses is a method that enables a predictive model to be fitted to data. The next section describes the regression analyses (general linear modelling approach) that was utilised to address Research Question Six.

4.8 RESEARCH QUESTION SIX:

DO ILLNESS PERCEPTIONS PREDICT ANXIETY, DEPRESSION AND REDUCED QUALITY OF LIFE IN DEVICE PATIENTS?

The present study was exploratory in nature, and did not explicitly test hypotheses. Hence, the standard model of multiple regression was deemed appropriate. This analysis involved all the variables of interest being entered into a regression equation; each variable was then assessed and evaluated in terms of what it added to the prediction (Tabachnick & Fidell, 2001).

Appendix E, Tables 11 to 14 show the results of the general linear modelling, which was used to examine to what extent illness perceptions predicted psychological distress and quality of life. The modelling was performed using six additional variables (i.e. device type, age, length of time since receiving a device, medication, previous history of anxiety or depression and additional health problems). The inclusion of these specific variables enabled exploration of whether the IPQ-R subscales retained the same effect when these potentially confounding variables were controlled or held constant.

4.8.1 ILLNESS PERCEPTIONS AND PSYCHOLOGICAL DISTRESS

❖ ANXIETY

After adjusting for other covariates, emotional representation ($F = 40.32$, $df = 1, 128$, $p<0.001$) and timeline cyclical ($F = 6.31$, $df = 1, 127$, $p = 0.013$) were found to be significant predictors of anxiety (i.e. participants who perceived

their heart condition/symptoms to be cyclical and associated with negative emotions experience increased anxiety). In this analysis there was a trend towards significance for illness coherence, indicating that the better participants perceived they understood their heart condition the less anxiety they experienced ($F = 3.39$, $df = 1, 127$, $p = 0.068$).

The covariate of previous experience of anxiety or depression (i.e. psychiatric history) was found to be a highly significant predictor of anxiety ($F = 8.34$, $df = 1, 127$, $p<0.01$, i.e. a previous history of anxiety or depression increased risk of anxiety). There was also a trend towards significance for medication ($F = 3.20$, $df = 1, 127$, $p = 0.076$, i.e. those patients who reported taking medication (related to mood) were more anxious than those not taking medication).

There was not a significant main effect of device type on reported anxiety ($F = 0.243$, $df = 2, 127$, $p>0.05$, i.e. device type did not effect the level of anxiety patients' experienced; Appendix E, Table 11 a&b).

❖ **DEPRESSION**

Emotional representation, symptoms and device control were found to be significant predictors of depression after adjusting for other covariates ($F= 5.58$, df 1, 127, $p = 0.02$; $F = 5.69$, df 1, 127, $p = 0.019$; $F = 7.14$, df 1, 127, $p<0.01$, i.e. patients who felt negatively about their heart condition, experienced a high number of symptoms and perceived their cardiac device to have limited control were more at risk of depression). The IPQ-R consequences subscale demonstrated a trend towards significance ($F = 3.39$,

df 1, 127, p = 0.068, i.e. patients who associated their heart condition with negative consequences were at increased risk of depression).

Medication appeared to be a significant predictor of depression (i.e. those participants on medication were estimated to score around 1.5 points higher on the depression subscale of the HADS versus those not taking medication (F = 4.72, df = 1, 127, p = 0.032). Age was close to having a significant main effect on level of depression reported (F = 3.77, df 1, 127, p = 0.054, i.e. older patients were more likely to experience clinically significant depression). Device type was not found to predict depression (F = 0.122, df = 1, 127, p>0.05; Appendix E, Table 12 a&b)

4.8.2 ILLNESS PERCEPTIONS AND QUALITY OF LIFE

❖ PHYSICAL QUALITY OF LIFE

Consequences, personal control, symptoms and emotional representation were found to be significant predictors of physical quality of life after adjusting for other covariates (F = 8.01, df = 1, 127, p <0.01; F = 4.86, df = 1, 127, p = 0.029; F = 33.19, df = 1, 127, p <0.001, F = 4.55, df = 1, 127, p = 0.035, respectively). Therefore, patients who associated their heart condition with negative consequences, a high number of symptoms, negative emotions and felt they had a limited degree of personal control were at risk of reduced physical quality of life.

Medication was close to having a significant main effect on physical quality of life ($F = 3.85$, $df = 1, 127$, $p = 0.052$, i.e. patients on mood medication were more likely to report poorer physical quality of life). Device type was not predictive of physical quality of life ($F = 0.728$, $df = 1, 127$, $p = >0.05$; Appendix E, Table 13 a&b).

❖ **MENTAL QUALITY OF LIFE**

Emotional representation and timeline cyclical were found to be significant predictors of mental quality of life after adjusting for other covariates ($F = 27.33$, $df = 1, 128$, $p = 0.000$; $F = 4.30$, $df = 1, 128$, $p = 0.040$, respectively, i.e. patients who perceived that their heart condition/symptoms were cyclical in nature and associated with negative emotions experienced reduced mental quality of life). There was a trend towards significance for device control ($F = 3.61$, $df = 1, 128$, $p = 0.06$, i.e. patients who perceived their device as being less able to control their heart condition were more likely to experience poorer mental quality of life).

Medication was found to be a highly significant predictor ($F = 12.94$, $df = 1, 128$, $p <0.001$, i.e. patients on medication reported poorer mental quality of life). Finally, there was a significant main effect of previous anxiety/depression on participants' mental quality of life ($F = 4.57$, $df = 1, 128$, $p = 0.034$, i.e. patients who had experienced anxiety/depression reported reduced mental quality of life). Device type was not predictive of patients' mental quality of life (Appendix E, Table 14 a&b).

4.8.3 SUMMARY

- Patients who experienced their heart condition/symptoms as cyclical in nature and associated with negative emotions showed a higher incidence of anxiety
- Patients who reported a history of anxiety/depression showed a higher incidence of anxiety
- Patients who perceived their device to have limited control; experienced a higher number of symptoms, and associated their heart condition with negative emotions showed a higher incidence of depression
- Patients who reported using mood related medication showed a higher incidence of depression
- Patients who perceived that they had limited control over their heart condition; experienced a higher number of symptoms, and associated their heart condition with negative consequences and emotions, reported reduced physical quality of life
- Patients who experienced their heart condition/symptoms as cyclical in nature and associated with negative emotions, reported reduced mental quality of life
- Patients who reported using mood medication and/or who had experienced anxiety/depression reported reduced mental quality of life
- Device type was not predictive of any outcome variables. This suggests that it is what patients think that counts (i.e. illness perceptions) and other psychosocial variables, not the type of device they receive

4.8.4 OVERALL RESULTS SUMMARY

Anxiety and depression are pertinent issues for CRT, CRT-D and ICD patients. Physical quality of life is significantly reduced for device patients but this affect does not necessarily translate to reduced mental quality of life. There are relationships between a number of the IPQ-R subscales and psychological distress and quality of life, which show similarities and differences between outcome variables. Overall the type of device appears 'irrelevant' as it is not predictive of any of the outcome variables. In general, perceptions of consequences and emotional representations are important predictors of all outcome variables. Furthermore, medication and previous experience of anxiety and/or depression also play an important predictive role for psychological distress and reduced quality of life.

CHAPTER FIVE

DISCUSSION

5.1 OVERVIEW OF DISCUSSION

This chapter will begin by summarising the main findings from the study using the overarching headings of psychological distress and quality of life. Following this, the clinical implications of the research will be outlined and the strengths and limitations considered. Finally, the discussion will conclude with recommendations for future research in CRT and CRT-D populations.

5.2 PSYCHOLOGICAL DISTRESS

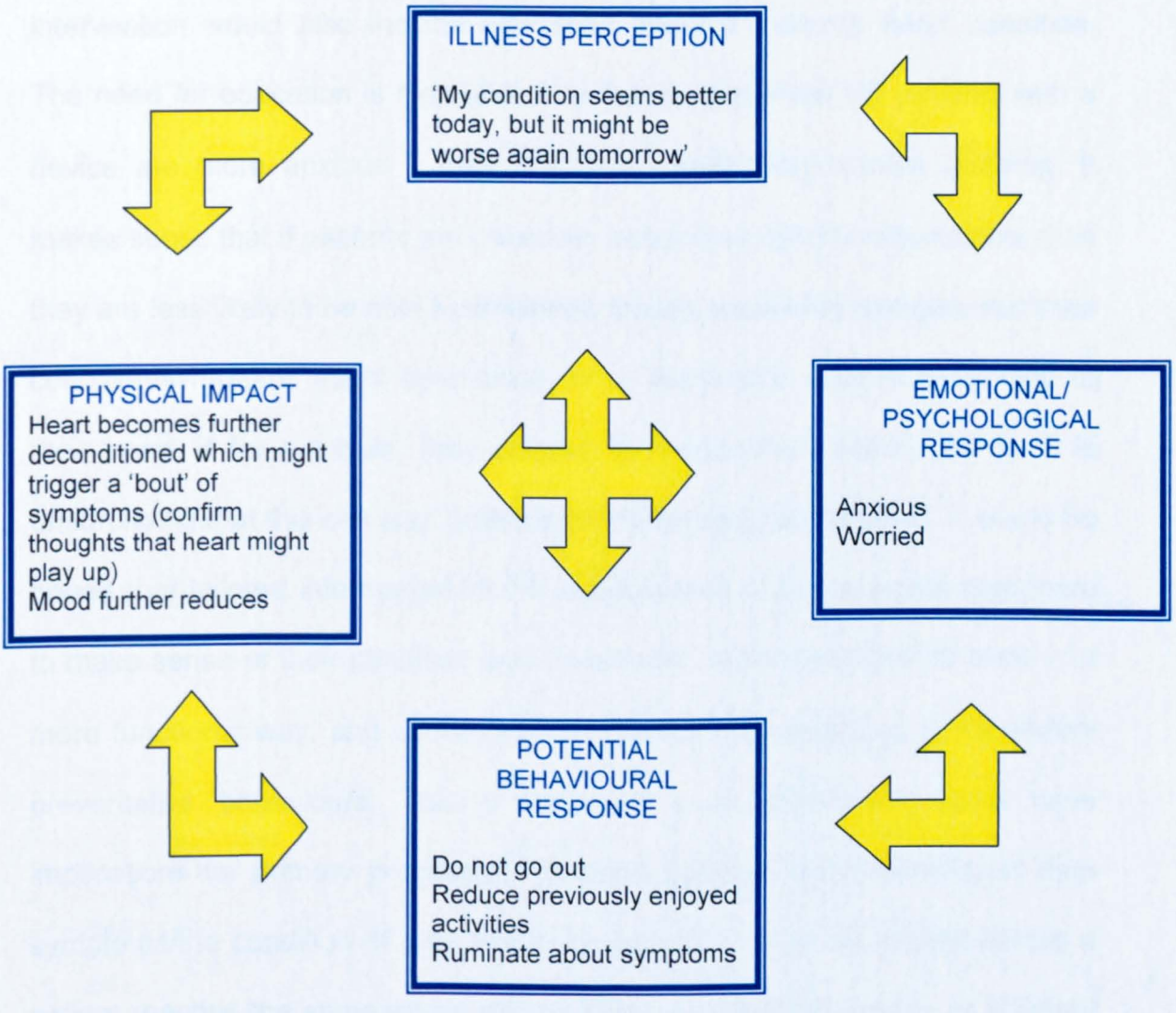
The results of the present study indicate that a significant proportion of patients, regardless of cardiac device type, experience clinically significant anxiety. The figures translate to one CRT and one ICD patient in every three and one CRT-D patient in every four reporting clinically significant anxiety. These results are comparable with existing research in other cardiac groups (e.g. post myocardial infarction, ICD) where approximately a third of patients experience anxiety (Frizelle, 2001; Sears et al, 1999). The prevalence is higher than reported by Haworth et al. (2005) in a group of patients with chronic heart failure where a fifth of patients had at least one anxiety disorder. Haworth et al. (2005) utilised the *Structured Clinical Interview* for the *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition* (SCID-I; DSM-IV, 1997) to measure anxiety. The rationale for using the SCID-I was that existing

measures for psychological distress were arguably inadequate and inaccurate at identifying patients who would attain a clinical diagnosis of either anxiety or depression through more formal assessment. The authors also proposed that existing measures were unduly influenced by somatic symptoms that are unrelated to mood (Haworth et al., 2005). It could be argued that the higher prevalence of anxiety in this study is due to the issues highlighted by Haworth et al. (2005). However, the measure of psychological distress (i.e. HADS) used in the present study, was specifically constructed to enable identification of patients struggling with anxiety and/or depression in addition to co-morbid medical illness. Furthermore, the literature suggests that use of the HADS as a screening tool with a cutoff score of eight has a sensitivity and specificity of approximately 80% (Bambauer et al., 2005). It is also of importance that in comparison to the SCID-I the HADS is a more practical and feasible screening tool, due to its brevity and self-administration.

When trying to understand the reasons for patients' anxiety the results of the present study show that there is a predictive relationship between patients' experience of their heart condition/symptoms as cyclical, and anxiety (i.e. patients who perceive their heart condition/symptoms to be cyclical, experience greater anxiety). Based on existing medical research it can be hypothesised that receipt of a cardiac device reduces overall symptoms, but does not preclude patients from 'bouts' of increased symptomatology. It is the anticipation of these cyclical 'bouts' that could lead patients to experience increased anxiety. Furthermore, an individual's experience of their condition/symptoms as cyclical could be viewed as a regular reminder of their underlying condition and their potential fragility, which led them to require an

implanted device in the first place (see Figure 5.1). Indeed, Radley (2004) proposed that the reduction of symptoms as a result of treatment (i.e. receipt of a cardiac device) does not erase patient knowledge of their underlying heart condition, or the perceived likelihood of symptoms recurring.

FIGURE 5.1 THE POTENTIAL IMPACT OF PERCEIVING CONDITION/SYMPTOMS AS CYCLICAL: A CBT FORMULATION



From an intervention perspective it would be of interest to examine and potentially challenge the reality base for patients' perceptions of the cyclical nature of their condition/symptoms. However, for some HF patients the experience of their condition/symptoms as cyclical will be a reality. Therefore, the focus could be exploring with patients how they respond both psychologically and behaviourally to the variations in their health status and the potential unpredictable nature of such changes. An important part of the intervention would also include education about a patient's heart condition. The need for education is highlighted by results that show HF patients with a device are more anxious if they find their condition/symptoms puzzling. It makes sense that if patients are uncertain about their condition/symptoms then they are less likely to be able to challenge anxiety provoking thoughts that their condition/symptoms might deteriorate, or to appreciate what is happening to their heart, if for example, they choose to reduce their activity levels. It is unsurprising that this can lead patients to feel anxious and worried. It would be hoped that tailored information for HF patients with a device would help them to make sense of their condition and symptoms, understand how to cope in a more functional way, and understand the reasons for engaging in secondary preventative behaviours. The provision of such information could have implications for primary prevention, whereby patients' understanding of their symptoms/the condition of their heart, for example, could be elicited before a patient reaches the stage where they require an implanted device, or a formal diagnoses, such as HF. The provision of such information could potentially

divert or reduce the risk of an individual's health deteriorating, which has obvious physical, psychological and economic benefits.

In line with existing ICD literature, CRT-D and ICD patients in the present study who experience device firings do not report higher levels of anxiety (Burke et al., 2003). It is interesting that CRT-D patients who have experienced a device firing perceive their condition/symptoms to be more cyclical in nature, whereas ICD patients do not. It can be hypothesised that, in contrast to ICD patients, CRT-D patients do not receive adequate information, preparation or potentially support for device firings. There is a growing body of research examining ICD patients' needs for information and support, but there is a dearth of research in this area for CRT-D patients. In line with this, at one centre CRT-D patients were provided with a standard information booklet produced by a well known heart rhythm charity. This charity also produces booklets for ICD patients giving information about the device; surgery; device firings and after care. Anecdotal information from a Cardiac Nurse Specialist highlighted that the information in the CRT-D booklet had been taken from the existing ICD booklet. As such, the information for CRT-D patients was not believed to be completely appropriate or comprehensive. It is unsurprising then that some CRT-D patients are less informed and prepared for device firings and thus experience their heart condition and symptoms as cyclical and potentially more unpredictable. This highlights an important area for future research (i.e. research examining the specific support and information needs of CRT-D patients, in line with research findings from studies with ICD patients).

Overall, anxiety is a prevalent issue for CRT and CRT-D patients and can affect patients' mood, thoughts, behaviour and physiological functioning (Rachman, 1998). The HADS has been demonstrated to provide a practical and sensitive means of screening patients to identify those who could benefit from additional psychological support. Implementation of such a screening tool, as part of the routine care of CRT and CRT-D patients, could help to identify those patients who might benefit from additional support. Depending on the reasons underlying the patient's anxiety additional support might be related to further discussions with Cardiac Nurse Specialists, Cardiologists, or possibly work with a Clinical Psychologist. Regardless of the type of additional support that is accessed, the key is that the HADS might help to provide patients with a means of communicating issues of psychological distress to those in charge of their care. This fits with NICE (2003) guidelines, which state that good communication underlies the best management of HF.

In comparison to the prevalence of anxiety in the three device groups, the prevalence of clinically significant cases of depression is lower (i.e. one in four CRT, one in five ICD and one in six CRT-D patients experience clinically significant depression). The prevalence of clinically significant depression for ICD patients is consistent with the findings of Frizelle (2001) but slightly lower than estimates from a number of studies reviewed by Sears et al (1999). The lower prevalence of depression in the present study may be an artefact of the centres where patients were recruited (i.e. the centres were organised and provided a high standard of care). Staff were 'psychologically minded' (e.g. staff understood that patients' heart condition and device could have a

psychological impact), and the majority of patients considered themselves to be well looked after[25].

CRT and CRT-D patients in the present study experience less depression compared to HF out-patients (Rumsfeld et al, 2003; Gottlieb et al, 2004). This could be related to CRT and CRT-D patients experiencing fewer symptoms than HF out-patients who do not have a device. This would fit with the medical literature highlighting the capability of CRT and CRT-D devices in addressing HF symptomatology (Cazeau et al, 2001; Abraham et al, 2002; CARE-HF, 2005). Indeed, the analyses show that the number of symptoms is predictive of depression (i.e. patients who experience fewer symptoms report lower levels of depression). It follows that HF patients who receive a CRT or CRT-D device and experience a reduction in symptoms, subsequently feel less depressed.

A further reason for the lower prevalence of depression in this sample compared to HF out-patients could be related to patients' perception of the device as 'in control'. The analyses show that patients' perception of the CRT or CRT-D device as 'in control' of their heart condition is predictive of lower levels of depression. It follows that HF patients who receive a CRT or CRT-D device and perceive that the device is able to exert some control over their heart condition subsequently feel less depressed. This also fits with the finding that device firings in CRT-D and ICD patients do not result in increased distress (i.e. anxiety and depression). It could be hypothesised that the firings

[25] A third of patients made comments on the questionnaires asking for thanks to be passed on to staff at the centres.

are interpreted as confirmation that the device is 'in control' which patients find reassuring (Lewin et al, 2001).

In summary the receipt of a cardiac device appears to help with the reduction of symptoms and also provides patients with the perception that there is something 'in control' of their heart condition. Both of these factors appear to help to reduce levels of depression in CRT and CRT-D patients. However, it must be remembered that there are still a significant number of patients for whom clinically significant depression is an issue. It might be that these patients do not experience a reduction in their symptoms and do not perceive that the device is 'in control'. It is important that these patients are identified and provided with the appropriate support. Again the HADS might be a practical and sensitive tool for use in routine care of CRT and CRT-D patients. Furthermore, patients who reported taking mood related medication experienced a higher level of depression. As such, this may be an additional factor that needs to be queried during assessment. Due to the cross sectional design of the present study it is not possible to know whether patients were using medication prior to receipt of their device or whether it was a response to poor reduction in symptoms and limited faith in the device to control their condition. Future research using a longitudinal design could help to answer this question.

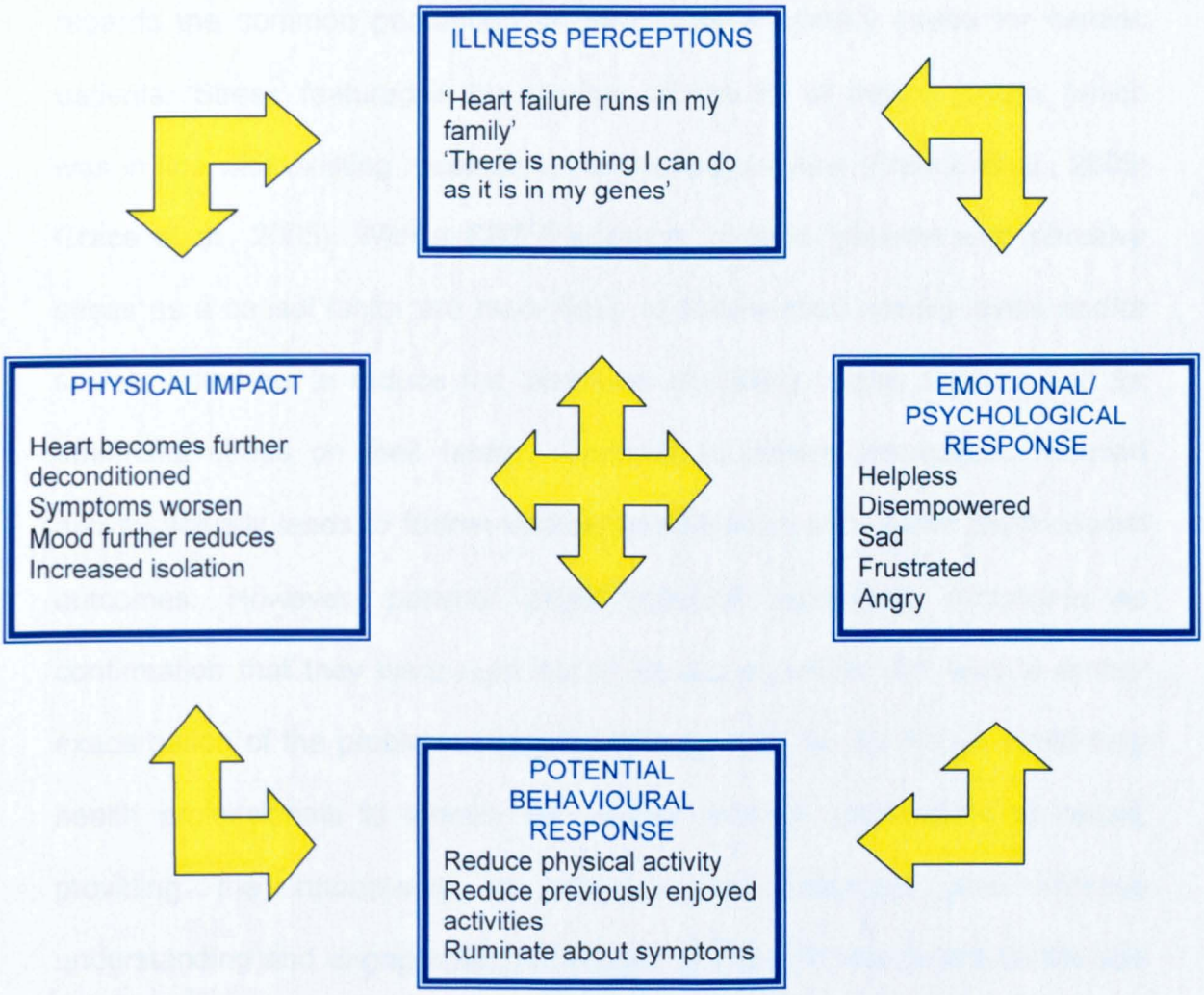
Although there are no significant differences between the device groups regarding the prevalence of anxiety or depression, it is of interest that the CRT-D group show the least distress out of the three groups. It might be expected that CRT-D patients would experience less distress than CRT patients as the

latter report a greater number of health problems. However, this is not the case when the CRT-D group is compared to the ICD group. Another hypothesis is that the higher percentage of male patients in the CRT-D group, compared to the CRT and ICD groups, might have led to lower distress levels. Although exploration of gender differences was beyond the remit of the present study, there is growing evidence in both general and cardiac samples to demonstrate gender differences on psychological outcomes (Evangelista, Dracup, Doering, Westlake, Fonarow and Hamilton, 2002; Grace, Krepostman, Brooks, Arthur, Scholey, Suskin, et al., 2005). Evangelista et al (2002) assessed mental well-being using the mental health subscale of the SF-12 and found that female HF patients (without a device) experience significantly lower emotional well-being than male HF patients. In a later study, Grace et al (2005) showed a trend toward greater depressive symptomatology (using the HADS) among female patients following an acute coronary event, compared with male patients. Although no firm conclusions can be drawn in the present study, the results indicate the importance of future research conducted with more balanced numbers of male and female device patients. This may prove to be more of a challenge, as cardiac patients tend to be two thirds male and one third female (BHF, 2002).

An alternative hypothesis regarding lower distress levels in the CRT-D group is related to patients' perceptions of the cause of their heart condition. CRT-D patients are arguably more likely to take responsibility for the cause(s) of their heart condition (i.e. they attribute cause to 'lifestyle' factors that are within their control to modify such as diet, smoking, stress). As such, these patients may

be more inclined to engage in secondary preventative health behaviours (i.e. stopping smoking, changing diet, starting to exercise, adhering to medication regimes), behaviours that have been associated with improved physical and psychological well-being in the HF population (Whitmarsh, Koutantji & Sidell, 2003; Gassner, Dunn & Piller, 2002; BHF, 2002). In contrast ICD, and particularly CRT, patients seem more inclined to see the cause(s) of their heart condition as due to factors that they cannot control (i.e. the cause is non-modifiable such as, heredity, ageing, a germ, chance or bad luck). It is possible that CRT and ICD patients' perceptions of non-modifiable cause(s) preclude these patients from appreciating the role and importance of engaging in secondary preventative health behaviours, which consequently has an adverse impact on patients' physical health and psychological well-being (see Figure 5.2). Indeed, Cooper, Lloyd, Weinman & Jackson (1999) found that causal attribution of heart problems (in a HF population) to lifestyle factors (i.e. diet, lack of exercise, etc) was a significant predictor of attendance at a cardiac rehabilitation (CR) programme. Importantly, CR has been shown to be effective in reducing the physical, psychological and socio-economic consequences of heart conditions, such as HF (World Health Organisation [WHO], 1993).

FIGURE 5.2 THE POTENTIAL IMPACT OF HEART CONDITION RELATED TO A NON-MODIFIABLE CAUSE: A CBT FORMULATION



From an intervention perspective it is possible that psychological distress could be reduced via patient education about cause and the importance and relevance of lifestyle changes (i.e. engagement in secondary preventative behaviours, which could perhaps be provided via out-patient CR programmes, offering exercise and educative counselling about HF and psychosocial issues). A crucial part of this education would involve addressing patients'

misconceptions about cause that may incline patients to be passive and potentially fatalistic in their thinking about their heart condition (i.e. 'It doesn't matter what I do, it won't make any difference'). Another example of this regards the common perception of 'stress' as a primary cause for cardiac patients. 'Stress' featured in the top five causes for all device groups, which was in line with existing research in cardiac populations (French et al., 2005; Grace et al., 2005). With a CBT framework in mind, patients who perceive stress as a causal factor are more likely to reduce their activity levels and/or socially withdraw to reduce the likelihood of putting undue physical and /or emotional stress on their heart. Contrary to patient perceptions reduced activity actually leads to further cardiac deterioration and poorer psychosocial outcomes. However, patients might interpret worsening symptoms as confirmation that they were right not to be active, which can lead to further exacerbation of the problem. Using a measure such as the IPQ-R could help health professionals to identify HF device patients' perceptions of cause, providing the opportunity to address misconceptions and improve understanding and engagement in behaviours that will help to reduce the risk of further deterioration (i.e. stopping smoking, changing diet, etc). As mentioned earlier, the IPQ-R could also provide information useful in primary prevention. Whereby the IPQ-R could enable clinicians to identify patients (who have come into hospital or primary care with a heart related issue) who might be struggling to appreciate the importance of risk factors such as smoking, poor diet, lack of exercise etc, and provide such patients with appropriate information and support to help prevent the development of a diagnosable condition.

As well as addressing patients' perceptions and misconceptions, interventions need to consider the goodness of fit between device patients' causal perceptions and treatment recommendations, such as lifestyle changes (i.e. patients need to be able to make sense of the link between changing their diet, taking exercise, stopping smoking, etc, and limiting the progression of their heart condition). This is important as research has shown that patients who do not recognise the link between their behaviour and physical/psychological outcomes, are less likely to make health related behavioural changes, whether this be for primary or secondary prevention (Hall, Weinman & Marteau, 2005).

To date the majority of available literature for HF patients either omits any explanation about the relevance of exercise, eating a healthy diet, stopping smoking, etc, or considers these issues in a very brief way. For example, with regards to exercise, one information booklet stated 'A certain level of exercise is needed to keep your heart healthy' and another noted 'Most of you can resume normal activities and exercise as soon as you feel able'. Neither of these booklets gave any further explanation about exercise aside from suggestions about the type of exercise a patient might choose to take. The Self Regulatory Model of Illness (Leventhal et al., 1997) purports that patients evaluate the need for treatment (e.g. positive behavioural changes) in light of their understanding of illness. It can be hypothesised that HF patients, for example, who perceive their condition to be hereditary may not see the point of making lifestyle changes as it doesn't fit with their understanding of their underlying condition. This could be compounded for patients who then receive a CRT or CRT-D device (i.e. patients' perceptions that they cannot do anything

to change their condition are further confirmed when they receive a device on the grounds that their condition is not controllable by medication).

The hypothesis that these patients would perceive themselves to have less personal control and thus reduce their level of activity is reflected in the physical quality of life scores and the associated IPQ-R subscales. These will be discussed in the next section.

5.3 QUALITY OF LIFE

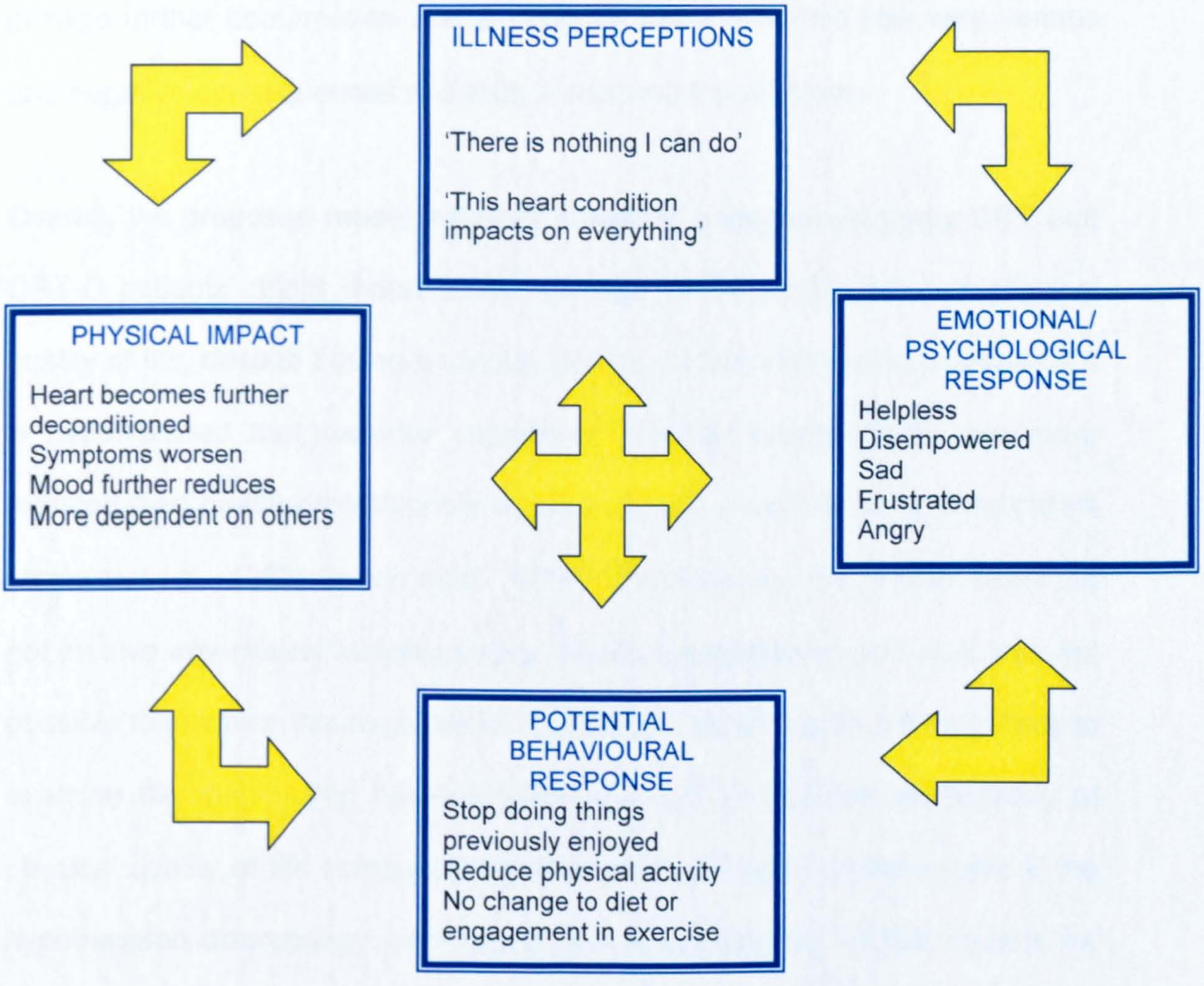
5.3.1 PHYSICAL QUALITY OF LIFE

Three quarters of CRT patients and just over two thirds of CRT-D patients report their physical quality of life to be lower than the majority of people in the general population. This finding is in line with quality of life literature in the HF population (Juenger et al, 2002; Martensson et al, 2002; Calvert et al, 2005). This provides support for the argument that physiological improvements based on medical outcomes do not necessarily translate to improvements in quality of life from the patients' perspective. The cross sectional design of the present study makes it difficult to draw comparisons with the existing quality of life literature in CRT and CRT-D patients (i.e. although CRT and CRT-D patients report lower than average physical quality of life it does not preclude patients having experienced improvements since receiving their device). Indeed, the finding that the number of symptoms is predictive of depression, and CRT and CRT-D patients are less depressed than HF out-patients suggests that the device may have reduced symptoms. It is possible therefore, in line with the

medical literature, that physical quality of life may also have improved (CARE-HF, 2005; MIRACLE, 2005). This could potentially go some way towards explaining why mental quality of life for the majority of patients is within the above or above average range. This highlights another important area for future research utilising a longitudinal design and incorporating a measure of patients' illness perceptions alongside quality of life and medical outcomes.

A number of the IPQ-R subscales are predictive of reduced physical quality of life across the device groups (i.e. consequences, personal control, symptoms and emotional representation). Using a CBT framework, Figure 5.3 illustrates how patients' thoughts and emotions (as captured by the IPQ-R) might interrelate and lead patients to experience reduced physical quality of life.

FIGURE 5.3 THE POTENTIAL IMPACT OF PERCEIVING LIMITED PERSONAL CONTROL: A CBT FORMULATION



Patients' perceptions of limited personal control could result in the feelings commonly reported by patients in the present study: anger, frustration, anxiety and sadness. Furthermore, it could reduce the likelihood of patients making lifestyle changes and stop some patients from doing their usually enjoyed activities. In turn, this could confirm for a patient that their condition does indeed have negative consequences, and impacts on all areas of their life. The situation is then further exacerbated as their lack of activity leads to worsening

of symptoms, providing further confirmation for their original negative thoughts (Figure 5.3). Using this model it also fits that reduced physical quality of life is related to patients taking mood medication. Although this may help, it may also provide further confirmation that a patient's heart condition has very serious and negative consequences and thus compound the problem.

Overall, the proposed model provides a way of understanding why CRT and CRT-D patients' might report below average or extremely reduced physical quality of life, despite having a cardiac device. In line with previous research it is hypothesised that patients' reports of physical quality of life are more reduced than health professionals would estimate, based on clinical indicators (Jachuck et al., 1982; Gorkin et al., 1993). Unfortunately, the present study did not involve any clinical indicators (e.g. NYHA classification) and so it was not possible to examine this hypothesis. It would be interesting for a future study to examine the relationship between CRT and CRT-D patients' perceptions of physical quality of life compared with the views of health professionals. If the hypothesised discrepancy were found, this would provide further impetus for exploration of psychosocial factors and the perspective of the patient in the CRT and CRT-D population.

It needs to be borne in mind that the cross sectional design of the present study means that the hypotheses, put in the context of the CBT model, are only tentative proposals. A longitudinal study examining patients' perceptions over time would provide information about how CRT and CRT-D patients' perceptions may develop, and more importantly how these perceptions relate to anxiety, depression, quality of life, behavioural and physiological outcomes.

Such a study would also enable the effectiveness of interventions, aimed at addressing patients' perceptions, to be examined. It would be hypothesised, based on the model above (Figure 5.3), that an intervention would be aimed at identifying and addressing patients' detrimental perceptions (i.e. negative automatic thoughts) about their degree of personal control and the consequences of their heart condition. The potential of such an intervention is illustrated in a study by Petrie et al (2002), in post myocardial infarction patients. The researchers found that an in-hospital intervention aimed at addressing (i.e. identifying, challenging and subsequently changing) patients' perceptions of serious, negative consequences, led to earlier return to work and lower level of symptom reporting. Return to work may not be such an important issue for CRT and CRT-D patients as a significant proportion are retired (see Table 4.3, Results). The main aim of intervention might be to increase the likelihood of patients making appropriate life style changes and continuing with enjoyed activities, which in turn would potentially improve their feelings about their heart condition and reduce symptoms. A longitudinal intervention study has the potential to provide a more detailed understanding of CRT and CRT-D patients' perceptions; how these develop over time; how amenable these perceptions are to change, and the subsequent impact of change on medical, physical, behavioural and psychosocial outcomes.

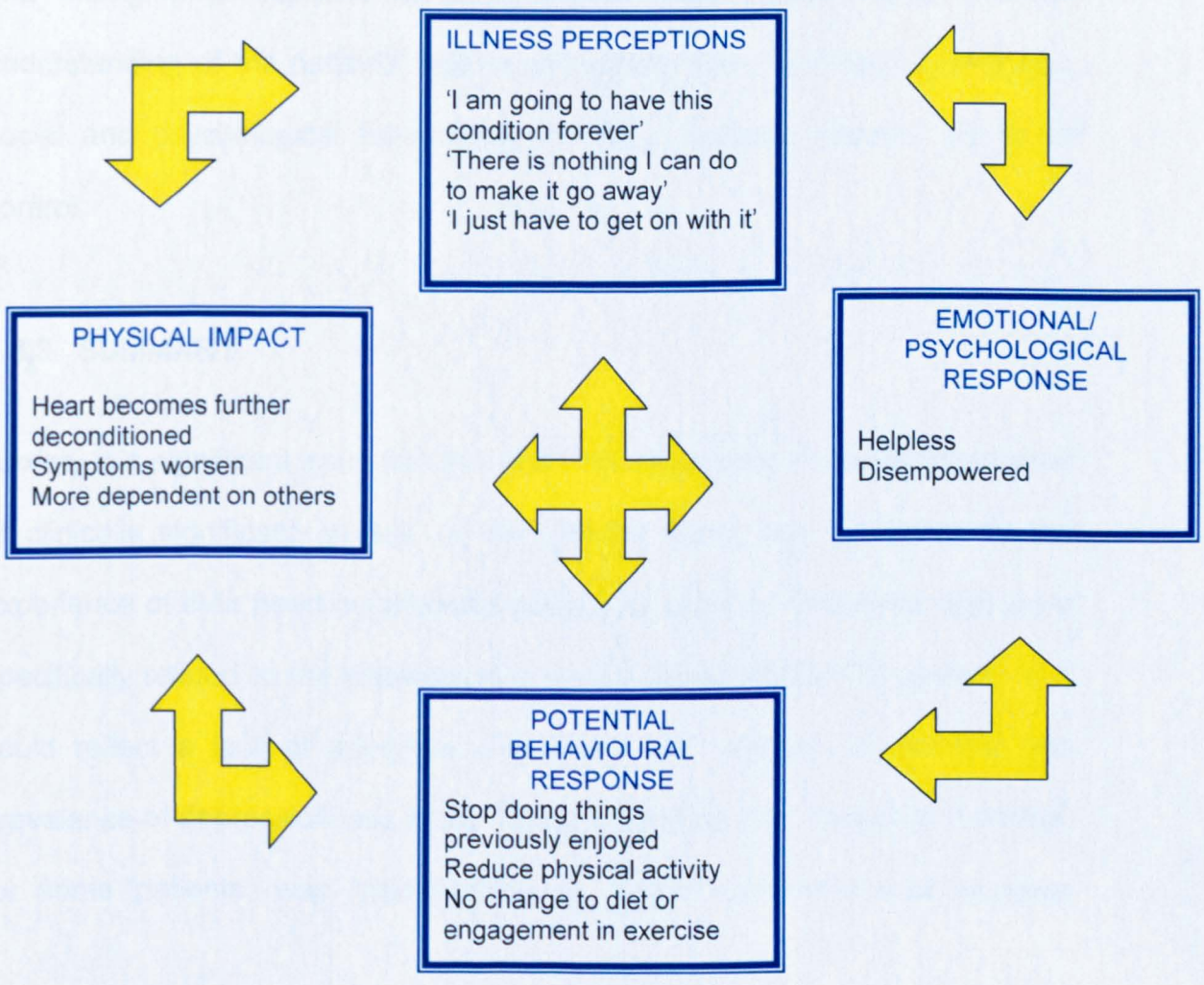
5.3.2 MENTAL QUALITY OF LIFE

In contrast to physical quality of life, patients in all device groups reported experiencing average or above average mental quality of life. These findings are similar to research conducted by Martensson, Dracup, Canary and Fridlund (2002), which examined depression and quality of life (measured by the SF-12, Ware et al., 1996) in HF patients and their spouses. Martensson et al. (2002) found that HF patients reported significantly reduced physical quality of life scores but better mental quality of life scores. Juenger et al. (2002) reported similar findings in HF patients in NYHA class II (using the SF-36, Ware, Kosinski & Keller, 1994). The present study did not examine NYHA class and therefore comparison with Juenger et als. (2002) findings are tentative. However, receipt of a CRT or CRT-D device is related to a reduction in NYHA class, therefore it is realistic that some patients in the present study were in NYHA II (CARE-HF, 2005; MIRACLE, 2005).

It is of interest that physiological/medical limitations, and not mental limitations, are perceived as the reason for reduced self-care, social and role activities in HF patients, with or without a cardiac device. It could be hypothesised that patients are in a state of 'learned helplessness' (i.e. perceiving limitations to be physically related (see Figure 5.3) means that patients do not have to take responsibility for doing anything about their heart condition. Whereas, to perceive limitations as the result of reduced mental quality of life could imply that patients have the power to change the way they are feeling and thus not be as helpless).

This state of 'learned helplessness' may be related to CRT and CRT-D patients having to come to terms with the fact that their condition is chronic (as reflected on the IPQ-R subscale timeline). In line with existing literature, the process of coming to terms with chronic ill health may reflect that CRT and CRT-D patients have integrated their heart condition into their sense of self and thus mental quality of life is protected (Radley, 2004). However, part of coming to terms with seeing their condition as chronic may involve an increased perception of helplessness (see Figure 5.4).

FIGURE 5.4 THE POTENTIAL IMPACT OF PERCEIVING HEART CONDITION AS CHRONIC: A CBT FORMULATION



Although in the short term perceptions of helplessness might not impact greatly on mental quality of life, this is not necessarily the case longer term. Indeed, ICD patients in the present study had had a device for significantly longer than CRT and CRT-D patients, and it was the ICD patients who reported the most reduced mental quality of life. It could be hypothesised that as time goes on, patients taking a passive (i.e. helpless) role experience greater medical deterioration. This eventually impacts on patients psychologically, which may be illustrated by the predictive relationship between medication, previous experience of anxiety/depression and emotional representation. Eventually patients' mental quality of life may begin to reduce. With this in mind, despite high mental quality of life in CRT and CRT-D patients in the present study, prophylactic interventions could be aimed at identifying and changing perceptions of helplessness. Interventions would promote understanding of the patients' role in enhancing their physiological, physical, social and psychological functioning and thus increase patients' sense of control.

5.3.3 SUMMARY

Anxiety is a significant issue for CRT and CRT-D patients. Patients' experience of clinically significant anxiety, in the present study, was predicted by the experience of their heart condition/symptoms as cyclical. This issue was more specifically related to the experience of device firings for CRT-D patients and could reflect a lack of adequate information and support. In contrast, the prevalence of depression was lower across all groups. The receipt of a device, for some patients, was hypothesised to reduce symptoms and increase

perceptions of something being 'in control' of their heart condition. Despite the lower prevalence of depression, there were still a significant number of patients who reported depression in the clinically significant range. Given research highlighting the association of depression with poor patient outcomes it is important that these patients are identified and provided with the appropriate support.

Physical quality of life was significantly reduced across all groups, more so than might be estimated from a medical perspective. Reduced physical quality of life was predicted by a number of the IPQ-R subscales. It was hypothesised that the perception of limited personal control might be fundamental in patients developing a view of themselves as 'helpless', thus triggering related negative perceptions (e.g. 'this condition impacts on everything'). In contrast, patients' mental quality of life was reported to be average or above average. It was hypothesised that mental quality of life was protected by patients' perceptions of physiological/medical factors as the reasoning for increased limitations. However, although this strategy was suggested to be functional in the short term, the poorer mental quality of life of ICD patients was hypothesised to reflect that these perceptions might become less functional over time.

The clinical implications discussed in sections 5.2 and 5.3 are summarised in the next section.

5.4 CLINICAL IMPLICATIONS

A significant number of CRT and CRT-D patients experience clinically significant anxiety and depression, which if not addressed can lead to poorer outcomes (i.e. medical, physical, social and psychological outcomes). Utilisation of the HADS, by health professionals as a routine screening tool, could help to identify patients who are experiencing clinically significant psychological distress (i.e. anxiety and/or depression). The HADS has been validated in somatic, psychiatric, and cardiac patients and in the general population and has been shown to be a valid and reliable instrument (Herrmann, 1997; Strik, Honig & Lousberg, 2001; Bjelland, Dahl & Haug, 2002). A cut-off score ≥ 8 for determining clinically significant cases on both subscales (i.e. anxiety and depression) has been suggested to yield an optimal balance between sensitivity and specificity (Bambauer, 2005). It is proposed that the HADS could be used at regular intervals (i.e. at clinic appointments, both prior to and following receipt of a CRT or CRT-D device) to monitor patients' psychological well-being and as a means of initiating discussion regarding possible additional sources of support. A part of this monitoring could also include routine questions regarding patients' experience of previous anxiety/depression and their use of mood related medication. This would be important as these factors, in line with previous research (Rumsfeld et al., 2003), have been shown to significantly predict anxiety and reduced mental quality of life (i.e. patients may report scores on the HADS below the clinically significant cut-off, however, they may be at risk of developing psychological problems and thus could be offered appropriate prophylactic support).

The IPQ-R could be utilised in a similar way to the HADS, if not alongside it. Routine use of the questionnaire (or important subscales of the questionnaire) could aid health professionals in a number of ways. Firstly, it could allow for greater insight into CRT and CRT-D patient responses from both a medical and psychological perspective. Secondly, it could potentially enhance physician-patient communication, and go some way towards 'putting heart failure patients at the centre of care' (NICE, 2003). Thirdly, it could be used as a screening tool to identify patients whose perceptions or misconceptions are currently causing distress or reduced quality of life, or have the potential to do so in the future. Finally, the IPQ-R could enable professionals to take an individualised approach when tailoring interventions. This is important as it fits with the current British Association of Cardiac Rehabilitation (BACR; Coats et al, 2007) evidence based guidelines for Cardiac Rehabilitation. BACR guidelines advocate that information should be individually tailored for patients to help them make sense of their condition, with a view to improving medical and psychological outcomes.

5.4 STRENGTHS AND LIMITATIONS

A real strength of the current study is that it is the first to examine psychological outcomes in CRT and CRT-D patients. The importance of this is emphasised by the fact that it brings research involving the CRT and CRT-D population in line with NICE (2003), BHF (2002) and NSF CHD (2005) evidence based guidelines. Furthermore, hypotheses regarding potential intervention strategies have been considered in the context of a cognitive

behavioural model. This is a model that has been recently advocated by the BACR (Coats et al, 2007) as a way of individualising cardiac rehabilitation.

Although a limited number of studies in the medical sphere have examined quality of life in CRT and CRT-D patients, no previous attempts have been made to try and account for the variability in outcomes, aside from medical variables. This study has therefore not only provided an initial insight into the factors that are important in influencing patients' responses, but it has also started to consider ways in which these patients can be supported.

Another strength regards the present study's function in adding to the current debate in the medical sphere regarding which patients will benefit the most from receiving a device. The findings have shown that patients identified for CRT or CRT-D using current medical criteria who, for example, perceive that they have limited personal control over their heart condition; associate their heart condition with non-modifiable causal factor(s); experience their condition/symptoms as cyclical in nature; are taking mood related medication, and/or have previously experienced anxiety or depression, are less likely to 'do well'[26]. As such, if the perceptions of these patients are routinely examined, along with consideration of mood medication and psychiatric history, it is possible that health professionals can reduce the risk and prevalence of psychological distress and reduced quality of life in CRT and CRT-D patients.

[26] Current medical criteria includes: QRS duration of less than 130 ms; left ventricular ejection less than 35%; left ventricular end diastolic diameter of more than 55mm and previous cardiac arrest or risk of cardiac arrest due to ventricular fibrillation or ventricular tachyarrhythmia.

With regards to limitations of the present study, one of the main issues concerns the cross sectional design. As discussed in Section 5.1 and 5.2 this design precludes the researcher from inferring causality and means that the hypotheses, put in the context of the CBT model, are only tentative. However, a positive element of the study was that it utilised predictive statistics, for which adequate numbers were recruited.

Another area where the study could have been improved regards the use of medical outcomes. The present study did not incorporate such measures and as such it limited comparison with the existing literature, particularly that in the medical sphere. It would have been particularly interesting to have had a measure of NYHA class to allow for comparison with the medical literature, but also to enable examination of the relationship between physician and patient estimates of physical functioning.

Another issue related to medical variables was that the present study did not utilise rigid medical criteria for inclusion. In one respect this is considered a positive, as the aim of the study was not to examine medical variables, but patients' perceptions. This was driven by existing literature demonstrating the lack of a predictive relationship between medical indicators and patient outcomes. However, from a medical perspective the sample would be considered very generic, which puts some limitations on the generalisability of the findings and also makes it more challenging to have such findings recognised by those in the medical sphere.

The generalisability of the present findings is also limited with regards to ethnicity. All patients were classified as White British, apart from one patient. This apparent bias was considered to be an artefact of the areas where patients were recruited, both of which were predominantly white. This sample is not representative of device patients nationally (BHF, 2002). It is very important that future studies in this area recruit a more nationally representative sample with regards to ethnicity.

With regards to the measures used in the present study there were a number of limitations identified. All measures were reliant on self-report and although this was important, given the focus being on gaining patients' perspectives, patients may have under or over reported their views or feelings, as they may have completed the questionnaires with someone else, possibly a spouse or partner, which may have affected the data. Also, some questions were left unanswered on the IPQ-R subscales, and although there did not seem to be a pattern to those left unanswered, possibly an interview process may have been more beneficial. Furthermore, there were some inconsistencies found in patients' responses on some of the IPQ-R subscales. Again, there was not a clear pattern to this; however, it was considered that some patients might have been confused by the reverse scoring that applied to a number of the items on the IPQ-R. This problem was not extensive enough to affect the reliability of the measure, but revision of the reversed scored items requires consideration for future research in CRT and CRT-D patients.

A number of potential areas for future research have been highlighted throughout Chapter Five. The main areas are summarised in the next section.

5.6 SUGGESTIONS FOR FUTURE RESEARCH

A future study could utilise a longitudinal and prospective design where patients' perceptions were examined prior to and at time points following CRT or CRT-D device implantation. This study would allow for patients' perceptions to be mapped through the implantation process, providing a more in depth insight into the predictive relationship between perceptions and psychosocial outcomes. Potentially this could start to build an evidence base for the tentative hypotheses and intervention suggestions in the present study. This design could also be utilised in future research to examine interventions aimed at identifying and changing patients' perceptions. Such research could be aimed at examining whether CRT and CRT-D patients' perceptions could be changed via intervention, and furthermore, whether any changes in perceptions result in reduced psychological distress, improved quality of life and increased positive health behaviours.

Another way in which future studies could add to the CRT and CRT-D research base is to explore the areas that seem relevant from this study in more detail and depth utilising a qualitative approach. For example, an important and complex issue for these patients relates to the perception of control, which it was not considered was adequately addressed by the IPQ-R. A qualitative

approach could provide a richer and potentially more informative understanding of this area.

Finally, it is considered important that future research in this area examines positive factors and resources (e.g. spirituality, spousal support, etc) that may play a role in protecting patients from experiencing psychological distress and motivate engagement in positive health behaviours. It is important to remember that despite a significant proportion of patients experiencing psychopathology and reduced quality of life, the majority of patients do not.

5.7 CONCLUSIONS

Overall, the prevalence of psychological distress was high in CRT and CRT-D patients and physical quality of life was significantly reduced. However, mental quality of life appeared relatively protected and levels of depression were lower than in the general HF population. Receipt of a device was hypothesised to be important in reducing symptom experience and providing patients with the perception that something was 'in control' of their heart condition. However, receipt of a device did not appear to impact beneficially on patients' perceptions of personal control or cyclical symptom experience.

Routine use of the HADS and the IPQ-R, as screening tools, was considered to be a potentially useful means of identifying patients in need of additional support.

The current study also highlighted the potential, for CRT and CRT-D patients, of interventions utilising a cognitive behavioural framework as a means of 'capturing' and modifying perceptions.

In conclusion, this study helped to provide a new insight into CRT and CRT-D patients. An insight that acknowledged these patients as individuals with the potential to affect their future well-being.

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APPENDICES

APPENDIX A

MEASURES

CONFIDENTIAL

Patient ID: .....

Date: ...../...../.....

Please fill this in when you complete the questionnaire.

Many thanks.

PLEASE TURN OVER

Thank you for agreeing to take part in this research study. Please try your best to complete all of the questions. Many thanks.

1. Are you? (Please circle as appropriate)

Single Married Cohabiting Separated/divorced Widowed

2. Are you working at the moment? (Please circle as appropriate)

Full-time Part-time Unemployed Retired

3. How would you describe your ethnic background? (Please circle as appropriate)

White Black Asian Other (please specify)

_____

4. Please list any health problems you currently have apart from your heart condition

_____

_____

5. Have you ever suffered from any problems such as anxiety or depression, etc?

Yes ☐ No ☐

PLEASE TURN OVER

6. If YES (to question 5):

   a. Do you relate the problems of anxiety or depression with your **heart condition**?

      Yes ☐ No ☐

   b. Do you relate the problems of anxiety or depression with **the device** you received?

      Yes ☐ No ☐

Please tell us more (if you wish)

.....
.....
.....
.....

7. Are you currently taking any medication to help with mood, anxiety or stress levels, or to help you sleep?

   Yes ☐ No ☐

8. If you have received a defibrillator (i.e. a device that can give the heart a shock, if needed) has it fired since your surgery?

   Yes ☐ No ☐

The following questions have been designed to assess how you have been feeling DURING THE LAST SEVEN DAYS. Please read each question and place a tick in the box opposite the reply, which comes closest to how you have been feeling during the past week. Do not take too long over your replies: your immediate reaction to each question will probably be more accurate than a long thought out response.

1. I feel tense and 'wound up':

Most of the time	
A lot of the time	
Time to time, occasionally	
Not at all	

2. I still enjoy the things I used to enjoy:

Definitely as much	
Not quite so much	
Only a little	
Hardly at all	

3. 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	

4. I can laugh and see the funny side of things:

As much as I ever could	
Not quite so much now	
Definitely not so much now	
Not at all	

5. Worrying thoughts go through my mind:

A great deal of the time	
From time to time but not too often	
Only occasionally	
Not at all	

6. I feel cheerful:

Not at all	
Not often	
Sometimes	
Most of the time	

7. I can sit at ease and feel relaxed:

Definitely	
Usually	
Not often	
Not at all	

8. I feel as if I am slowed down:

Nearly all of the time	
Very often	
Sometimes	
Not at all	

9. I get a sort of frightened feeling like 'butterflies' in the stomach:

Not at all	
Occasionally	
Quite often	
Very often	

10. I have lost interest in my appearance:

Definitely	
I don't take as much care as I should	
I may not take as much care	
I take just as much care as ever	

11. I feel restless as if I have to be on the move:

Very much indeed	
Quite a lot	
Not very much	
Not at all	

12. I look forward with enjoyment to things:

As much as I ever did	
Rather less than I used to	
Definitely less than I used to	
Hardly at all	

13. I get sudden feelings of panic:

Very often indeed	
Quite often	
Not very often	
Not at all	

14. I can enjoy a good book or Radio or television programme:

Often	
Sometimes	
Not often	
Not at all	

PLEASE TURN OVER

This questionnaire asks about how your **heart condition** has affected you physically and emotionally. Please read each question and place a tick in the box opposite the reply, which comes closest to how you have been feeling.

1. In general, would you say your health is:

Excellent	
Very good	
Good	
Fair	
Poor	

2. Does your health limit you in moderate activities such as moving a table, pushing a vacuum cleaner, bowling or playing golf? If so, how much?

Limited a lot	
Limited a little	
Not limited at all	

3. Does your health limit you in climbing several flights of stairs? If so, how much?

Limited a lot	
Limited a little	
Not limited at all	

4. During the past four weeks, have you accomplished less than you would like as a result of your physical health?

No	
Yes	

5. During the past four weeks, were you limited in the kind of work or other regular activities you do as a result of your physical health?

No	
Yes	

6. During the past four weeks, have you accomplished less than you would like to as a result of any emotional problems, such as feeling depressed or anxious?

No	
Yes	

7. During the past four weeks, did you not do work or other regular activities as carefully as usual as a result of any emotional problems such as feeling depressed or anxious?

No	
Yes	

PLEASE TURN OVER

8. During the past four weeks, how much did pain interfere with your normal work, including both work outside the home and housework?

Not at all	
Slightly	
Moderately	
Quite a bit	
Extremely	

9. How much time during the past 4 weeks have you felt calm and peaceful?

All of the time	
Most of the time	
A good bit of the time	
Some of the time	
A little of the time	
None of the time	

10. How much of the time during the past 4 weeks did you have a lot of energy?

All of the time	
Most of the time	
A good bit of the time	
Some of the time	
A little of the time	
None of the time	

11. How much time during the past 4 weeks have you felt down?

All of the time	
Most of the time	
A good bit of the time	
Some of the time	
A little of the time	
None of the time	

12. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities like visiting with friends, relatives etc?

All of the time	
Most of the time	
A good bit of the time	
Some of the time	
A little of the time	
None of the time	

YOUR VIEWS ABOUT YOUR HEART CONDITION

Listed below are a number of symptoms that you may or may not have experienced since your condition was diagnosed. Please indicate by circling ***Yes*** or ***No***, whether you believe you have experienced any of the symptoms since diagnosis, and whether you believe these symptoms are related to your condition.

	I have experienced this symptom ***since my diagnosis***			This symptom is **related** ***to my condition***	
Pain	Yes	No	----------	Yes	No
Breathlessness	Yes	No	----------	Yes	No
Fatigue	Yes	No	----------	Yes	No
Wheeziness	Yes	No	----------	Yes	No
Sleep Difficulties	Yes	No	----------	Yes	No
Joint Stiffness	Yes	No	----------	Yes	No
Weight Gain	Yes	No	----------	Yes	No
Reduced Concentration	Yes	No	----------	Yes	No

PLEASE TURN OVER

YOUR VIEWS ABOUT YOUR HEART CONDITION

We are interested in your own personal views of how you currently see your heart condition. There are NO right or wrong answers. We are interested in what YOU think and feel at this point in time.

Please indicate how much you agree or disagree with the following statements about your condition by ticking the appropriate box.

PLEASE REMEMBER WE ARE ASKING ABOUT WHAT YOU THINK ABOUT YOUR HEART CONDITION

VIEWS ABOUT YOUR HEART CONDITION	STRONGLY DISAGREE	DISAGREE	NEITHER AGREE NOR DISAGREE	AGREE	STRONGLY AGREE
My condition will last a short time					
My condition is likely to be permanent rather than temporary					
My condition will last for a long time					
This condition will pass quickly					
I expect to have this condition for the rest of my life					
My condition is serious					
My condition has major consequences on my life					
My condition **does not** have much effect on my life					
My condition seriously effects the way others see me					
My condition has serious financial consequences					
My condition causes difficulties for those who are close to me					

PLEASE TURN OVER

VIEWS ABOUT YOUR HEART CONDITION	STRONGLY DISAGREE	DISAGREE	NEITHER AGREE NOR DISAGREE	AGREE	STRONGLY AGREE
My sexual relationship with my partner has changed **as a result of my condition.** (Please put N/A if this does not apply to you)					
My partner is less interested in a sexual relationship with me **as a result of my condition.** (Please put N/A if this does not apply to you)					
There is a lot I can do to control my symptoms					
What I do can determine whether my condition gets better or worse					
The course of my condition depends on me					
Nothing I do will effect my condition					
I have the power to influence my condition					
My actions will have **no** effect on the outcome of my condition					
My condition will improve in time					
There is very little that can be done to improve my condition					
My device will be effective in curing my condition					
The negative effects of my condition can be prevented (avoided) by my device					

PLEASE TURN OVER

VIEWS ABOUT YOUR HEART CONDITION	STRONGLY DISAGREE	DISAGREE	NEITHER AGREE NOR DISAGREE	AGREE	STRONGLY AGREE
My device can control my condition					
There is nothing that can help my condition					
The symptoms of my condition are puzzling to me					
My condition is a mystery to me					
I don't understand my condition					
My condition doesn't make any sense to me					
I have a clear picture or understanding of my condition					
The symptoms of my condition change a great deal from day to day					
My symptoms come and go in cycles					
My condition is very unpredictable					
I go through cycles in which my condition gets better and worse					
I get depressed when I think about my condition					
When I think about my condition I get upset					
My condition makes me feel angry					
My condition makes me feel worried					
Having this condition makes me feel anxious					
My condition makes me feel afraid					

PLEASE TURN OVER

CAUSES OF MY HEART CONDITION

I am interested in what **YOU** consider may have been the cause of your heart condition. As people are very different, there is **NO** correct answer for this question. I am most interested in your own views about the factors that caused your condition rather than what others, including doctors or family, may have suggested to you. Below is a list of possible causes for your heart condition. Please indicate how much **YOU** agree or disagree that they were causes for you by ticking the appropriate box.

POSSIBLE CAUSES	STRONGLY DISAGREE	DISAGREE	NEITHER AGREE NOR DISAGREE	AGREE	STRONGLY AGREE
Stress or worry					
Hereditary – it runs in the family					
A germ or virus					
Diet or eating habits					
Chance or bad luck					
Poor medical care in my past					
Pollution in the environment					
My own behaviour					
My mental attitude e.g. thinking about life negatively					
Family problems or worries caused by my condition					
Overwork					
My emotional state e.g. feeling down, lonely, anxious, empty					
Ageing					
Alcohol					
Smoking					

PLEASE TURN OVER

POSSIBLE CAUSES	STRONGLY DISAGREE	DISAGREE	NEITHER AGREE NOR DISAGREE	AGREE	STRONGLY AGREE
Accident or injury					
My personality					
Altered immunity					

In the space below, please note the most important factor that you now believe **CAUSED YOUR HEART CONDITION.** You may use any of the items from the box above (on page 11 & 12), or you may have additional ideas of your own.

The most important cause for me: -

1. _____

THIS IS THE END OF THE QUESTIONNAIRE. MANY THANKS FOR YOUR TIME AND YOUR HONESTY. PLEASE RETURN THIS QUESTIONNAIRE, TO SARAH EATON, IN THE ENVELOPE PROVIDED. THANK YOU.

PLEASE TURN OVER

APPENDIX B

HEART FAILURE MEDICATIONS

Heart Failure Medication

Diuretics

Diuretics (water tablets) are the most common medicines used in heart failure. Diuretics reduce the amount of fluid in the body. Diuretics help the patient to breath more easily and also lower blood pressure. There are three main types of diuretic – Thiazide diuretics (such as Bendrofluazide), loop diuretics (such as Frusemide) and potassium-sparing diuretics (such as Spironolactone). A common side effect is that blood pressure falls to too low a level, and if this happens a patient may feel giddy or dizzy when getting up from sitting or lying down. Diuretics also make patients need to urinate more often.

ACE Inhibitors ('angiotensin converting enzyme inhibitor')

These medicines help the heart to pump more blood and are also often used to lower blood pressure. Side effects can include dizziness on getting up from sitting or lying down.

Beta-blockers

These medications help control heart rate and reduce the heart's tendency to beat faster. They are used to help the heart maintain a slower rate and lower blood pressure and are often used in combination with diuretics, digoxin and ACE inhibitors. The most common side effects are slowing of the rate, tiredness, cold hands and feet, insomnia, dizziness or giddiness and impotence in men.

Digitalis

Digitalis, or the drug Digoxin which is made from digitalis, was for many years the main type of drug used to treat heart failure. Digoxin is still very useful in some patients who have a rigid, irregular heart rhythm (known as 'artrial fibrillation'), which can lead to heart failure. It is not often prescribed now for people with a normal heart rhythm, but is still a useful treatment for heart failure in certain patients. Digoxin helps the heart to beat more strongly and regularly. The most common side effect is nausea

Anticoagulants

This drug thins the blood and prevents blood clots from forming. The main side effect is that it can thin the blood too much and cause bleeding.

APPENDIX C

ETHICS DOCUMENTATION

Ethical Considerations

- The patients' will be given the freedom of choice to participate without direct or indirect pressures.
- Informed consent will be gained from all participants. Every patient who is approached will be provided with an information sheet, which will explain clearly and concisely the purpose of the study and what their role will be. This form will also include a description of the potential risks and benefits of participation.
- All patients' GPs will be informed of their consent to participate in the research. In addition, if clinically significant levels of anxiety or depression are reported, patients will be contacted and, if they agree, their GP will be informed.
- Patients will also be informed that in the event of any queries arising regarding their understanding of their heart condition, then they will be contacted and, if they agree, a cardiac nurse will be informed and a meeting arranged.
- The information sheet will give details about the demographic and medical data that participants will be asked to provide and the reasons for this.
- The consent form will clearly state that participants have the right to withdraw from the research at any point without their current or future treatment being effected. Moreover, participants will be made aware that they can have their data destroyed at any stage. There will be a space at the end of the consent form for the patient to sign in acknowledgement that he/she understands what the study involves and agrees to participate.
- Privacy and Confidentiality: Participants have the right to withhold information from being declared in the study. Any patient information gathered during the course of the research will be kept strictly confidential. Hence only the researcher (Sarah Eaton) will be privy to non-anonymised data.
- All information will be anonymised as patients will be allocated a unique identifying number and the master list will be kept separately from the data.
- No deception will be involved in the research.
- Patients will not be excluded if they are currently taking antidepressants or anxiety medication. Participating patients will be asked on the demographics form: 'are you currently taking any medication to help with mood, anxiety or stress levels or to help you sleep?'. Patients have the right to refuse to provide this information, a point that is made on the information sheet.
- Patients will receive no incentive for their participation in the study.

NHS

Local Research Ethics Committee

Telephone:
Facsimile:

31 July 2006

Miss Sarah K Eaton
Trainee Clinical Psychologist
University of Hull
Dept of Clinical Psychology
University of Hull
Cottingham Road
Hull
HU6 7RX

Dear Miss Eaton

Full title of study: **Patients' Illness Perceptions, Psychological Distress and Quality of Life in Patients Receiving Cardiac Device Therapy -- a Prospective Exploratory Study**

REC reference number: **06/Q1105/29**

The Research Ethics Committee reviewed the above application at the meeting held on 26 July 2006.

Documents reviewed

The documents reviewed at the meeting were:

Document	*Version*	*Date*
Application		12 July 2006
Investigator CV	Sarah Eaton	09 July 2006
Protocol	version 2	07 July 2006
Covering Letter		11 July 2006
Peer Review	University Peer review	07 July 2006
Questionnaire: Group 2 - 9 page Questionnaire Pack	2 months post surgery	07 July 2006
Questionnaire: Group 2 - 9 page Questionnaire Pack	2 weeks post surgery	07 July 2006
Questionnaire: Group 2 - 11 Page Questionnaire Pack	Pre Surgery	07 July 2006
Questionnaire: Group 1 - 12 page Questionnaire pack		07 July 2006
Letter of invitation to participant	Groups 1+2 Hull + Leeds (1 letter each)	07 July 2006
GP/Consultant Information Sheets	Groups 1+2	09 July 2006
Participant Information Sheet: Group 2	version 5	07 July 2006
Participant Information Sheet: Group 1	version 5	07 July 2006

Participant Consent Form: Consent form	CF version 5	07 July 2006
Supervisor CV	Dr Frizelle	07 July 2006

Provisional opinion

The Committee would be content to give a favourable ethical opinion of the research, subject to receiving a complete response to the request for further information set out below.

Authority to consider your response and to confirm the Committee's final opinion has been delegated to the Chair.

Further information or clarification required

- It was noted that A24 of the application form stated that Healthy Volunteers would be participating in this study. However, after discussions with the researcher it was noted that A24 would be left blank.
- Members questioned the travel expenses - it was noted that the 2nd group of participants would be seen at the hospital if possible and the appointments would be arranged in conjunction with a normal clinical appointment - therefore, expenses would not be paid.
- However, if they wished the researcher would visit them in their own homes. Concern was expressed that safe guards would need to be in place if the researcher was visiting patients on her own.
- The researcher stated that she would inform her supervisor who she was visiting and ring her before and after each visit.
- It was noted that consent was not required for the 1st group as consent was implied by returning the anonymous questionnaire.
- However, consent would be required for the 2nd group and checks should be made to make sure that the 2nd group were still alive via the database.

When submitting your response to the Committee, please send revised documentation where appropriate underlining or otherwise highlighting the changes you have made and giving revised version numbers and dates.

The Committee will confirm the final ethical opinion within a maximum of 60 days from the date of initial receipt of the application, excluding the time taken by you to respond fully to the above points. A response should be submitted by no later than 24 November 2006.

Ethical review of research sites

The Committee agreed that all sites in this study should be exempt from site-specific assessment (SSA). There is no need to complete Part C of the application form or to inform Local Research Ethics Committees (LRECs) about the research. However, all researchers and local research collaborators who intend to participate in this study at NHS sites should notify the R&D Department for the relevant care organisation and seek research governance approval.

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

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.

06/Q1105/29	**Please quote this number on all correspondence**

Yours sincerely

Dr
Chair

Email:

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

Copy to:

[R&D Department for NHS care organisation at lead site]

NHS

Local Research Ethics Committee

Telephone: (
Facsimile: .

14 August 2006

Miss Sarah K Eaton
Trainee Clinical Psychologist
University of Hull
Cottingham Road
Hull
HU6 7RX

Dear Miss Eaton

Full title of study: **Patients' illness perceptions, psychological distress and quality of life in patients receiving cardiac device therapy - a prospective, exploratory study.**

REC reference number: **06/Q1105/29**

Thank you for your letter of 8 August 2006, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information was considered by the Chair

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 Committee has designated this study as exempt from site-specific assessment (SSA. There is no requirement for [other] Local Research Ethics Committees to be informed or for site-specific assessment to be carried out at each site.

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	Version 5.1	8 August 2006
Investigator CV	Sarah Eaton	09 July 2006

Protocol	Version 2	07 July 2006
Covering Letter		8 August 2006
Peer Review	University Peer Review	07 July 2006
Questionnaire: Group 2 - 9 page Questionnaire Pack	2 months post surgery	
Questionnaire: Group 2 - 9 page Questionnaire Pack	2 weeks post surgery	
Questionnaire: Group 2 - 11 Page Questionnaire Pack	Pre Surgery	
Questionnaire: Group 1 - 12 page Questionnaire pack		
Letter of invitation to participant	Groups 1+2 Hull + Leeds (1 letter each)	07 July 2006
GP/Consultant Information Sheets	Groups 1+2	09 July 2006
Participant Information Sheet: Group 2	version 5	07 July 2006
Participant Information Sheet: Group 1	version 5	07 July 2006
Participant Consent Form: Consent form	CF version 5	07 July 2006
Supervisor CV	Dr Frizelle	

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.

06/Q1105/29	**Please quote this number on all correspondence**

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

Yours sincerely

Dr
Chair

Email:

Enclosures:

Standard approval conditions [SL-AC1 for CTIMPs, SL-AC2 for other studies]
Site approval form

Hospitals NHS
NHS Trust

Research & Development Department
Clinical Governance Directorate
Admin Porta Cabin
01482 875875 Ext 2681/3936

Miss Sarah Eaton
Humber Mental Health Teaching NHS Trust
Department of Clinical Psychology
University of Hull
Hull
HU6 7RX

Dear Miss Easton#

Re: Illness perceptions, distress, quality of life in CRT patients Trust ref R0380

Subject to receiving a copy of the Ethics Committee approval letter,I am pleased to notify you formally that this study has been approved by the Trust and may now proceed.

Hospitals NHS Trust conducts all research in accordance with the requirements of the Research Governance Framework, and the NHS Intellectual Property Guidance. In undertaking this study, you agree to comply with all reporting requirements, systems and duties of action put in place by the Trust to deliver research governance, and you must comply with Trust information management and data protection policies (see intranet Policies Nos: 134, 135, & 192). In addition, you agree to accept the responsibilities associated with your role that are outlined within the Research Governance Framework as follows:

- the study should follow the agreed protocol;
- all potential subjects should have enough information to make a free and informed decision about participation;
- participants should receive appropriate care while involved in the study;
- the integrity and confidentiality of clinical and other records and data generated by the study will be maintained;
- all adverse events must be reported forthwith to the Trust and other authorities specified in the protocol;
- any suspected misconduct by anyone involved in the study must be reported;

The Trust is required to return information on the progress of studies to the National Research Register, and to report research findings. We will, therefore, ask you every quarter for such updates, and would be very grateful if you would provide this information.

I would like to wish you every success with this project.

Yours sincerely

Research & Development Manager

Hospitals NHS
NHS Trust

Research & Development Directorate

21 July 2006

Ms Sarah Eaton

Tel:
Fax:

Dear Ms Eaton

Re: R&D Approval of Project No EX06/7645: Patients illness perceptions psychological distress and quality of life in patients receiving cardiac device therapy

I write with reference to the above research study. I can now confirm that this study has R&D approval and the study may proceed at The NHS Trust (LTHT). This organisational level approval is given based on the information provided in the Research Ethics Committee and Trust R&D Project Approval form.

As principal investigator you have responsibility for the design, management and reporting of the study. In undertaking this research you must comply with the requirements of the *Research Governance Framework for Health and Social Care* which is mandatory for all NHS employees. This document may be accessed on the Department of Health website at http://www.dh.gov.uk/PolicyAndGuidance/ResearchAndDevelopment/

R&D approval is therefore given on the understanding that you comply with the requirements of the *Framework* as listed in the attached sheet "Conditions of Approval".

If you have any queries about this approval please do not hesitate to contact the R&D Department on telephone

Indemnity Arrangements

The NHS Trust participates in the NHS risk pooling scheme administered by the NHS Litigation Authority 'Clinical Negligence Scheme for NHS Trusts' for: (i) medical professional and/or medical malpractice liability; and (ii) general liability. NHS Indemnity for negligent harm is extended to researchers with an employment contract (substantive or honorary) with the Trust. The Trust

only accepts liability for research activity that has been managerially approved by the R&D Department.

The Trust therefore accepts liability for the above research project and extends indemnity for negligent harm to cover you as principal investigator and the researchers listed on the R&D approval form provided that each member of the research team has an employment contract (substantive or honorary) with the Trust. Should there be any changes to the research team please ensure that you inform the R&D Department and that s/he obtains an employment contract with the Trust if required.

Yours sincerely

Associate Director of R&D

Note: Please send the confirmation from your supervisor

NHS

NHS Trust

Direct Tel no:
Direct Fax No:
Email:

In Confidence
Sarah Eaton

Dear Miss Eaton

HONORARY CONTRACT

I am instructed by the , to offer you an Honorary Contract in the Department of Academic Cardiology – Hospital, as a Trainee Clinical Psychologist from 2007.

Your ased supervisor will be – Research Fellow. If you wish to raise concerns or complaints about your commitments under this honorary contract, you should first raise the matter with Dr The agreed procedure for settling differences between you and will be in accordance with the Trust's Grievance Procedure. This information will be fed back to your employing body.

This post allows you to undertake the duties as a Trainee Clinical Psychologist on the premises and using the facilities of If your duties involve clinical or administrative duties connected with patient care, you are granted access to the associated records.

manages all research in accordance with the requirements of the Research Governance Framework[1]. If, in the course of your duties, you undertake any form of research, you agree to make yourself familiar with the Research Governance Framework and agree to accept the responsibilities associated with your role that are outlined within it. You agree to comply with all reporting requirements, systems and duties of action put in place by the Trust to deliver research governance.

You and your employer recognise the Trust's right to benefit from Intellectual Property [IP] arising from work undertaken under this contract in accordance with the Health and Social Care Act 2001. In circumstances where there is potential IP, you are required to notify the Trust Research and Development department. Specific IP agreements will be negotiated on an individual case-by-case basis.

[1] Department of Health [2001] The Research Governance Framework for Health and Social Care

You are required to observe the policies and procedures of the HEYHT in so far as they apply to this appointment and to observe all NHS policies and procedures in respect of clinical and research activities.

You must act, at all times, in accordance with the Trust's policies, Procedures and Guidance, copies of which are available in the Human Resources department. The Trust reserves the right to terminate this Honorary Contract where your conduct is inconsistent with the high standards of work and behaviour expected in your continued honorary placement with the Trust.

If you observe practice which you feel is a cause for concern, please refer to the Trust's "Policy for Staff Reporting Concerns about Patient Care and Other Matters [Whistleblowers]", available on the intranet.

The Trust accepts liability in respect of your acts and omissions to the degree that those acts and omissions were carried out whilst working on behalf of the Trust and in accordance with your appointment under this contract. You must, however, observe the same standards of care and propriety in dealing with patients, staff, visitors, equipment and premises as is expected of any other honorary contract holder. You must also act appropriately and responsibly at all times.

Whilst undertaking officially sanctioned NHS duties, you are covered by the NHS indemnity against claims for negligence. In other circumstances, [eg when providing services for which you receive a separate fee, or if undertaking research which has not received the Trust's approval] you are not covered by the indemnity. If you intend to treat private patients on Trust premises, you must have a valid indemnity. Medical practitioners are advised to maintain membership of a medical defence organisation and submit a copy of current membership to both Human Resources Departments.

You are required to ensure the security and confidentiality of all information regarding patients or staff at all times. You should not release any such information to anyone other than an approved person in the course of your duties. If, as an honorary contract holder, you handle patient or staff related information stored on computers, you must ensure that it remains on Trust-owned computers and is not transferred to computers owned by other organisations, including those of your substantive, without appropriate authorisation. This authorisation might be in the form of a formal agreement between HEYHT and your substantive employer with regard to specific types of information or a specific agreement between yourself and the Trust with regard to storage of such information. You should be aware of your responsibilities under the Data Protection Act and only use such information for a registered purpose, not disclosing it to any unauthorised person. You should make yourself familiar with relevant Trust policies[2].

In the event of sickness or unavoidable absence, you must notify your line manager and The Human Resources Department immediately. You must report any accident or injury, however trivial, arising out of or in the course of your activities in the Trust to your line manager and make appropriate records and statements as required.

[2] Policy No. 134 Confidentiality and Information Security Policy, and Policy No. 135 Information Management Policy: Research and Clinical Audit

Mandatory Training

You are required to attend the Trust's mandatory training courses such as Moving and Handling, Health and Safety, Fire Training etc. Your employing department is responsible for ensuring you are booked on to this training as part of your induction.

Dress Code

The Trust wishes to ensure a smart, professional image to be conveyed at all times to the patients and other visitors. Please refer to the Trust's Corporate "Uniform Policy" for further details.

Please ensure that you wear your name badge at all times, or be able to prove your identity, if challenged.

If you agree to accept this honorary contract on the terms specified above, please sign the form of acceptance at the foot of this page and return it to the Human Resources Department. A second copy of this letter is attached, which you should also sign and keep for further reference.

Yours sincerely

Senior HR Assistant
Human Resources
Alderson House

PLEASE DO NOT DETACH

I have read and agree to the above conditions.

Signed: .....

Dated: .....

NHS Trust

PRIVATE & CONFIDENTIAL

Sarah Eaton

Direct Line
Fax:

Date:

Dear Sarah,

HONORARY CONTRACT IN THE POST OF – Trainee Clinical Psychologist

1. I am instructed by NHS Trust ("the Trust") to offer you an honorary contract conferring honorary status in the post of Trainee Clinical Psychologist commencing on

   The purpose of the contract is to conduct research to constitute doctoral thesis.

   This Contract is for a fixed period of 1 year and will terminate on 14th July 2007 the continuance of the fixed term this Honorary Contract may be terminated by the Trust at any time upon giving one week's notice in writing to you.

2. The title and status does not create an employment relationship with the Trust and attracts no remuneration from the Trust. You are required to observe the policies and procedures of the Trust in so far as they apply to this appointment and to observe all policies and procedures in respect of clinical and research activities. In addition you will be expected to comply with the Trusts general conditions of employment in as far as they apply to you e.g. working hours.

3. You must notify Dr of your presence within the Trust and the likely duration of each visit.

4. Under the terms of this Contract you are permitted access to the Trust premises and equipment within the Trust's Cardiology Department for the purpose of carrying out the functions associated with the position of Trainee Clinical Psychologist.

5. Whilst undertaking NHS duties you are normally covered by the NHS Hospital and community Health Services indemnity against claims for medical negligence. However in certain circumstances (especially in services for which you receive a separate fee) you may not be covered by the indemnity. You are therefore advised to maintain membership of your defence organisation.

c) Any disciplinary action that needs to be taken will be done so following the Procedures of your substantive employer.

16. You will be expected to carry your Trust and University ID card at all times whilst undertaking Trust business.

17. Should your honorary contract take you into an area that requires staff to undergo a Criminal Records Bureau check then you will be expected to undertake the relevant checks before commencing work in the Trust.

18. If you agree to accept this honorary contract on the terms specified above, please sign the form of acceptance at the foot of this page and one copy to me at the above address. A second signed copy of this letter is also attached, which you should also sign and retain for your future reference.

19. The Trust reserves to withdraw this honorary contract at any time but will not do so without good reason. If you leave your post with your substantive employer your honorary contract will automatically be terminated – you should at this time return all Trust property e.g. ID badges to the Trust. It is the responsibility of your employer to inform the Trust when an individual holding an honorary contract leaves their employment.

20. During the period of your honorary contract your contact point will be Dr

Yours sincerely

Recruitment Assistant

DO NOT DETACH

I hereby accept the honorary contract mentioned in the letter to me dated 2006 of which the above is a copy, on the terms and subject to the conditions referred to in that letter.

Signed: ..... **Date:** .....

Please sign both copies, returning one to your line manager and keeping one for own records.

APPENDIX D

PATIENT & GP CORRESPONDENCE

Patient Letter of Invitation

Dear

We are writing to ask for your help with some research that we are doing in the Cardiology Department at .
The research is to find out about your individual thoughts and feelings about your condition. We would be very pleased if you would take part.

If you are in agreement, we would be grateful if you could take a couple of minutes to have a read through this information. In a weeks time we will be contacting you by telephone to answer any questions you may have. If you agree to take part we will be sending you on the questionnaires in the post. If you would rather we didn't contact you please ring us on 01482 or email us on . If this were the case it would still be really useful for us to use your basic medical information (This is **ONLY** your age, gender and the length of time you have had your heart device). This basic information will be stored in a completely anonymous form and is simply used to show that there is no overall difference between the people who did and did not take part in the study. If you would rather we did not use this information, again please let us know by phone or email and we will do as you ask.

Thank you for your help with this research.

Consultant Cardiologist Nurse Specialist

Sarah Eaton
Trainee Clinical Psychologist and Researcher

INFORMATION SHEET

Patients' illness perceptions, psychological distress and quality of life in patients receiving cardiac device therapy

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

- Part 1 tells you the purpose of this study and what will happen to you if you take part.
- Part 2 gives you more detailed information about how the study will be run

Please feel free to contact the researcher if there is anything that is not clear or if you would like further information. Please take time to decide whether or not you wish to take part.

PART ONE

What is the purpose of the study?

The purpose of the research is to try and find out about patients' thoughts and feelings about their heart condition. The patients who take part will be from one of three groups. These groups are:

Group One: Patients who have received a Cardiovascular Resynchronisation Therapy device (CRT)
Group Two: Patients who have received a Cardiovascular Resynchronisation Device with a defibrillator function (CRT-D)
Group Three: Patients who have received an Implantable Cardioverter Defibrillator (ICD).

Why have I been chosen?

You have been chosen to take part in the research study, as you have been identified as falling into one of the three groups above.

All patients who are identified as falling into one of the three groups are being asked to take part. It is expected that approximately 500 people will be invited to take part in the study.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do, you will be given this information sheet to keep and you will be asked to sign a consent form. You are still free to withdraw from the study 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 you receive.

What will happen to me if I take part?

If you are interested in taking part in the study, you will be contacted in a week's time, by Sarah Eaton (Researcher). Sarah will hope to answer any questions that you might have. If you agree to take part you will be sent the study questionnaires in the post to complete. The questionnaires are short and will take about 30 minutes to complete.

The study will be running for nine months, but you will only be asked to complete the study questionnaires once.

Standard treatment or appointments will not be affected by taking part in the research.

If you decide not to participate, basic medical information will be collected if you consent to this.

What are the possible disadvantages and risks of taking part?

The study involves completing two questionnaires that ask about your feelings, which will require you to think about how you have been affected by your heart condition. Consequently, there is the possibility that you might find completing these measures distressing. However, you will have the option of a referral via your GP, for some help, should you feel you want it.

The study also involves completion of a questionnaire exploring what you think about your heart condition. There is a possibility that this measure might highlight where there may be some misunderstanding about your heart condition. If this is the case, you will have the option of discussing these issues with a Cardiac Nurse, should you wish to do so.

What are the possible benefits of taking part?

If you are experiencing any distress in relation to your heart condition, the questionnaires will indicate this and you will be offered a referral for some help should you want this. Similarly, if there is some misunderstanding about your heart condition this can also be addressed, which has been shown to be useful. There is a good body of research evidence to suggest that correcting peoples misconceptions about their heart condition can lead to improvements in how they feel and manage.

It is hoped that the information gained from the study will contribute to improved care for future patients who receive CRT and/or an ICD.

What happens when the research study stops?

Revert to usual care.

Will my taking part in this study be kept confidential?

Yes. All the information about your participation in this study will be kept completely confidential. The details are included in Part 2.

Contact for further information (or concerns during study)

Sarah Eaton
Department of Clinical Psychology
University of Hull
Cottingham Road
Hull
HU6 7RX

Tel:
Mobile:
Email:

This completes Part 1 of the Information Sheet.

If the information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision.

INFORMATION SHEET

PART TWO

Will my taking part in this study be kept confidential?

All information that is collected about you during the course of the research will be kept strictly confidential. All information about you that leaves the hospital will have your name and address removed so that you cannot be recognised from it. All data held on computer will be password protected and only accessible to the researcher (Sarah Eaton).

Involvement of the General Practitioner/Family doctor (GP)

With your consent: your GP will be informed that you have chosen to participate and a referral will be made to your GP if clinically significant distress is identified through the research questionnaire at any stage.

What will happen to the results of the research study?

The results of the research will be written up as part of the researcher's doctoral qualification. You will have the option of receiving a short written report outlining the main findings of the study, although no individual results will be available. Results will also be published in peer review journals to allow other clinicians to access them. In such publications, there will be no identifying names or details, ensuring your confidentiality.

Who is organising and funding the research?

The research is being undertaken as part of a Postgraduate Doctorate qualification in Clinical Psychology. The researcher is salaried by Humber Mental Health Teaching Trust to carry out the research and no external funding will be sought.

Who has reviewed the study?

The research has been peer reviewed by Clinical Psychologists at the University of Hull. The study has also been reviewed by the South Humber Local Research Ethics Committee and has gained ethical approval.

Thank you very much for taking the time to read this information sheet

GP Letter (1)

Dear Dr ,

Re: Mr XXXXXX XXXXXX (DOB)

I would like to inform you that the above named patient has agreed to participate in a questionnaire based research study investigating their thoughts and feelings about their heart condition.

The study will last nine months and patient involvement entails 30 minutes at home to complete the study questionnaires.

The study questionnaires might highlight that the aforementioned patient is experiencing clinically significant distress (anxiety and/or depression). If this is the case they will be informed and will be given the option of a referral to yourself for further support.

If you require any further information, please do not hesitate to contact me on or email me on .

Yours Sincerely

Sarah Eaton
Trainee Clinical Psychologist

Supervised by Dr
Clinical psychologist

GP Letter (2)

Date

Dear Dr

Re:

I wrote to you on to inform you that had agreed to participate in a research study investigating his/her thoughts and feelings about his/her heart condition. has since completed and returned the questionnaires enquiring in to his/her psychological well being.

I write today to inform you that some of scores on the questionnaires were elevated indicating possible clinical levels of anxiety and depression. I contacted to discuss his/her results and he/she reported that .....he/she agreed that I should write to inform you of this in the hope that you can review his mental state next time he/she attends your surgery.

If you require any further information, please do not hesitate to contact me on .

Many Thanks

Yours Sincerely

Sarah Eaton
Doctoral Trainee in Clinical Psychology

Supervised by Dr
Clinical psychologist

Patient Letter of Thanks Following Return of Questionnaire

Dear

RE: Patients' illness perceptions, psychological distress and quality of life in patients receiving cardiac device therapy

I wanted to take this opportunity to say a huge thank you for the time and effort you put in to completing the research questionnaires. I am very grateful for your support, without which this study would not have been possible.

I wish to confirm that you will be receiving a summary of the research results, via post, at the end of July 2007. Please let me know if your address details change before this date, so that I can make sure that you receive the summary report, if you wish to.

Please do not hesitate to get in touch, if you have any queries related to the research study, the results of the study, etc. I would really like to encourage you to please leave an answer phone message (your name and telephone number is sufficient) if I am not available when you ring. It is important to me that you are able to discuss any issues, no matter how big or small, and I will always endeavour to contact you as soon as possible.

Thank you again for your support with this research. I look forward to sharing the results with you in July 2007.

Yours sincerely

Sarah Eaton
Trainee Clinical Psychologist and Researcher
(Contact details were enclosed)

APPENDIX E

SPSS OUTPUT

Table 1 (a, b, c & d)

Demographic Differences between CRT-P Participants and Non-Participants

Age

	PARTICIPANTS	N	Mean	Std. Deviation	Std. Error Mean
Age	Participant	53	69.83	8.274	1.136
	Non-Participant	44	69.16	11.316	1.706

Independent Samples t-test – Participants and Non-Participants Age

		t-test for Equality of Means						
		t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
							Lower	Upper
Age	Equal variances assumed	.337	95	.737	.671	1.992	-3.284	4.626
	Equal variances not assumed	.327	77.083	.744	.671	2.049	-3.410	4.752

Number of Months Since Receiving Device

	PARTICIPANTS	N	Mean	Std. Deviation	Std. Error Mean
Number of months Since Receiving Device	Participant	53	24.98	12.176	1.672
	Non-Participant	44	25.91	12.349	1.862

Independent Samples t-test – Participants and Non-Participants Number of Months Since Receiving Device

		t-test for Equality of Means						
		t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
							Lower	Upper
Number of months Since Receiving Device	Equal variances assumed	-.371	95	.711	-.928	2.499	-5.889	4.034
	Equal variances not assumed	-.371	91.260	.712	-.928	2.503	-5.899	4.043

Table 2 (a, b, c & d)

Demographic Differences between CRT-D Participants and Non-Participants

Age

	PARTICIPANTS	N	Mean	Std. Deviation	Std. Error Mean
Age	Participant	47	66.68	8.638	1.259
	Non-Participant	36	66.83	8.027	1.338

Independent Samples t-test – Participants and Non-Participants Age

		t-test for Equality of Means						
		t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
							Lower	Upper
Age	Equal variances assumed	-.082	81	.935	-.152	1.856	-3.845	3.540
	Equal variances not assumed	-.083	77.959	.934	-.152	1.838	-3.811	.506

Number of Months Since Receiving Device

	PARTICIPANTS	N	Mean	Std. Deviation	Std. Error Mean
Number of months Since Receiving Device	Participant	47	25.62	15.707	2.291
	Non-Participant	36	24.61	16.522	2.754

Independent Samples t-test – Participants and Non-Participants Number of Months Since Receiving Device

		t-test for Equality of Means						
		t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
							Lower	Upper
Number of months Since Receiving device	Equal variances assumed	.283	81	.778	1.006	3.558	-6.073	8.085
	Equal variances not assumed	.281	73.449	.780	1.006	3.582	-6.132	8.144

Table 3 (a, b, c & d)

Demographic Differences between ICD Participants and Non-Participants

Age

	PARTICIPANTS	N	Mean	Std. Deviation	Std. Error Mean
Age	Participant	51	65.31	10.504	1.471
	Non-Participant	36	61.11	18.156	3.026

Independent Samples t-test – Participants and Non-Participants Age

		t-test for Equality of Means						
		t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
							Lower	Upper
Age	Equal variances assumed	1.363	85	.176	4.203	3.083	-1.928	10.333
	Equal variances not assumed	1.249	51.481	.217	4.203	3.365	-2.550	10.956

Number of Months Since Receiving Device

	PARTICIPANTS	N	Mean	Std. Deviation	Std. Error Mean
Number of Months Since Receiving Device	Participant	51	43.88	17.481	2.448
	Non-Participant	36	41.83	14.677	2.446

Independent Samples t-test – Number of Months Since Receiving Device

		t-test for Equality of Means						
		t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
							Lower	Upper
Number of Months Since Receiving Device	Equal variances assumed	.575	85	.567	2.049	3.567	-5.042	9.140
	Equal variances not assumed	.592	82.374	.555	2.049	3.461	-4.835	8.932

Table 4 (a &b)

One Way ANOVA – Time Since Receiving Device

Number of Months Since Receiving Device

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	11697.771	2	5848.885	25.210	.000
Within Groups	34337.382	148	232.009		
Total	46035.152	150			

Multiple Comparisons

Dependent Variable: Number of Months Since Receiving Device
Gabriel Procedure

(I) Device Type	(J) Device Type	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
CRT-D	CRT-P	.63589	3.05187	.995	-6.7283	8.0001
	ICD	-18.26533(*)	3.07987	.000	-25.6989	-10.8318
CRT-P	CRT-D	-.63589	3.05187	.995	-8.0001	6.7283
	ICD	-18.90122(*)	2.98776	.000	-26.1136	-11.6888
ICD	CRT-D	18.26533(*)	3.07987	.000	10.8318	25.6989
	CRT-P	18.90122(*)	2.98776	.000	11.6888	26.1136

* The mean difference is significant at the .05 level.

Table 5 (a&b)

One Way ANOVA – Age

Patient Age

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	558.434	2	279.217	3.304	.039
Within Groups	12508.665	148	84.518		
Total	13067.099	150			

Multiple Comparisons

Dependent Variable: Patient Age
Gabriel Procedure

(I) Device Type	(J) Device Type	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
CRT-D	CRT-P	-3.14934	1.84199	.244	-7.5941	1.2954
	ICD	1.36713	1.85889	.844	-3.1195	5.8537
CRT-P	CRT-D	3.14934	1.84199	.244	-1.2954	7.5941
	ICD	4.51646(*)	1.80330	.039	.1633	8.8696
ICD	CRT-D	-1.36713	1.85889	.844	-5.8537	3.1195
	CRT-P	-4.51646(*)	1.80330	.039	-8.8696	-.1633

* The mean difference is significant at the .05 level.

Table 6 (a&b)

General Linear Modal – Device Firings and IPQ Timeline Cyclical

Tests of Between-Subjects Effects

Dependent Variable: IPQTimelinecyclical

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	104.618(a)	3	34.873	2.158	.098
Intercept	7511.630	1	7511.630	464.774	.000
Device Type	1.184	1	1.184	.073	.787
DefibFirings	30.757	1	30.757	1.903	.171
Device * DefibFirings	73.054	1	73.054	4.520	.036
Error	1519.219	94	16.162		
Total	13394.000	98			
Corrected Total	1623.837	97			

a R Squared = .064 (Adjusted R Squared = .035)

Parameter Estimates

Dependent Variable: IPQTimelinecyclical

Parameter	B	Std. Error	t	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
Intercept	10.226	.722	14.162	.000	8.792	11.659
[Device=CRT-D]	1.800	.967	1.861	.066	-.121	3.721
[Device=ICD]	0(a)	.	.	.	.	.
[DefibFirings=YES]	.724	1.153	.628	.531	-1.565	3.014
[DefibFirings=NO]	0(a)	.	.	.	.	.
[Device=CRT-D] * [DefibFirings=YES]	-4.125	1.940	-2.126	.036	-7.977	-.273
[Device=CRT-D] * [DefibFirings=NO]	0(a)	.	.	.	.	.
[Device=ICD] * [DefibFirings=YES]	0(a)	.	.	.	.	.
[Device=ICD] * [DefibFiings=NO]	0(a)	.	.	.	.	.

a This parameter is set to zero because it is redundant.

Table 7 (a&b)

General Linear Modal – Device Firings and Consequences Timeline Cyclical

Tests of Between-Subjects Effects

Dependent Variable: Consequences

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	498.169(a)	3	166.056	4.716	.004
Intercept	56273.064	1	56273.064	1598.058	.000
Device Type	124.434	1	124.434	3.534	.063
DefibFirings	31.861	1	31.861	.905	.344
Device * Defibfirings	115.559	1	115.559	3.282	.073
Error	3204.421	91	35.213		
Total	82557.000	95			
Corrected Total	3702.589	94			

a R Squared = .135 (Adjusted R Squared = .106)

Parameter Estimates

Dependent Variable: Consequences

Parameter	B	Std. Error	t	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
Intercept	25.533	1.083	23.568	.000	23.381	27.685
[Device=CRT-D]	5.335	1.449	3.681	.000	2.456	8.214
[Device=ICD]	0(a)	.	.	.	.	.
[DefibFirings=YES]	3.993	1.740	2.295	.024	.537	7.449
[DefibFirings=NO]	0(a)	.	.	.	.	.
[Device=CRT-D] * [DefibFirings=YES]	-5.236	2.891	-1.812	.073	-10.978	.505
[Device=CRT-D] * [DefibFirings=NO]	0(a)	.	.	.	.	.
[Device=ICD] * [DefibFirings=YES]	0(a)	.	.	.	.	.
[Device=ICD] * [DefibFirings=NO]	0(a)	.	.	.	.	.

a This parameter is set to zero because it is redundant.

Table 8 (a&b)

One Way ANOVA – Physical Quality of Life

Physical Quality of Life

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	704.860	2	352.430	2.999	.053
Within Groups	17275.977	147	117.524		
Total	17980.837	149			

Multiple Comparisons

Dependent Variable: Physical Quality of Life

						95% Confidence Interval	
	(I) Device Type	(J) Device Type	Mean Difference (I-J)	Std. Error	Sig.	Lower Bound	Upper Bound
Gabriel Procedure	CRT-D	CRT-P	2.39200	2.18456	.617	-2.8788	7.6628
		ICD	-2.81266	2.20437	.494	-8.1328	2.5075
	CRT-P	CRT-D	-2.39200	2.18456	.617	-7.6628	2.8788
		ICD	-5.20466(*)	2.12646	.046	-10.3383	-.0711
	ICD	CRT-D	2.81266	2.20437	.494	-2.5075	8.1328
		CRT-P	5.20466(*)	2.12646	.046	.0711	10.3383

* The mean difference is significant at the .05 level.

Table 9 (a&b)

One Way ANOVA – IPQ Timeline

IPQ Timeline

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	80.816	2	40.408	2.994	.053
Within Groups	1956.886	145	13.496		
Total	2037.703	147			

Multiple Comparisons

Dependent Variable: IPQ Timeline
Gabriel Procedure

(I) Device Type	(J) Device Type	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
CRT-D	CRT-P	1.03930	.74359	.414	-.7554	2.8340
	ICD	1.83391(*)	.75053	.046	.0220	3.6458
CRT-P	CRT-D	-1.03930	.74359	.414	-2.8340	.7554
	ICD	.79462	.72763	.620	-.9623	2.5515
ICD	CRT-D	-1.83391(*)	.75053	.046	-3.6458	-.0220
	CRT-P	-.79462	.72763	.620	-2.5515	.9623

* The mean difference is significant at the .05 level.

Table 10 (a&b)

One Way ANOVA – Consequences

Consequences

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	327.483	2	163.742	4.540	.012
Within Groups	5193.551	144	36.066		
Total	5521.034	146			

Multiple Comparisons

Dependent Variable: Consequences
Gabriel Procedure

(I) Device Type	(J) Device Type	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
CRT-D	CRT-P	.97910	1.21558	.805	-1.9549	3.9131
	ICD	3.57054(*)	1.23292	.013	.5936	6.5475
CRT-P	CRT-D	-.97910	1.21558	.805	-3.9131	1.9549
	ICD	2.59144	1.19567	.092	-.2956	5.4785
ICD	CRT-D	-3.57054(*)	1.23292	.013	-6.5475	-.5936
	CRT-P	-2.59144	1.19567	.092	-5.4785	.2956

* The mean difference is significant at the .05 level.

Table 11 (a&b)
Illness Representations and Anxiety

Tests of Between-Subjects Effects

Dependent Variable: HAD Anxiety Total score

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	1713.541(a)	14	122.360	16.067	.000
Intercept	56.727	1	56.469	7.415	.007
Device Type	3.545	2	1.849	.243	.785
AnxDep	62.990	1	63.506	8.339	.005
Medication	24.889	1	24.394	3.203	.076
Age	13.165	1	12.717	1.670	.199
MONTHSDEVICE	.569	1	.609	.080	.778
IPQSymptoms	.284	1	.349	.046	.831
IPQTime	2.953	1	3.263	.428	.514
IPQTimelinecyclical	48.457	1	48.040	6.308	.013
IPQConsequences	9.528	1	9.312	1.223	.271
IPQPersonalControl	7.349	1	7.438	.977	.325
IPQDeviceControl	7.064	1	6.858	.901	.344
IPQIllnessCoherence	25.916	1	25.851	3.394	.068
IPQEmotionalRepresentation	305.817	1	307.025	40.316	.000
Additional healthprobs	.500	1	.500	.065	.799
Error	974.277	127	7.671		
Total	7681.000	143			
Corrected Total	2687.818	142			

a R Squared = .638 (Adjusted R Squared = .595)

Parameter Estimates

Dependent Variable: HAD Anxiety Total score

Parameter	B	Std. Error	t	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
Intercept	-9.328	2.985	-3.134	.002	-15.261	-3.449
[Device=CRT-D]	-.366	.687	-.532	.595	-1.725	.994
[Device=CRT-P]	-.473	.691	-.684	.495	-1.840	.895
[Device=ICD]	0(a)	.	.	.	.	.
[AnxDep=1.00]	1.696	.587	2.888	.005	.534	2.858
[AnxDep=2.00]	0(a)	.	.	.	.	.
[Medication=1.00]	1.220	.682	1.790	.076	-.129	2.568
[Medication=2.00]	0(a)	.	.	.	.	.
Age	.034	.026	1.292	.199	-.018	.086
MONTHSDEVICE	.005	.016	.283	.778	-.027	.036
IPQSymptoms	.030	.138	.214	.831	-.244	.303
IPQTime	.049	.074	.655	.514	-.098	.195
IPQTimelinecyclical	.190	.076	2.512	.013	.040	.340
IPQConsequences	.058	.052	1.106	.271	-.045	.161
IPQPersonalControl	-.050	.051	-.988	.325	-.150	.050
IPQDeviceControl	.079	.083	.949	.344	-.086	.244
IPQIllnessCoherence	.129	.070	1.842	.068	-.010	.267
IPQEmotionalRepresentation	.327	.051	6.349	.000	.225	.429
[Additional healthprobs=1.00]	-.126	.495	-.255	.799	-1.107	.854
[Additional healthprobs=2.00]	0(a)	.	.	.	.	.

a This parameter is set to zero because it is redundant

Table 12 (a&b)

Illness Representations and Depression

Tests of Between-Subjects Effects

Dependent Variable: HAD Depression Total score

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	984.654(a)	14	69.809	8.629	.000
Intercept	67.590	1	68.925	8.520	.005
Device Type	1.343	2	.984	.122	.920
AnxDep	26.346	1	25.342	3.133	.074
Medication	32.316	1	38.170	4.718	.048
Age	26.165	1	30.497	3.770	.054
MONTHSDEVICE	14.570	1	13.847	1.712	.193
IPQSymptoms	48.702	1	46.024	5.689	.019
IPQTime	.011	1	.163	.020	.887
IPQTimelinecyclical	2.466	1	3.017	.373	.543
IPQConsequences	25.737	1	27.411	3.388	.068
IPQPersonalControl	3.711	1	3.485	.431	.513
IPQDeviceControl	55.036	1	57.795	7.144	.009
IPQIllnessCoherence	17.363	1	17.576	2.173	.143
IPQEmotionalRepresentation	46.318	1	45.116	5.577	.020
Additional healthprobs	7.329	1	7.329	.905	.343
Error	1028.171	127	8.096		
Total	5638.000	143			
Corrected Total	2012.825	142			

a R Squared = .486 (Adjusted R Squared = .429)

Parameter Estimates

Dependent Variable: HAD Depression Total score

Parameter	B	Std. Error	t	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
Intercept	-10.446	3.076	-3.395	.001	-16.533	-4.359
[Device=CRT-D]	.043	.708	.061	.952	-1.358	1.444
[Device=CRT-P]	.299	.712	.420	.676	-1.111	1.708
[Device=ICD]	0(a)	.	.	.	.	.
[AnxDep=1.00]	1.071	.605	1.770	.079	-.126	2.269
[AnxDep=2.00]	0(a)	.	.	.	.	.
[Medication=1.00]	1.526	.702	2.172	.032	.136	2.916
[Medication=2.00]	0(a)	.	.	.	.	.
Age	.053	.027	1.942	.054	-.001	.106
MONTHSDEVICE	.022	.017	1.308	.193	-.011	.054
IPQSymptoms	.340	.142	2.385	.019	.058	.621
IPQTime	-.011	.076	-.142	.887	-.162	.140
IPQTimelinecyclical	.048	.078	.611	.543	-.107	.202
IPQConsequences	.099	.054	1.841	.068	-.007	.205
IPQPersonalControl	-.034	.052	-.656	.513	-.137	.069
IPQDeviceControl	.230	.086	2.673	.009	.060	.400
IPQIllnessCoherence	.106	.072	1.474	.143	-.036	.249
IPQEmotionalRepresentation	.125	.053	2.362	.020	.020	.230
[Additional healthprobs=1.00]	.484	.509	.951	.343	-.523	1.491
[Additional healthprobs=2.00]	0(a)	.	.	.	.	.

a This parameter is set to zero because it is redundant.

Table 13 (a&b)

Illness Representations & Physical Quality of Life

Tests of Between-Subjects Effects

Dependent Variable: Physical Quality of Life

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	9018.469(a)	14	644.176	10.280	.000
Intercept	3867.508	1	3867.508	61.717	.000
Device Type	91.280	2	45.640	.728	.485
AnxDep	6.673	1	6.673	.106	.745
Medication	241.065	1	241.065	3.847	.052
Age	78.058	1	78.058	1.246	.266
MONTHSDEVICE	67.542	1	67.542	1.078	.301
IPQSymptoms	2079.716	1	2079.716	33.188	.000
IPQTime	6.769	1	6.769	.108	.743
IPQTimelinecyclical	195.875	1	195.875	3.126	.079
IPQConsequences	501.955	1	501.955	8.010	.005
IPQPersonalControl	304.556	1	304.556	4.860	.029
IPQDeviceControl	191.163	1	191.163	3.051	.083
IPQIllnessCoherence	.174	1	.174	.003	.958
IPQEmotionalRepresentation	285.126	1	285.126	4.550	.035
Additional healthprobs	181.710	1	181.710	2.944	.089
Error	8021.080	127	61.727		
Total	190636.120	143			
Corrected Total	17039.548	142			

a R Squared = .529 (Adjusted R Squared = .478)

Parameter Estimates

Dependent Variable: Physical Quality of Life

Parameter	B	Std. Error	t	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
Intercept	70.028	8.633	8.112	.000	52.947	87.109
[Device=CRT-D]	1.330	1.955	.680	.498	-2.539	5.198
[Device=CRT-P]	-.713	1.968	-.362	.718	-4.607	3.181
[Device=ICD]	0(a)	.	.	.	.	.
[AnxDep=1.00]	-.551	1.687	-.326	.745	-3.889	2.788
[AnxDep=2.00]	0(a)	.	.	.	.	.
[Medication=1.00]	-3.835	1.956	-1.961	.052	-7.705	.034
[Medication=2.00]	0(a)	.	.	.	.	.
Age	-.087	.078	-1.116	.266	-.241	.067
MONTHSDEVICE	.048	.046	1.038	.301	-.043	.139
IPQSymptoms	-2.279	.396	-5.761	.000	-3.062	-1.496
IPQTime	.070	.213	.329	.743	-.351	.491
IPQTimelinecyclical	-.387	.219	-1.768	.079	-.819	.046
IPQConsequences	-.420	.148	-2.830	.005	-.713	-.126
IPQPersonalControl	-.324	.147	-2.205	.029	-.615	-.033
IPQDeviceControl	-.421	.241	-1.747	.083	-.898	.056
IPQIllnessCoherence	.011	.201	.053	.958	-.388	.409
IPQEmotionalRepresentation	.314	.147	2.133	.035	.023	.606
[Additional healthprobs=1.00]	-2.415	1.407	-1.716	.089	-5.200	.370
[Additional healthprobs=2.00]	0(a)	.	.	.	.	.

Table 14 (a&b)

Illness Representations and Mental Quality of Life

Tests of Between-Subjects Effects

Dependent Variable: Mental Quality of Life

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	9740.775(a)	14	695.770	11.441	.000
Intercept	4904.401	1	4904.401	80.643	.000
Device Type	106.019	2	53.010	.872	.421
AnxDep	277.772	1	277.772	4.567	.034
Medication	787.042	1	787.042	12.941	.000
Age	67.216	1	67.216	1.105	.295
MONTHSDEVICE	21.618	1	21.618	.355	.552
IPQSymptoms	28.420	1	28.420	.467	.495
IPQTime	.268	1	.268	.004	.947
IPQTimelinecyclical	261.536	1	261.536	4.300	.040
IPQConsequences	.250	1	.250	.004	.949
IPQPersonalControl	181.581	1	181.581	2.986	.086
IPQDeviceControl	219.356	1	219.356	3.607	.060
IPQIllnessCoherence	14.618	1	14.618	.240	.625
IPQEmotionalRepresentation	1662.330	1	1662.330	27.334	.000
Additional healthprobs	.987	1	.987	.016	.899
Error	7784.488	127	61.287		
Total	392708.690	143			
Corrected Total	17525.263	142			

a R Squared = .556 (Adjusted R Squared = .507)

Parameter Estimates

Dependent Variable: Mental Quality of Life

Parameter	B	Std. Error	t	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
Intercept	80.801	8.504	9.501	.000	63.974	97.629
[Device=CRT-D]	.782	1.926	.406	.686	-3.029	4.592
[Device=CRT-P]	2.400	1.939	1.238	.218	-1.436	6.237
[Device=ICD]	0(a)	.	.	.	.	.
[AnxDep=1.00]	-3.552	1.662	-2.137	.034	-6.841	-.263
[AnxDep=2.00]	0(a)	.	.	.	.	.
[Medication=1.00]	-6.930	1.926	-3.597	.000	-10.742	-3.118
[Medication=2.00]	0(a)	.	.	.	.	.
Age	-.081	.077	-1.051	.295	-.233	.071
MONTHSDEVICE	-.027	.046	-.596	.552	-.117	.063
IPQSymptoms	-.266	.390	-.684	.495	-1.038	.505
IPQTime	-.014	.210	-.066	.947	-.429	.401
IPQTimelinecyclical	-.447	.215	-2.074	.040	-.873	-.020
IPQConsequences	.009	.146	.064	.949	-.280	.298
IPQPersonalControl	.250	.145	1.728	.086	-.036	.537
IPQDevceControl	-.451	.238	-1.899	.060	-.921	.019
IPQIllnessCoherence	-.097	.198	-.490	.625	-.490	.295
IPQEmotionalRepresentation	-.759	.145	-5.228	.000	-1.046	-.472
[Additional healthprobs=1.00]	.178	1.402	.127	.899	-2.597	2.953
[Additional healthprobs=2.00]	0(a)					

APPENDIX F

IPQ-R CAUSAL SUBSCALE

TABLE A: FREQUENCY OF CRT PARTICIPANTS' PERCEPTIONS OF CAUSE

CAUSAL FACTOR	AGREE	NEUTRAL	DISAGREE
Smoking	20	3	30
Hereditary	19	7	27
Overwork	19	11	23
Ageing	18	11	24
Stress or worry	17	10	26
A germ or virus	15	5	33
Chance or bad luck	13	21	19
My own behaviour	13	6	34
Diet or eating habits	12	7	34
Family problems or worries caused by my heart condition	6	9	38
Pollution in the environment	5	9	39
Accident or injury	4	2	47
Poor medical care in the past	3	5	45
My mental attitude	3	4	46
My emotional state	3	9	41
Alcohol	2	6	45
Altered immunity	2	7	44
My personality	0	4	49

TABLE B: FREQUENCY OF CRT-D PARTICIPANTS' PERCEPTIONS OF CAUSE

CAUSAL FACTOR	AGREE	NEUTRAL	DISAGREE
Smoking	24	2	21
My own behaviour	22	6	19
Stress or worry	21	3	23
Diet or eating habits	20	5	22
Hereditary	19	6	22
Ageing	18	3	26
Overwork	17	4	26
Chance or bad luck	13	9	25
Alcohol	11	3	33
A germ or virus	7	2	38
Pollution in the environment	7	7	33
My mental attitude	7	4	36
My personality	5	3	39
Poor medical care in the past	5	3	39
Family problems or worries caused by my heart condition	5	4	38
My emotional state	5	6	36
Altered immunity	1	7	39
Accident or injury	0	3	44

TABLE C: FREQUENCY OF ICD PARTICIPANTS' PERCEPTIONS OF CAUSE

CAUSAL FACTOR	AGREE	NEUTRAL	DISAGREE
Hereditary	25	4	22
Chance or bad luck	23	2	26
Diet or eating habits	21	8	22
Smoking	21	2	28
Stress or worry	20	7	24
My own behaviour	20	10	21
Overwork	15	12	24
Ageing	14	6	31
Alcohol	8	4	39
My mental attitude	8	10	33
Poor medical care in the past	7	10	34
Family problems or worries caused by my heart condition	6	6	39
My emotional state	6	10	35
My personality	6	5	40
Altered immunity	6	5	40
A germ or virus	4	7	40
Accident or injury	2	3	46

TABLE D: NUMBER ONE CAUSAL FACTOR: CRT PARTICIPANTS

RANK	CAUSAL FACTOR	FREQUENCY (%) N = 53
1	Hereditary	11 (20.8)
2	A Germ	11 (20.8)
3	Smoking	9 (17.0)
4	Stress	7 (13.2)
5	Diet	4 (7.5)
6	Overwork	3 (5.7)
7	Poor medical care	2 (3.8)
8	Ageing	2 (3.8)
9	Accident/injury	2 (3.8)
10	Chance/bad luck	1 (1.9)
11	Reaction to cancer treatment	1 (1.9)

TABLE E: NUMBER ONE CAUSAL FACTOR: CRT-D PARTICIPANTS

RANK	CAUSAL FACTOR	FREQUENCY (%) N = 47
1	Hereditary	10 (21.3)
2	Smoking	8 (17.0)
3	Stress	7 (14.9)
4	A Germ	5 (10.6)
5	Chance/bad luck	5 (10.6)
6	Overwork	4 (8.5)
7	Diet	3 (6.4)
8	Emotional state	1 (2.1)
9	Alcohol	1 (2.1)
10	Lifestyle	1 (2.1)
11	Self abuse	1 (2.1)
12	No idea	1 (2.1)

TABLE F: NUMBER ONE CAUSAL FACTOR: ICD PARTICIPANTS

RANK	CAUSAL FACTOR	FREQUENCY (%) N = 51
1	Hereditary	14 (27.5)
2	Smoking	11 (21.6)
3	Chance/bad luck	6 (11.8)
4	Stress	4 (7.8)
5	A Germ	3 (5.9)
6	Altered immunity	3 (5.9)
7	Overwork	2 (3.9)
8	Diet	2 (3.9)
9	Ageing	2 (3.9)
10	Poor past medical care	1 (2.0)
11	Accident/injury	1 (2.0)
12	Own behaviour	1 (2.0)
13	Pollution	1 (2.0)