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School of Psychology

Development and Evaluation of a Theory-Based Intervention to Promote Heart Failure Self-Management

by

Narinder Kaur Shergill

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ABSTRACT

FACULTY OF MEDICINE, HEALTH AND LIFE SCIENCES
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DEVELOPMENT AND EVALUATION OF A THEORY-BASED INTERVENTION TO PROMOTE HEART FAILURE SELF-MANAGEMENT

By Narinder Kaur Shergill

Previous research has suggested that heart failure patients lack knowledge about their illness and are therefore less able to successfully manage their illness. NICE guidelines for heart failure management emphasise the importance of patients being involved in their care. Previous interventions to implement guidelines or promote heart failure self-management have had variable success, and the absence of a theoretical framework has made it difficult to identify why interventions have proven effective or ineffective in changing behaviour. Working within the framework of the Theory of Planned Behaviour (TPB), this programme of research intended to develop and evaluate a theory-based intervention to implement the 'communication of the management plan' and the 'shared responsibility' guidelines for heart failure management.

A qualitative study (N = 21) was conducted to examine health professionals' views regarding the implementation of the NICE guidelines for heart failure management and the communication of the management plan. Health professionals felt that they had insufficient time to deliver adequate information to patients and were uncertain about what information patients wanted or could cope with. The findings from this study indicated that a written patient intervention might be a suitable way of implementing these guidelines within the context of current service provision.

A theory-based booklet intervention, entitled 'Improving Heart Function' (IHF) was developed. This booklet provided patients with information about their illness and its management. A qualitative study (N = 14) was conducted to elicit patients' salient beliefs about four key self-management behaviours, and to pilot the booklet on intended users. Patients' feedback was then used to improve the booklet and patients' beliefs were targeted to promote a more positive attitude and to increase perceived behavioural control (PBC). Strategies selected from other leading theories of behaviour and behaviour change were also incorporated into the booklet.

A pilot randomised controlled trial (N =94) assessed the effectiveness of the IHF booklet in increasing heart failure patients' knowledge and self-management. This theory-based booklet was found to be more effective in improving knowledge, and initiating change in the mediators of behaviour compared to an atheoretical booklet and no-booklet control. Results showed that the IHF booklet promoted more favourable attitudes and increased PBC for regular physical activity, and produced greater improvements in attitude and intention for regular weighing. Future research should continue to explore and evaluate the utility of social cognitive theories in the development of patient education materials. Written health information that is rigorously developed and evaluated has the potential to be a valuable resource in helping heart failure patients to understand and cope with their illness, and its self-management.

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ABBREVIATIONS

ACE:	Angiotensin-converting enzyme
GP:	General practitioner
IHF:	Improving heart function
MEMS:	Medication event monitoring systems
MRC:	Medical Research Council
NCC-CC:	National Collaborating Centre for Chronic Conditions
NHS:	National Health Service
NICE:	National Institute of Clinical Excellence
PBC:	Perceived behavioural control
PEI:	Patient Enablement Instrument
RCT:	Randomised controlled trial
RNIB:	Royal National Institute of the Blind
TPB:	Theory of Planned Behaviour
TRA:	Theory of Reasoned Action
UK:	United Kingdom

Chapter One: Introduction

1.1 Heart Failure

Heart failure is a term used to describe a clinical syndrome characterised by a variety of signs and symptoms, most of which are non-specific. Heart failure is considered the end stage of all diseases of the heart (Peterson, Rayner, & Wolstenholme, 2002; Remme, Swedberg, & Task Force for the Diagnosis and Treatment of Chronic Heart Failure, 2001). The National Collaborating Centre for Chronic Conditions (NCC-CC) (2003) defines heart failure as: '...a complex syndrome that can result from any structural or functional cardiac disorder that impairs the ability of the heart to function as a pump to support a physiological circulation' (p.3). Heart failure is difficult to diagnose and no definitive test or investigation is available (Remme et al., 2001; Struthers, 2000). Instead clinicians consider a patient's history, their signs and symptoms, and results from appropriate investigations (e.g. electrocardiogram, echocardiography) to establish the presence of this medical condition (Remme et al., 2001; Struthers, 2000).

The causes of heart failure include coronary heart disease (including past myocardial infarction), hypertension, cardiomyopathy, and arrhythmias (Lip, Gibbs, & Beevers, 2000). Heart failure is commonly due to left ventricle failure and has two main forms: systolic (more common) and diastolic. Systolic failure occurs when the left ventricle loses its ability to contract normally and is unable to pump blood back into circulation. Diastolic heart failure arises when the ventricle becomes less compliant (i.e. stiffer) and loses its ability to relax properly; this prevents the heart from filling adequately with blood (Davis, Davies, & Lip, 2006).

In the United Kingdom (UK), the incidence rate of heart failure is estimated at 1.4 per 1,000 for men (aged 25 years and older) and 1.2 per 1,000 for women (aged 25 years and older) (Cowie et al., 1999). Projections using these rates predict that there will be 66,000 new incidences of heart failure each year (Allender, Peto, Scarborough, Boxer, & Raynor, 2006). Heart failure is more common in men, and increases with age from 0.2 per 1000 people per year in the 25 to 34 age group to 11.6 in people aged 85 years and over, with onset mainly occurring later in life (Cowie et al., 1999). Indeed, the median age at diagnosis is 76 years (Cowie et al., 1999). In 2005, just fewer than 10,000 deaths were attributed to heart failure (Office for National Statistics, 2005). However, these figures are likely to be an underestimation, as guidance on death certificates categorises heart failure as a mode and not a cause of death (Peterson et al., 2002). The prognosis for heart failure is poor. The five year survival rate for heart failure is only 25% (Stewart, MacIntyre, Hole, Capewell, & McMurray, 2001). One year survival rates are similar to those for colon cancer and worse than breast, uterus, prostate, and bladder cancer (Peterson et al., 2002). The unpredictable, potentially treatable and reversible episodes of worsening heart failure, and the increased risk of sudden death, makes an estimation of prognosis for this medical condition very difficult (Cowie, 2003).

The responsibility for heart failure management is distributed across primary care, cardiology, geriatrics, and general medicine. Little consistency exists in the management of heart failure in the UK (English & Channer, 1999). This medical condition is largely managed in primary care and accounts for a substantial proportion of NHS expenditure. The total NHS expenditure for heart failure in 1995 was estimated at approximately £716 million (1.8% of total expenditure), with projected estimates for the year 2000 of £905 million (Stewart et al., 2002). The increasing prevalence of heart failure due to the ageing population, and the greater survival of people with other heart problems who may go on to develop this medical condition (Berry, Murdoch, & McMurray, 2001; Department of Health, 2000), will further increase the burden of heart failure on healthcare services and its resources over the following years.

1.2 National Institute of Clinical Excellence Guidelines for Managing Heart Failure

The current focus in the National Health Service (NHS) is on evidence-based practice. Therefore, clinical guidelines, such as those produced by the National Institute of Clinical Excellence (NICE), have been disseminated to encourage clinical effectiveness and thereby improve the quality of healthcare. Clinical guidelines have the potential to improve patient outcomes, promote effective interventions, highlight gaps in service provision and research, and reduce variations in the delivery of healthcare across services and health professionals (Woolf, Grol, Hutchinson, Eccles, & Grimshaw, 1999). The benefits of clinical guidelines to individual health professionals include guidance in uncertainty and confirmation of updated and effective treatments (Woolf et al., 1999). Clinical guidelines can also inform patients about the quality of care and treatment options available, empower patients to make informed choices and improve doctor and patient communication (NICE, 2007; Woolf et al., 1999). Most importantly, guidelines provide a standard against which service delivery and clinical practice can be evaluated.

In July 2003, NICE published guidelines developed by the NCC-CC for the diagnosis and management of heart failure in primary and secondary care. These guidelines consisted of recommendations for establishing a diagnosis of heart failure, pharmacological and non-pharmacological treatments, and supporting patients and carers (NCC-CC, 2003; NICE, 2003a). NICE also published a lay version of the guidelines to provide information to patients, carers and the public (NICE, 2003b).

NICE have identified eight guidelines which are priorities for implementation and essential to provide evidence-based and quality care to patients (see appendix A). This thesis will focus on two key guidelines from those strongly recommended by NICE. The first guideline "The primary care team, patient, and carer must be aware of the management plan" (NICE, 2003a, p.3) emphasises that patients discharged from hospital and professionals within primary care should be fully aware of the management plan. It is not feasible with the resources available to investigate all lines of communication specified by this guideline. Therefore, this thesis will be concentrating on the communication of the management plan to patients. Further guidelines are provided by NICE for good communication and include listening to patients, fulfilling patients information needs, using simple language, tailoring information, providing specific advice, confirming patient understanding and preparing materials (e.g. written/taped) to back up handwritten notes (NICE, 2003a). The second key guideline "Management of heart failure should be seen as a shared responsibility between patient and healthcare professional" (NICE, 2003a, p.3) emphasises the active involvement of the patient in the management of their illness. NICE approve patient understanding as an audit criterion for this guideline and propose that the lay version of the guidelines for patients, carers and the public (NICE, 2003b) should assist in the implementation of this recommendation (see appendix B).

1.3 Why Research the Management of Heart Failure?

NICE guidance has stressed the importance of communicating information about the management plan to patients, and the shared responsibility that must exist between patient and health professional in the management of heart failure. So why is it important to implement these recommendations and promote heart failure management, and why should health psychologists be involved?

Patients have insufficient knowledge to enable successful self-management and report dissatisfaction with information provision. Health professionals design the management plan in concordance with patients. The management plan would detail pharmacological treatments, lifestyle changes and self-monitoring behaviours recommended for the effective management of heart failure. Research suggests, however, that heart failure patients do not feel involved in decision-making, and describe a professionally led model of care (Boyd et al., 2004; Murray et al., 2002). These findings differed from the 'working relationship' described by Holman and Lorig (2000, p.527) that is required between health professional and patient to promote patients management of a chronic illness. In addition, it is repeatedly reported that heart failure patients do not have the knowledge to take responsibility for their care (e.g. Field, Ziebland, McPherson, & Lehman, 2006; Agard, Hermeren, & Herlitz, 2004; Buetow & Coster, 2001; Rogers et al., 2000; Ni et al., 1999). Patients will only benefit from a management plan if health professionals effectively communicate it to them and if patients understand the significance of management behaviours for managing their illness. The literature available indicates that the provision of information to heart failure patients is inadequate (NCC-CC, 2003). Barriers experienced by health professionals in communicating with patients further hinder the effective communication of health information to heart failure patients. In particular, doctors are hesitant to provide information to heart failure patients about their diagnosis and prognosis (Barnes et al., 2006; Murray, Boyd, Sheikh, Thomas, & Higginson, 2004; Hanratty et al., 2002). Previous research has paid very little attention to health professionals' motivation and attitudes to communicating with heart failure patients. Adopting psychological theories to research this area would enable the identification of key processes and theoretical constructs that are important to current patterns of doctor-patient communication. This process could also detect amenable factors that could be effective targets in interventions to promote communication of the management plan to patients.

The management of heart failure by patients and health professionals is sub-optimal. It is widely recognised that the dissemination of clinical guidelines alone does not automatically result in changes to healthcare practice (Oxman, Thomson, Davis, & Haynes, 1995). Evaluations of the implementation of NICE guidance have identified variable changes in clinical practice, with implementation occurring at different rates dependent on the disease and procedures required (Abacus International, 2005; Sheldon et al., 2004). Two large European surveys reported insufficient implementation of guidelines for the management of heart failure, thereby indicating that patients received sub-optimal standards of care (Cleland et al., 2003; Komajda et al., 2003). The recommended pharmacological therapy for heart failure is a combination of angiotensin-converting enzyme (ACE) inhibitors, beta blockers and diuretics; only 17% of patients within Europe received this combination (Komajda et al., 2003). Ideally, the best available evidence should inform treatments: however, multiple and complex barriers often exist to the delivery of evidence-based practice. This gap between guideline recommendations and clinicians' behaviour raises interesting questions. Health psychology models could be utilised to facilitate a greater understanding of the motivational factors that underlie clinical practice.

The management of a chronic illness is life-long and requires the active involvement of the patient (Holman & Lorig, 2000). The literature for heart failure reports that patients do not effectively manage their illness (van der Wal, Jaarsma & van Veldhuisen., 2005). Patients' inability to self-manage has been identified as a cause of worsening heart failure. Indeed, a review of previous research estimated that 21% to 64% of heart failure exacerbations were a direct result of patient non-adherence (van der Wal, Jaarsma & van Veldhuisen., 2005). To prevent avoidable exacerbations in heart failure, improve patients' quality of life, and reduce the burden on healthcare services, the effective management of heart failure is of primary importance. This can only be achieved if patients implement the necessary behavioural changes required to successfully self-manage their illness. Health psychology models of behaviour change identify amendable factors, predictive of behaviour, which could be effectively targeted by interventions to promote heart failure self-management.

Interventions to implement clinical guidelines or improve heart failure patients' self-management lack a sufficient evidence base. Implementation interventions are developed to promote evidence-based practice. Interventions such as educational efforts, audit and feedback, reminders and patient interventions, have produced modest to moderate improvements in implementing guidelines (Grimshaw et al., 2004). However, no interventions have been identified which are consistently effective at changing clinical behaviour in all settings and circumstances (Oxman et al., 1995). Interventions designed to influence self-management in heart failure patients have demonstrated the potential to reduce hospitalisations, improve self-care activities and increase survival (e.g. McAlister, Stewart, Ferrua, & McMurray, 2004; Holland et al., 2005). Despite these findings very little is known about the mechanisms underlying the effectiveness of interventions. It is assumed that behaviour change has occurred for the improvements in the desired outcomes (e.g. survival, mortality, implementation of guidelines) to be observed. However, what accounted for these changes is unknown. Questions are being raised about the lack of information that implementation interventions and heart failure interventions provide about how they influence behaviour (see Molloy, 2005; Grimshaw et al., 2004). This lack of insight has been attributed to the atheoretical nature of previous research resulting in very little understanding about how interventions function, and the mechanisms by which intervention outcomes are achieved or not achieved. As a consequence very little is learnt from previous research that can inform future research.

In recent years, there has been an increasing focus on the theoretical basis of interventions designed to produce behaviour change. The UK Medical Research Council (MRC) recommends the establishment of a theoretical basis in the development and evaluation of complex interventions (MRC, 2000). Health psychologists have at their disposal a range of theoretical models to draw upon, which identify modifiable factors that influence behaviour and could be targeted in interventions. The development of interventions targeting known predictors of behaviour may improve the ability of these approaches to stimulate behaviour change. Similarly, the adoption of a theoretical evaluation to assess the effectiveness of interventions is important. This would provide a much needed insight into the reasons why change has, or has not, been achieved (e.g. Walker et al., 2003; The Improved Clinical Effectiveness through Behavioural Research Group (ICEBeRG), 2006; Bonetti et al., 2003; Grimshaw, Eccles, Walker, & Thomas, 2002; Michie et al., 2005). To generate understanding which will inform subsequent research, there is a need to develop theory informed interventions and/or conduct theory informed evaluations, to gain insights into how interventions have their effects on behaviour.

1.4 Outline of the Thesis

The programme of research presented in this thesis intended to develop and evaluate a theory-based intervention to implement the 'communicating the management plan' and 'shared responsibility' guidelines for heart failure. This thesis initially set out to develop an intervention to change health professional behaviour, but findings from the first study suggested that patient intervention would be more useful and feasible. Therefore, research pertaining to both health professional behaviour and heart failure patients' self-management is reviewed.

The existing literature on the effectiveness of interventions to promote health professional behaviour change is discussed in chapter 2. The literature shows that interventions to change clinical behaviour have had variable success, and a multitude of barriers may potentially influence the implementation of evidence-based practice. Chapter 3 reviews literature suggesting that heart failure patients lack understanding and do not self-manage their illness adequately. This chapter also outlines commonly used methods to provide information to patients, and shows that written and computerised approaches can facilitate patients' comprehension and retention of health information. Interventions to promote self-management are reviewed, and have demonstrated some success in improving survival, thus reducing hospitalisations or increasing self-management. However, a notable shortcoming of previous research in both of the research areas above is the absence of a theoretical framework, which makes it difficult to identify the reasons for positive or negative outcomes.

Chapter 4 presents the Theory of Planned Behaviour, which is the main theoretical framework employed throughout this research programme. In the first part of this chapter, it is argued that this model should prove useful for gaining further understanding of health professionals' behaviour in relation to the NICE guidelines for heart failure management. This chapter also discusses the application of the TPB to behaviour change interventions, and in particular reviews studies which have utilised this model in the development of written interventions. Chapter 5 presents the methodology utilised in the empirical studies of this thesis. It is argued that both qualitative and quantitative methods are required to plan, develop, and evaluate the intervention in this research programme.

In Chapter 6 a qualitative study is presented, which seeks to identify the factors influencing health professionals' management of heart failure, in particular concerning the guideline 'communicating the management plan to patients'. Thematic analysis indicated that health professionals believed that they had insufficient time to communicate information to patients, and were at times unsure about what information patients wanted or could cope with. Health professionals stressed the importance of a partnership with patients in the management of heart failure, and recommended written patient interventions as a suitable approach within current service provision to communicate information about the management plan to patients. This stage was used to inform the development of the written intervention in this research programme.

Chapter 7 describes the development of a theory-based booklet to implement the communication of the management plan and shared responsibility guidelines. This booklet was developed by drawing upon health psychology models and previous literature relating to heart failure self-management. A qualitative study was conducted with heart failure patients, to elicit their salient beliefs about self-management and to ascertain whether the booklet was acceptable and useful to patients. The booklet was then modified to target the salient beliefs underlying self-management behaviour and the patient feedback was incorporated to improve the booklet. A pilot evaluation of a knowledge scale, to measure knowledge about heart failure, was also presented.

Chapter 8 presents the major quantitative study, which evaluated the theory-based booklet in a pilot randomised controlled trial (RCT), in comparison with an atheoretical booklet and a no-booklet control group. The primary outcome was knowledge, as this outcome was recommended by NICE to evaluate the implementation of the shared responsibility guideline. Secondary outcomes included enablement, self-management behaviour and the mediators of behaviour change identified by the TPB. This study found that the theory-based booklet was more effective in improving knowledge and initiating change in the mediators of behaviour, compared to the NICE booklet and control group. The limitations of this study included an insufficient sample size, the use of self-report measures, and a short-term follow-up.

Chapter 9 provides a summary of the findings of the empirical studies in this thesis. The strengths, limitations, and implications of this research programme are discussed. This chapter proposes that this thesis has made a substantial contribution to the under-researched area of theory informed written interventions, and the use of such interventions for promoting knowledge and self-management in heart failure patients. This thesis suggests that written interventions, informed by psychological models of behaviour change, offer advantages beyond those delivered by atheoretical interventions. Furthermore, considerable insights were gained by the utilisation of a theory-based evaluation to assess the effectiveness of the booklets. This evaluation enabled a greater understanding of the changes these booklets promoted in the psychological mediators of behaviour change.

Chapter Two: The Effectiveness of Interventions for Behaviour Change in Health Professionals

2.1 Introduction

The successful implementation of clinical guidelines developed by the NICE would produce ample benefits to the NHS. This would ensure the delivery of high quality health care, and keep health professionals updated on the most evidence-based and effective health care practices and interventions (Centre for Reviews and Dissemination, 1999; Oxman, Thomson, Davis, & Haynes, 1995; Grimshaw et al., 1995). However, it is well established that medical practice often departs from guideline recommendations resulting in patients not receiving optimal treatment- as proven by medical research. A report investigating the implementation of NICE guidelines in 28 distinct disease areas concluded that 'NICE guidance is driving change but at different rates for different disease areas' (Abacus International, 2005, p. 39). It appears that, for some guidelines, additional efforts are required to ensure their successful implementation. The dissemination of clinical guidelines alone is unlikely to produce clinical behaviour change (e.g. Lomas, 1991; Oxman et al., 1995; Bero et al., 1998; Davis, Thomson, Oxman, & Haynes, 1995), and even well resourced national guidelines may be unsuccessful in reaching relevant health professional groups (e.g. Rix et al., 1999; Petrie, Grimshaw, & Bryson, 1995; Oxman et al., 1995).

A number of interventions are potentially available for implementing the communication of the management plan and shared responsibility guidelines for heart failure. The aim of this chapter is to provide an overview of the effectiveness of frequently employed interventions adopted to promote health professional behaviour change and the implementation of clinical guidelines. These findings will assist in deciding the implementation strategy that will be developed in this research programme to implement the NICE guidelines for heart failure management.

Research findings for implementation strategies are a substantive literature, and vary considerably, making it difficult to discern the most effective interventions. Reviewing and evaluating all the literature would be beyond the scope of this research programme. Therefore, conclusions about the effectiveness of implementation approaches will be reached by consulting research syntheses of rigorous studies, such as meta-analyses and systematic reviews. Interventions that applied purely administrative changes, incentives, coercion (e.g. financial rewards or sanctions), or the use of complex computer systems are not evaluated as these can only be developed and implemented by policy makers and would be unfeasible in this study.

The reasons why clinical guidelines are not routinely adopted into clinical practice are often complex. This chapter will summarise the various factors that may hinder or promote health professional behaviour change and, when available, literature relevant to the management of heart failure will be reviewed. This chapter outlines the key barriers and facilitators in relation to the individual health professional, the social context of healthcare and organisational factors in the healthcare setting.

2.2 Implementation Interventions

2.2.1 Educational Interventions

Educational interventions are described as 'any attempt to persuade physicians to modify their practice performance by communicating clinical information' (Davis et al., 1995, p. 701). Educational interventions can incorporate a range of approaches, including written materials, lectures, presentations, conferences, interactive workshops (including role play, case discussions or opportunity to practice skills), and seminars.

2.2.1.1 Educational materials.

Educational materials include published or printed clinical care recommendations, and audiovisual or electronic materials. In comparison to a non-intervention control, educational materials resulted in only modest or short-term effects on guideline implementation (Grimshaw et al., 2004). An earlier systematic review reported that educational materials alone failed to produce any improvements in professional performance or health outcomes (Oxman et al., 1995). This inability of information alone to stimulate health professional behaviour change may be explained by findings in the health psychology literature which indicate that knowledge alone is insufficient to produce changes in behaviour (Ajzen & Fishbein, 1980). However, the findings presented should be judged cautiously, as the research evidence for educational materials has tended to be 'sparse and of low quality' (Grimshaw et al., 2004, p.19)

2.2.1.2 Didactic or interactive interventions.

A comprehensive systematic review by Thomson O'Brien et al (2001) identified 32 studies evaluating educational interventions. These were analysed separately as didactic or interactive. Didactic interventions are predominantly lectures or presentations and interactive interventions are group based sessions that involve interactive elements such as role plays and case discussion (Thomson O'Brien et al., 2001). In comparison to a non-intervention control or group based/lecture intervention, interactive workshops delivered moderate or moderately large improvements, in clinical practice. Similar findings were also reported for approaches that combined interactive workshops with didactic presentations. In contrast, didactic presentations alone were generally ineffective in promoting changes in professional or health outcomes. These findings suggest that passive educational interventions are unlikely to facilitate change in clinical behaviour. Nonetheless, interventions such as didactic presentations may prove useful, when barriers to performing a recommended clinical behaviour include health professionals' lack of knowledge. In these circumstances, educational methods would enable the dissemination of relevant information (Feder, Eccles, Grol, Griffiths, & Grimshaw, 1999).

Systematic reviews have identified several methodological problems with educational interventions. The development of interventions rarely involves the target group, even when attempting to change very complex professional behaviours (Thomson O'Brien et al., 2001). This may be particularly important as findings suggest that conferences and workshops that failed to determine the needs of the target group or healthcare setting were less successful in promoting behaviour change (Oxman et al., 1995). Moreover, the majority of studies only delivered brief educational interventions and evaluation was usually short-term. These shortcomings have provided very little insight into the length of intervention likely to produce greater clinical behaviour change and the expected duration of effects, following the delivery of an intervention (Thomson O'Brien et al., 2001). Key primary and secondary care informants judged educational meetings and lectures as very feasible interventions (Grimshaw et al., 2004). Identifying key speakers, however, may be problematic, and when the target group comprises primary care professionals, the financial implications of locum fees to release general practitioners (GPs) to attend the intervention also need to be considered (Grimshaw et al., 2004).

2.2.1.3 Academic detailing/educational outreach visits.

Academic detailing/outreach visits comprise a personal visit within a healthcare setting by an outside expert who provides information with the intent of changing health professionals' practice. These sessions are normally interactive and may involve a discussion about factors that may hinder the proposed change. Expert clinicians, nurse facilitators, pharmacists, study investigators, or patients are usually employed to deliver this intervention.

Educational outreach has proven particularly effective in improving prescribing decisions (Davis et al., 1995; Soumerai & Avorn, 1990; Thomson O'Brien et al., 2000; Oxman et al., 1995), and in the provision of preventative services (Oxman et al., 1995). These interventions have reduced inappropriate prescriptions by 12% to 49% (Oxman et al., 1995) and produced a relative improvement in prescribing behaviour of 24% to 50% (Thomson O'Brien et al., 2000). Small increases of 5% to 27% were also reported in the delivery of 10 preventative services (Dietrich et al., 1992). Outreach visits are more effective when combined with other complementary interventions such as reminders, and audit and feedback; these multifaceted interventions have demonstrated a 15% to 68% relative improvement in outcomes (Thomson O'Brien et al, 2000).

In relation to the implementation of clinical guidelines, educational outreach is usually adopted in multifaceted interventions; a comprehensive systematic review reported that multiple strategies which include educational outreach may produce modest effects on guideline implementation (Grimshaw et al., 2004). Outreach interventions vary considerably, delivering anything from a single visit to weekly visits for several months (Thomson O'Brien, 2000). Therefore, it is still unclear how many outreach visits are required to achieve optimal professional behaviour change. The majority of studies also incorporated a very short follow-up period, making it difficult to determine when, whether, and how, a change in performance deteriorates over time (Thomson O'Brien et al, 2000). Research suggests that this intervention is likely to be expensive, since its implementation may involve the employment of additional health professionals, or include the fees for qualified professionals to deliver the intervention. However, educational outreach removes the need to consider locum fees to release GPs, since the intervention is delivered to primary care health professionals within their health care setting (Grimshaw et al., 2004).

2.2.2 Local Opinion Leaders

Health professionals do not work in isolation. Practitioners often report that they rely on discussions with colleagues to gain information (Hayward, Guyatt, Moore, McKibbon, & Carter, 1997; Greer, 1988). It is, therefore, likely that the opinions and knowledge of 'others' within significant reference groups can influence clinical behaviour. This potential influence of 'significant others' is incorporated by interventions using local opinion leaders and is derived from principles of social influence theory. Local opinion leaders are medical practitioners who are considered by their colleagues as 'educationally influential' (Oxman et al., 1995, p.1424). These influential peers are sought for their advice and knowledge, and colleagues model their own clinical behaviour after them (Wenrich, Mann, Morris, & Reilly, 1971). Local opinion leaders model appropriate behaviour in accordance with guideline recommendations, leading to the creation and distribution of norms for the desired clinical behaviour.

Opinion leader interventions have demonstrated variable effectiveness in influencing clinical behaviour with results ranging from non-significant to a very substantial effect (Thomson O'Brien et al., 1999; Oxman et al., 1995). Uncertainty about the overall effectiveness of local opinion leaders can be partly attributed to the relatively few good quality controlled studies evaluating this intervention; extensive systematic reviews have been unable to identify any rigorous clinical studies which compared local opinion leaders with a non-intervention control (Grimshaw et al., 2004; Thomson O'Brien et al., 1999). However, two studies reported that local opinion leaders were more effective in increasing vaginal births after prior caesarean sections, and improving care for patients after myocardial infarctions, compared to audit and feedback (Thomson O'Brien et al., 1999). Studies incorporating this intervention vary substantially in the activities that are assigned to local opinion leaders, making it difficult to identify the components that increase the effectiveness of this intervention (Thomson O'Brien et al., 1999). The literature available is unable to provide insights into how local opinion leaders influence others, or what traits a local opinion leader must possess to successfully influence and produce changes in others (Thomson O'Brien et al., 1999). Moreover, key primary and secondary care informants suggest that suitable local opinion leaders may not always be present within the health care setting (Grimshaw et al., 2004).

2.2.3 Reminder Systems

Reminders prompt clinicians to perform or avoid a particular behaviour and may consist of information they already know or would be expected to know. Feder and colleagues (1999) suggest that this approach may be more useful when practitioners have problems processing information in consultations. A systematic review by Grimshaw and colleagues (2004) identified 38 studies that evaluated the effects of reminders against a non-intervention/usual care group control in implementing clinical guidelines. This review reported that reminders may have a moderate effect on guideline implementation. These findings have received support from Davis et al. (1995) who found that reminders stimulated change in 22 out of 26 interventions. Reminder systems have been more readily employed to implement guidelines aimed at improving preventative services, or the general management of health problems (Grimshaw et al., 2004). The adoption of this intervention relies exclusively on whether a suitable information technology system exists within the healthcare setting; the manual implementation of reminders substantially increases time and administration, thereby reducing its feasibility (Grimshaw et al., 2004).

2.2.4 Audit and Feedback

Audit and feedback has been defined as a summary of clinical performance over a specific period of time (Jamtvedt, Young, Kristoffersen, Thomson O'Brien, & Oxman, 2003). This intervention enables clinicians to identify discrepancies between their performance and that of others, or in comparison to guideline recommendations. It is proposed that this difference motivates health professionals to change their clinical practice to be more consistent with recommended practice (Jamtvedt et al., 2003). Grimshaw and colleagues (2004) identified 10 rigorous studies evaluating the effects of audit and feedback upon the implementation of guideline recommendations, compared to a non-intervention control. The most common behaviours targeted for change were preventive services, test ordering, general management, and discharge planning. All the audit and feedback interventions produced improvements in care, with the effects reported to be modest (Grimshaw et al., 2004). Other systematic reviews have also produced similar findings, and concluded that audit and feedback alone can be as effective in producing clinical behaviour change as multifaceted interventions (Jamtvedt et al., 2003).

Insights into the features of audit and feedback which can improve effectiveness can be found in the literature. Audit and feedback is more effective in producing desired behaviour change when it incorporates specific recommendations (Anderson & Lexchin, 1996) and is presented close to the time of decision-making (Mugford, Banfield, & O'Hanlon, 1991). The effectiveness of audit and feedback is improved if the tasks being targeted are associated with moderate to low motivation (Palmer et al., 1985). This perhaps indicates that audit and feedback is superfluous in highly motivated clinicians (Jamtvedt et al., 2003), or that other barriers exist which prevent motivated clinicians from performing the desired behaviour (Palmer et al., 1985). Moreover, clinicians' perceptions and motivations can also influence the effectiveness of audit and feedback. If GPs disagree with guidelines then even data indicating that clinical practice could be improved cannot initiate change (Marshall, Mead, Jones, Kaba, & Tovey, 2002). As outlined in previous interventions, the literature is unable to explain when, whether, or how a change in professional practice deteriorates over time once audit and feedback is removed, as only a fifth of studies incorporated a follow-up period (Jamtvedt et al., 2003). The delivery of this intervention is more manageable if a suitable information technology system fulfills some or all of the audit and feedback requirements. However, when data abstraction is required from manual records then the resource implications, in terms of people and time, intensify, thereby reducing its feasibility (Grimshaw et al., 2004).

2.2.5 Patient Interventions

Patient interventions to implement guidelines vary from those that prompt patients to influence health professional behaviour to those that intend to change the knowledge or behaviour of patients. The emergence of lay guidelines, such as the shared responsibility guideline for heart failure, recognises the benefits of evidence-based information for patient decision-making and the influential role of the patient in facilitating evidence-based practice (Howitt & Armstrong, 1999; Woolf, Grol et al., 1999; Coulter, 1997).

Patient interventions such as invitation letters, mailed reminders, phone calls, or written information can be used to encourage patients to schedule an appointment, keep appointments, prompt physicians to perform a due test, and improve patients' knowledge or adherence (Snell & Buck, 1996). Patient interventions have improved the provision of preventive care (Davis et al., 1995) and have been adopted to encourage female patients to share responsibility for their own preventative care (Dickey & Petitti, 1992). Wagner (1998) found that the provision of direct education to patients increased the likelihood of women receiving a mammogram by 50%.

A meta-analysis of patient interventions reported that they were as successful as physician interventions in increasing adherence with established cancer screening guidelines (Snell & Buck, 1996). This meta-analysis also discovered that when interventions targeted both the patient and the physician, or when the number of interventions targeted at the patient increased, then the effect of the interventions on screening behaviour decreased. The authors suggest that patients may perceive multiple interventions as bothersome and, therefore, may respond negatively to such approaches. However, in contrast, Oxman and colleagues (1995) observed greater improvements in professional practice when patient education was combined with physician education. With regard to the implementation of clinical guidelines, Grimshaw et al. (2004) reported that patient interventions produced moderate to large effects. All seven patient mediated interventions identified in this review successfully implemented guidelines regarding preventative services and the general management of illness. The findings for patient interventions are promising, however, the evidence base for patient directed interventions is sparse, and future research is needed to discern the effectiveness of these interventions more accurately.

2.2.6 Multifaceted Interventions

Multifaceted interventions are when two or more single implementation interventions are combined to promote a change in clinical practice. Multifaceted interventions are expensive and resource-intensive (Wensing, van der Weijden, & Grol, 1998). However, the evidence suggests that they are more likely to be effective in stimulating health professional behaviour change than single interventions (Davis et al., 1995; Bero et al., 1998; Wensing et al., 1998). Davis and colleagues (1995) reported that 64% of interventions that combined two strategies and 79% of interventions incorporating more than two strategies produced positive changes in professional behaviour and, in some instances, in health care outcomes. The authors also report that multifaceted interventions combining more effective single strategies (e.g. patient-mediated, reminders, outreach visits) were more likely to produce positive results than interventions combining less effective single approaches (e.g. continuing medical education, educational materials). The increased effectiveness of multifaceted interventions has been attributed to the cumulative effect of using multiple methods (Oxman et al., 1995); however, effectiveness does not increase incrementally with the number of components (Grimshaw et al., 2004). The number of strategies required to maximise the effectiveness of an intervention is unclear. The findings above, however, have been disconfirmed by more recent reviews which present evidence suggesting that multifaceted interventions are not more effective than single interventions in changing health professional behaviour (Grimshaw et al., 2004; Grimshaw et al., 2002). Perhaps these contradictory findings reflect the difficulty in interpreting and synthesising the results of interventions comprising different components. Grimshaw and colleagues (2004) identified only 11 multifaceted interventions, out of a total of 137, which evaluated the same combination of strategies within an intervention. This lack of uniformity in the literature hinders the formation of firm conclusions about the effectiveness of interventions which combine different strategies.

2.3 Factors that Facilitate or Inhibit the Implementation of Guidelines

There are numerous internal and external factors that might influence clinical behaviour, and these elements may facilitate or impede change in accordance with guideline recommendations. Obstacles to change within the NHS may include the behaviour of individual health professionals, the conduct of clinical groups (e.g. primary healthcare teams), the structure of larger health organisations (e.g. NHS trusts) or involve the NHS as a whole. Research suggests that even well-trained, confident and motivated practitioners may be prevented from adhering with guidelines when confronted with barriers such as time limitations and patient requests (Cabana et al., 1999). Furthermore, implementation interventions may not succeed in changing clinical behaviour purely because guideline implementers lack understanding about the target group, healthcare setting, and barriers to change (Grol, 1997). Therefore, it is advised that barriers to change are routinely assessed prior to developing interventions (Wensing & Grol, 1994).

Interventions based on an assessment of potential barriers are more likely to be effective in producing clinical behaviour change (Centre for Reviews and Dissemination, 1999; Oxman et al., 1995). The effectiveness of multifaceted interventions may be partly explained by the ability of multiple methods to address a variety of barriers to change.

Nonetheless, some attempts at tailored interventions have been unsuccessful. For instance, a study conducted in Norway delivered an intensive multifaceted intervention specifically designed to address barriers to change in implementing sore throat and urinary tract infection guidelines. However, despite incorporating patient educational materials, computer-based decision support, telephone consultations and interactive courses for health professionals, no changes in the main outcomes were achieved (Flottorp, Havelsrud, & Oxman, 2003). Subsequent process evaluations indicated that the failure of the intervention was associated with lack of time and resources. This disparity in the findings for interventions based on an assessment of barriers could be attributed to the variation in factors inhibiting or facilitating behaviour according to the targeted behaviour, potential participants, and healthcare setting. The potential influence of barriers upon the success of an intervention has led some researchers to endorse the view that intervention studies should report baseline barriers to the proposed behaviour change, just as clinical trials report baseline patient co-morbidities (Cabana et al., 1999). The barriers related to the individual practitioner, social context of healthcare, and organisational environment will now be discussed.

2.3.1 Barriers Related to the Individual Practitioner

The literature has identified a diverse range of reasons reported by health professionals for not practising according to guidelines or evidence-based recommendations. These include perceived shortcomings in knowledge, lack of previous experience and skills, stress, tiredness, and lack of motivation (Tomlin, Humphrey, & Rogers, 1999). Furthermore, fatigue and time pressures may result in health professionals missing opportunities to deliver evidence-based practice (Summerskill & Pope, 2002). Clinicians also refer to oversight and forgetfulness as reasons for departing from best practice (Mottur-Pilson, Snow, & Bartlett, 2001). For example, lack of knowledge, poor communication skills, difficulty conveying information to patients, and pressure of work were reasons provided by GPs who deviated from a guideline recommending the use of risk tables to support the management of patients without established cardiovascular disease (van Steenkiste, van der Weijden, Stoffers, & Grol, 2004). Health professionals may also make a conscious decision not to follow best practice, particularly when patients are perceived to have other more pressing health problems, or when recommendations are not deemed suitable due to the advanced age or disease progression in patients (Mottur-Pilson et al., 2001). The delivery of evidence-based practice is further complicated when patients present with more than one type of illness. In these circumstances, GPs reported having to prioritise the management needs of the patient and, therefore, were unable to comply with evidence-based practice for all the problems presented (Tomlin et al., 1999). In relation to heart failure, GPs conveyed a lack of confidence in initiating ACE inhibitor medication in patients, particularly when past experiences with this medication included adverse patient experiences (Khunti, Hearnshaw, Baker, & Grimshaw, 2002). The under utilisation of echocardiograms by GPs has been related to their lack of understanding and confidence in establishing a diagnosis of heart failure when using this investigation (Fuat, Hungin, & Murphy, 2003).

Some of the reasons mentioned above for not implementing guideline recommendations fit into the 'professional perception model' developed by Cabana and colleagues (1999). This review of 76 studies categorised barriers into three domains, two of which involved the individual practitioner: physician knowledge (e.g. lack of awareness, lack of familiarity, or oversight) and physician attitudes (e.g. lack of agreement, lack of self-efficacy, lack of outcome expectancy). This review also identified self-efficacy and outcome expectancies as barriers to implementing guidelines. Self efficacy refers to the belief that one can actually perform a behaviour, and outcome expectancy is the expectation that a given behaviour will lead to a particular consequence (Bandura, 1986). Interestingly, poor self efficacy and negative outcome expectancies were more likely barriers in the implementation of guidelines involving preventive health education and counselling (Cabana et al, 1999). Perhaps this indicates that these barriers may be more common in adherence to such guidelines.

2.3.2 External Factors Related to the Social Context of Healthcare

Since health professionals do not work entirely in isolation, their interactions with other staff and patients may have a powerful influence on their decisions to follow guideline recommendations. The influence of peers and patients on evidence-based practice is discussed further below.

2.3.2.1 Influence of colleagues and outside agencies.

Within the literature, fellow colleagues have been referred to as sources of information (Tomlin et al., 1999), with personal contact valued over written resources (Fairhurst & Huby, 1998; Tomlin et al., 1999). As discussed earlier, in local opinion leader interventions, respected colleagues can potentially promote clinical behaviour change in others (Armstrong, Reyburn, & Jones, 1996). Medical training, anecdotal experiences, and outside agencies (e.g. health authorities, primary care trusts, pharmaceutical industry) have also been mentioned as influences on individual clinicians' behaviour and professional culture (Fuat et al., 2003).

2.3.2.2 Patient related factors.

Patient related factors have been found to influence clinical decision-making. Patient consent to accept treatment offered by practitioners has been considered the third level of implementation, and the absence of this can limit the delivery of evidence-based practice (Howitt & Armstrong, 1999). Indeed, GPs' hesitation in applying evidence in specific areas has been attributed to patients' unwillingness to accept medication (Howitt & Armstrong, 1999). Furthermore, patients' failure to modify lifestyle or non-attendance at appointments can limit the application of best practice.

The doctor-patient relationship plays a pivotal role in the implementation of clinical guidelines. GPs reported that their relationship with patients acted as a barrier to providing secondary prevention (Summerskill & Pope, 2002). GPs were concerned about the adverse effects of possible new treatments on their relationship with patients, and were reluctant to change medication if patients' symptoms were well controlled by existing medication (Marshall, Mead et al., 2002). GPs also revealed that treatments of doubtful effectiveness may be prescribed if they experienced an emotional response to a patient, such as sympathy (Tomlin et al., 1999). GPs provided examples of patients demanding antibiotics, requesting investigations or wanting inappropriate referrals, which suggested that on occasions there may be a clash between a patient's background, beliefs, attitudes, and clinical recommendations (Tomlin et al., 1999; Veldhuis, Wigersma, & Okkes, 1998). When these situations arise, the GP, in an attempt to maintain a good relationship with the patient, might depart from evidence-based practice. This suggests that perhaps maintaining a good doctor-patient relationship might be more important to GPs than staying within the bounds of a 'statistically defined consensus on clinical effectiveness' (Tomlin et al., 1999, p.1534). It is possible, as suggested by James, Cowan, and Graham (1998) that the departure of practitioners from clinical guidelines may reflect the attention they give to patient care goals as opposed to clinical goals. In heart failure management, GPs have reported that at times they are hesitant to refer ill patients suspected of having heart failure for an echocardiography, because of the difficulty patients encounter in attending appointments (Fuat et al., 2003). It is likely that patient related factors will be particularly important in relation to the communication of the management plan and shared responsibility guidelines, as both require the cooperation of the patient for effective heart failure management.

2.3.3 Barriers Related to the Organisational Environment

Organisational barriers are beyond the control of an individual practitioner and can restrict any attempt to practice according to evidence-based practice. Lack of time is consistently mentioned as a barrier to implementing guidelines and can result in ineffectiveness across all areas. Practitioners reported not having the time to input or retrieve information (Langley, Faulkner, Watkins, Gray, & Harvey, 1998), to critically review information (Fairhurst & Huby, 1998), and to access information during consultations (Langley et al., 1998). Furthermore, physicians were significantly less likely to recommend a mammography to patients when they ran behind schedule and had less time (Hamblin, 1991). In the management of heart failure, GPs' perceived insufficient time to deal with patients suspected of having heart failure (Khunti et al., 2002; Fuat et al., 2003). In addition, the increasing clinical and administrative duties of GPs acted as a barrier to the optimal management of heart failure (Fuat et al., 2003) and the unavailability of diagnostic tests, such as echocardiograms, prevented GPs from practicing according to evidence-based recommendations (Khunti et al., 2002; Fuat et al., 2003).

The reaction of an organisation to a proposed change can influence the response of individuals within the organisation. Andersen (2002) found that when an organisation provided insufficient training for a new system then physicians viewed the desired behaviour change as a 'low priority'. In addition, an organisation perceived by GPs as 'inward looking' was unlikely to facilitate change (Andersen, 2002). Research suggests that organisations which already had a culture of guideline use resulted in greater clinical behaviour changes (Marshall, Sheaff, et al., 2002). The evidence indicates that, even when practitioners may be motivated to change, an organisational culture that does not facilitate this will not successfully promote evidence-based practice (Grol & Grimshaw, 2003).

2.4 Chapter Summary

The literature presented suggests that there is no single intervention that is consistently effective at changing clinical behaviour in all settings and circumstances. A comprehensive evaluation of the effectiveness of various interventions in implementing clinical guidelines and research findings can be found in two influential reviews (Grimshaw et al., 2004; Bero et al., 1998) (see tables 1 and 2).

The majority of interventions for implementing guidelines result in modest to moderate effects (Grimshaw et al., 2004). The evidence suggests that passive intervention methods (e.g. didactic educational meetings, educational materials) result in little or no effect on clinical behaviour. The literature on interventions such as reminders, interactive educational meetings, and educational outreach appears more convincing and provides evidence for their potential to influence health professional behaviour. The evidence for reminders is more substantial compared to alternative approaches, and research suggests that this method generally produces moderate improvements in the process of care. Research evidence for the effectiveness of interventions such as educational materials, audit and feedback, local opinion leaders, and patient directed interventions is lacking (Grimshaw et al., 2004). It is important to note, however, that the findings for patient interventions do appear promising.

Table 1. *The effectiveness of guideline implementation interventions (Grimshaw et al, 2004)*

Small effects	Modest effects	Moderate effects	Large effects
Educational meetings	Educational materials	Reminders	
	Audit and feedback	Patient directed interventions	
Multifaceted interventions depending on components			
e.g. educational materials and educational meetings	e.g. educational materials and audit and feedback	e.g. reminders and patient directed interventions	

Table 2. *The effectiveness of interventions to promote health professional behaviour change*
(Bero et al, 1998)

Little or no effect	Variable effectiveness	Consistently effective interventions
Educational materials	Audit and feedback	Educational outreach visits
Didactic educational meetings	Local opinion leaders	Reminders
	Patient mediated interventions	Interactive educational meetings
		Multifaceted interventions

Although earlier reviews suggested that multifaceted interventions are more effective (Davis et al., 1995; Bero et al., 1998; Wensing et al., 1998), this has been disconfirmed by a more recent comprehensive review on guideline implementation (Grimshaw et al., 2004). Grimshaw and colleagues (2004) concluded that multifaceted interventions typically resulted in small to moderate effects depending on the components within the intervention, and single methods alone could also achieve this level of effectiveness. This is a very pertinent finding, as it indicates that single methods which require less resources and finances could be as effective in promoting behaviour change as multifaceted interventions which require substantial resources for their delivery.

Consideration must also be given to the factors that may have influenced the reliability of the findings. The heterogeneity within this field, in regards to the components of interventions, targeted behaviours, and study settings, makes it increasingly difficult to discern the effectiveness of interventions (Bonetti et al., 2005). Furthermore, studies identified as successful in producing changes in behaviour may have only produced positive results in one or two of several possible outcomes (Davis et al., 1995), which may, in turn, exaggerate the likely effectiveness of interventions. The applicability of findings from different healthcare contexts must also be assessed. The majority of studies in an extensive systematic review by Grimshaw and colleagues (2004) on interventions for implementing guidelines were conducted within the USA, therefore it is questionable whether the results of this review would be applicable to the NHS setting in the UK.

At present there are substantial gaps within the literature. The non-existent or short-term follow-up of interventions has resulted in very little understanding of when, whether, and how performance deteriorates over time. Thus, for the majority of interventions it is difficult to determine whether improvements observed are sustained for short or long periods of time. In some interventions, evidence has emerged of the components that may increase effectiveness. For example, including interactive components within an educational intervention, or presenting audit information close to the time of decision-making, can increase the effectiveness of these interventions. Nonetheless, this type of insight is very rare. The inconsistencies, within similar interventions, hinder the accumulation of evidence that will enable identification of elements within an intervention that are consistently effective, or ineffective.

The barriers to change highlighted the complexity of changing health professional behaviour. A diverse range of factors could potentially impede or facilitate professional behaviour change. Research evidence suggests that interventions based on an assessment of potential barriers are more likely to be effective. However, even the most well developed interventions can be unsuccessful, if factors such as lack of time and resources hinder attempts to implement evidence-based practice (Flottorp et al., 2003). Research conducted in this field generally fails to report details of potential barriers present within the clinical setting, providing no indication of the factors that may have increased or reduced the effectiveness of the applied intervention.

Despite this substantive body of literature, the inconsistencies in the characteristics of interventions, behaviours targeted and the healthcare context, make it difficult to reach a consensus about the effectiveness of intervention types. Furthermore, the literature is unable to provide answers as to why an intervention is successful or unsuccessful in producing professional behaviour change. The atheoretical nature of previous research may have contributed to this problem. Thus, previous research has been unable to identify the mechanisms by which change can be achieved. In recent years attention has been directed to the potential of theory-based approaches, in particular the contribution that psychological models of behaviour change can make to understanding clinical behaviour, and informing the design of implementation strategies. This development within implementation research will be discussed further in chapter 4.

2.5 Implications for this Study

Having provided an overview of the approaches that have been frequently employed to change health professional behaviour, it is now necessary to identify the implications these findings have for designing an intervention to implement the communication of the management plan and shared responsibility guidelines for heart failure. Interventions based upon an assessment of potential barriers may promote greater changes in health professionals' behaviour. Therefore, the first stage of this research programme will involve identification of the potential barriers to implementation of the communication of the management plan guideline. The findings from this study will determine the selection and development of an intervention to implement these heart failure guidelines. The resources available within the healthcare context also influence the feasibility of an intervention. For example, reminder systems, and audit and feedback, would only be feasible if a suitable information technology system existed in the clinical setting. Therefore, it is necessary in this research programme to gain an understanding of the healthcare context, and resources available, prior to the development of the intervention.

The findings to emerge from the literature of patient related factors having an influence on the delivery of evidence-based practice is a pertinent one, particularly as the communication of the management plan and shared responsibility guidelines include direct involvement of the patient for implementation. In this research programme particular attention will, therefore, centre on the facilitating or inhibiting patient related factors identified in the context of these guidelines. It is likely that the perceptions of clinicians could be influential in the effectiveness of any intervention used to implement guidelines. It is thus imperative that the perceptions and views of clinicians towards the NICE guidance for heart failure management and its implementation are sought. A single strategy was adopted in this research programme as it was a more feasible option in the resources available.

2.6 Conclusions

The overall indication is that implementation strategies have variable success in promoting evidence-based practice. Little concrete evidence exists to guide the design or selection of appropriate interventions. It has in fact been suggested that intervention selection is usually determined by the 'researcher's intuition or optimism' (Bonetti et al., 2005, p2146). The limited understanding about the factors that can impede or promote an intervention's success in achieving behaviour change implies that 'the success or failure of an implementation intervention may well be left to chance' (Grol & Wensing, 2004, pS60). The incorporation of a theoretical basis to intervention development and evaluation in future studies might provide answers to the many unanswered questions in this research area. Such an approach may enable a greater understanding of the motivational influences on clinical behaviour, along with the underlying mediators involved in behaviour change, and the reasons why an intervention has proven effective or otherwise in changing professional behaviour.

Chapter Three: Communication and Promotion of Self-management in Heart Failure Patients

3.1 Introduction

The aim of this thesis was to improve the communication of management plans to patients and to promote patients' self-management of heart failure, thereby facilitating the implementation of two NICE guidelines for heart failure management. This chapter firstly reviews previous research examining heart failure patients' knowledge and their ability to self-manage their illness. Secondly, this chapter will evaluate approaches commonly used to communicate information to patients. It addresses doctor-patient communication, and the effectiveness of written and computer-based information interventions. Thirdly, this chapter will provide an overview of the effectiveness of interventions to promote self-management. In particular, this chapter will focus on self-management interventions that incorporate a substantial educational component. Due to the substantial heterogeneity in these interventions, conclusions about the effectiveness of interventions will be reached by examining research syntheses, such as meta-analyses and systematic reviews, to discern the effectiveness of these approaches.

3.2 Patients' Knowledge and Management of Heart Failure

It is widely accepted that the patient is primarily responsible for the majority of their own care in chronic illnesses, and will only benefit from treatment regimens if they follow them. The role of the patient as an active partner in their own care is, therefore, strongly endorsed by guidelines, government initiatives, and the literature (NICE, 2003a; Department of Health, 2002; Holman & Lorig, 2000). The self-management regimen for heart failure is very complex. Its components include adherence to medication, engagement in regular physical activity, reduction in salt intake, symptom monitoring, restriction in alcohol consumption, and smoking cessation (NICE, 2003a, NCC-CC, 2003). By adhering to their medications, lifestyle and self-monitoring behaviours, patients can prevent exacerbations of their illness, and alleviate their symptoms (van der Wal, Jaarsma & van Veldehuisen, 2005).

Non-pharmacological treatments are an important part of the heart failure self-management regimen. Regular exercise for stable heart failure patients has been shown to have positive effects on symptoms, physiological outcomes (e.g. oxygen intake, heart rate), and quality of life (Lloyd-Williams et al, 2002; McKelvie et al, 1995). Patients with heart failure are also advised to restrict their salt (sodium) intake (Davis et al, 2006; Swedberg et al., 2005; Soler-Soler et al, 1994). The physiological rationale for this suggestion is that the reduced cardiac output due to heart failure triggers a number of reactions within the body, one of which is for the kidneys to retain fluid. Excess salt in the body also increases fluid retention (Berry, 2001) and, therefore, patients are advised to reduce their salt intake in order to prevent this from occurring. Patients are also required to effectively monitor their symptoms. NICE guidelines state that "patients who wish to be involved in the monitoring of their condition should be provided with sufficient education and support from their healthcare professional to do this" (NICE, 2003a, p.18). In particular, patients should be aware of gradual changes in their symptoms which indicate worsening heart failure, and the appropriate action to take in these circumstances. An important aspect of self-monitoring is regular weighing, which enables patients to identify the early signs of fluid retention, and to initiate appropriate self-management behaviours (e.g. increase diuretic therapy, reduce salt and fluid intake), or seek medical assistance to prevent further worsening of symptoms.

Researchers frequently conclude that heart failure patients lack the knowledge and skills to effectively perform self-management. This assertion is illustrated by findings in the literature which show that heart failure patients have partial knowledge, doubts and misconceptions about their illness (e.g. Agard, Hermeren, & Herlitz, 2004; Horowitz, Rein & Leventhal, 2004; Rogers et al., 2000; Ni et al., 1999). By way of an example, Buetow and Coster (2001) reported that 37% of heart failure patients did not understand the nature and seriousness of their illness. Horan and colleagues (2000) found that nearly 25% of patients did not understand that their medical problems were related to heart dysfunction, 66% did not know their medications, and only 15% understood how their actions affected their illness. In addition, older adults with heart failure were found to have considerably less knowledge about their illness, compared to patients with other illnesses (Halling & Berglund, 2006). It is well established in the literature that knowledge alone does not directly result in the performance of a behaviour (Prohaska & Lorig, 2001; Raynor, 1998). It is, however, a necessary prerequisite to enable involvement in self-care (van der Wal., 2006).

Patients' non-adherence has been identified as a central problem in the management of heart failure. An overview of the literature estimated patients' adherence as 70% for medication taking, 50% to 89% for restricted salt intake, 42% to 59% for regular physical activity, and 12% to 75% for daily weighing (van der Wal, Jaarsma & van Veldhuisen., 2005). The literature investigating patients' adherence to medication has shown that patients forget, stop, or take their medications intermittently (Stromberg, Brostrom, Dahlstrom, & Fridlung, 1999; Michalsen, Konig, & Thimme, 1998). It was also found that patients lacked knowledge, and had misunderstandings about their medication regimen (e.g. Martinez-Selles et al., 2004; Rogers et al., 2002). Indeed, Field, Ziebland, McPherson and Lehman (2006) indicated that only 24% of patients in their study had a level of awareness about their medication that enabled informed exchanges with health professionals.

The research investigating patients' adherence to salt restricted diets found that lack of knowledge, interference with socialisation (e.g. eating out), poor palatability of food, lack of motivation, and lack of food selections (van der Wal et al., 2006; Bentley, De Jong, Moser, & Peden, 2005; Evangelista et al., 2003) are factors that hindered the performance of this behaviour. The literature has identified that patients consider daily weighing as unimportant (22% in Ni et al., 1999; 50% in Carlson & Riegel, 2001) and even when patients weighed themselves regularly they were uncertain of what action to take as a result of weight increases (Carlson & Riegel, 2001; Sulzbach-Hoke, Kagan, & Craig, 1997). The reasons proposed by patients for not weighing themselves include lack of motivation, forgetfulness, and not knowing that they should be monitoring their weight (van der Wal et al., 2006). Knowledge has been found to be associated with adherence to daily weighing in multivariate analysis (van der Wal et al., 2006), and patients with a history of heart failure were more likely to implement a self-care strategy (e.g. limit salt intake, take additional diuretics) in response to weight gain than newly diagnosed patients (Carlson & Riegel, 2001).

A common reaction of patients to a diagnosis of heart failure is to reduce or stop their regular physical activity. Indeed, studies have reported that 30% of patients ceased physical activity following their diagnosis (Ni et al., 1999; Carlson & Riegel, 2001), and decreasing activity levels was a strategy adopted amongst patients to cope with their symptoms (Bennett, Cordes, Westmoreland, Castro, & Donnelly, 2000). Heart failure patient's encountered uncertainty in determining the type and amount of exercise needed to maintain good health (Bennett et al., 2000). In addition, physical symptoms and lack of energy, skills, and motivation made following physical activity recommendations very difficult (van der Wal et al., 2006; Evangelista et al., 2003; Jaarsma, bu-Saad, Dracup, & Halfens, 2000).

The literature suggests that some heart failure patients lack the knowledge and skills to effectively manage their illness. However, relatively little is known about patients' management (or non-management) of heart failure, which can inform the development of interventions intended to promote self-care in patients. Relatively few studies have incorporated health psychology theories to advance understanding about heart failure patients' management, and to move beyond a purely descriptive account of behaviour. Those studies that have drawn upon these models have provided valuable insights into patients' ability to self-care. For example, Horowitz and colleagues (2004) used the Self Regulation Model (Leventhal, Meyer, & Nerenz, 1980) to organise patients' accounts of their self-management, and found that heart failure patients predominantly responded to their symptoms and illness using an acute model of illness management. Patients, therefore, did not respond to gradual changes in their symptoms with actions to prevent further deterioration of their condition. This study showed that patients dissociated self-management behaviours from their illness: for example, patients did not relate increases in swelling (fluid retention) with their salt intake. Other researchers have adopted the components of perceived barriers and benefits from the Health Belief Model (Becker, 1974) to develop measures specifically designed to identify the beliefs related to adherence with medication and diet (Bennett, Milgrom, Champion, & Huster, 1997; Bennett et al., 2001). The utilisation of these constructs in subsequent studies has shown that perceived benefits to medication and diet were associated with overall adherence, and more benefits and fewer barriers were associated with diet adherence (van der Wal et al., 2006). These studies demonstrate that the use of health psychology models could assist in the development of a more complete understanding of heart failure self-management.

However, shortcomings exist in this area that should be taken into account when evaluating the research findings. The majority of studies measuring knowledge in heart failure populations have used questionnaires, specifically designed for the purpose of the study, whose validity and reliability have been limited. Validated instruments measuring knowledge are scarce, and only two have recently been published (van der Wal, Jaarsma, Moser & van Veldhuisen, 2005; Lainscak & Keber, 2005). However, even these instruments have limitations including too few items, and insufficient or missing items on relevant areas of heart failure (Stromberg, 2005). Nonetheless, findings from qualitative investigations have confirmed that heart failure patients lack knowledge (e.g. Rogers et al, 2000; 2002; Agard et al, 2004), indicating that the findings, that have emerged from studies employing measures attempting to quantify knowledge, have not been inaccurate. In addition, variances in the adherence rates maybe reported partly due to the variety of measurement methods used, including surveys, interviews, reviews of medical records and electronic devices (medication event monitoring systems), to determine management behaviour (van der Wal, Jaarsma & van Veldhuisen., 2005). Patient populations across studies have also differed. In their overview of the adherence literature in heart failure, van der Wal, Jaarsma and van Veldhuisen. (2005) found that participants in studies differed according to age (mean age 51 to 81 years) and representation of women (1 to 58%). Notwithstanding these shortcomings, the literature discussed thus far has demonstrated that heart failure patients lack knowledge about their illness, and most lacked the ability to self-manage their illness adequately. Interventions have therefore been designed to provide patients with information and to improve their involvement in their own care. The remainder of this chapter will review approaches commonly used to provide information to patients and interventions designed to promote heart failure self-management.

3.3 Doctor-Patient Communication

Patients receive information about their general health, health problems, and possible treatments through consultations with their doctor. Patients have been found to value personalised information from their health providers (Grime, Blenkinsopp, Raynor, Pollock, & Knapp, 2007), and research suggests that doctor-patient communication can improve health outcomes (Stewart, 1995). NICE (2003a) guidelines outline that good communication between patients and doctors is necessary for the optimal management of heart failure. Indeed 'The Patient's Charter' (Department of Health, 1991) stresses patients' entitlement to information, and more recent initiatives have emphasised the importance of quality health information in the delivery of healthcare services (Department of Health, 2004). The literature reflects the importance of patients' relationships with their doctors in the long term management of medical conditions. Patients with chronic conditions perceive the doctor-patient relationship as a mechanism through which to receive information of trusted quality, meet information needs, and feel more adequately informed and confident about self-management (Thorne, Harris, Mahoney, Con, & McGuinness, 2004).

The consultation serves three separate functions; creating a good interpersonal relationship between doctor and patient, the exchange of information, and health decision-making (Ong, de Haes, Hoos, & Lammes, 1995). Within cancer care, good information exchange was found to increase patients' control and involvement in care, reduce anxiety, increase compliance, and promote self-care (Mills & Sullivan, 1999). A number of factors, however, have been identified that may hinder the transmission and assimilation of verbal information. For example, health care providers' delivery of information is primarily determined by their perceptions of patients' information needs. These estimations, however, may not reflect patients' actual informational needs. Indeed, nurses have been found to underestimate heart failure patients' information needs, and their ability to cope with information about their illness (Frattini, Lindsay, Kerr, & Park, 1998; Hagenhoff, Feutz, Conn, Sagehorn, & Moranville-Hunziker, 1994; Wehby & Brenner, 1999). Hagenhoff and colleagues (1994) found that patients rated information about physiology, medication, activity, diet, and risk factors as more important to learn when compared with similar assessments made by health care providers.

Within the consultation process, the patient has the opportunity to seek further information and clarification by utilising communicative behaviours such as question asking (Beisecker & Beisecker, 1990). However, research suggests that patients who desire further information may not readily adopt information seeking behaviours in the consultation (Beisecker & Beisecker, 1990). A similar finding has emerged from the heart failure literature. Patients feel unable to raise issues about their medications, and do not want to impinge on the limited time of doctors (Aldred, Gott & Gariballa, 2005; Rogers et al., 2000). Furthermore, some patients believed that their doctor knew best and that they should not ask questions (Aldred et al., 2005; Rogers et al., 2000). The literature recognises that patients also need to develop skills to enable them to effectively communicate with doctors, and attempts to enable this have been reviewed and described in the literature (see Harrington, Noble, & Newman, 2004).

Health professionals also report challenges in their communication with heart failure patients. In particular, doctors reported difficulty providing a diagnosis to patients because of the perceived negative connotations associated with the term 'heart failure', and the inherent difficulty in establishing a diagnosis (Barnes et al., 2006). Doctors preferred to use euphemisms instead of the term heart failure to communicate information to patients about their illness (Barnes et al., 2006; Tayler & Ogden, 2005). The patient literature also reflects this, as patients report being unaware that they have a diagnosis of heart failure (Field et al., 2006). Furthermore, the delivery of prognostic information was hindered due to the difficulty in estimating prognosis, concerns about giving bad news too soon, and the potential negative impact on the patient (Barnes et al., 2006; Hanratty et al., 2002).

The literature suggests that heart failure patients are dissatisfied with the information they receive from health care providers (Barnes et al., 2006; Buetow & Coster, 2001). Indeed, a focus group of heart failure patients, commissioned by the NCC-CC, judged provision of information about diagnosis, condition, and care as inadequate (NCC-CC, 2003). Patients perceived health care providers as being short of time, and hesitant or unwilling to deliver prognostic information or to provide as much information as desired (Aldred et al., 2005; Rogers et al., 2000; Buetow & Coster, 2001). Carers of people who died from heart disease reported that, although patients believed they were dying, few had discussed end-of-life issues with their doctors (McCarthy, Addington-Hall, & Ley, 1997). In fact, one UK study found that most patients would have welcomed the opportunity to receive information about their prognosis (Aldred et al., 2005). However, not all heart failure patients want better or even more information (Agard et al., 2004; Buetow & Coster, 2001). This finding has been partly attributed to patients' lack of awareness of their information deficits (Agard et al., 2004; Buetow & Coster, 2001). Moreover, research within the field of cancer has reported that patients may encounter times during their illness trajectory where they do not wish to receive further information (see Leydon et al., 2000).

It is widely recognised that patients experience difficulty retaining and recalling information provided by health professionals (Kenny et al., 1998). Ley (1985) suggests that patients retain and recall as little as 40% to 50% of the health information provided during the consultation. In a small study by Golden and Johnston (1970), patients were unable to repeat information about a surgical procedure immediately after its provision, and distortions existed in their recall. The authors proposed that these distortions stemmed from healthcare providers' inadequate explanations. In addition, Ley and Spelman (1965) reported that 37% of medical information recalled by patients was inaccurate, and 56% of instructions were recalled incorrectly. Patients with heart failure also reported these difficulties (Buetow & Coster, 2001; Cline, Bjorck-Linne, Israelsson, Willenheimer, & Erhardt, 1999), and the use of complex terminology by health professionals hindered their comprehension of health information (Barnes et al., 2006). Furthermore, patients encountered problems in assimilating information due to reduced cognitive capacity, short-term memory loss, or even confusion (Rogers et al., 2000).

3.4 Provision of Written Information

The provision of written materials alongside verbal information is regarded as good clinical practice (Kenny et al., 1998). Written information can serve to supplement and reinforce verbal information provided by health professionals (Semple & McGowan, 2002; McPherson, Higginson, & Hearn, 2001; Raynor, 1998; Dunkelman, 1979), and is easier to retain when compared with verbal information (Ley & Morris, 1984; Ley, 1988; Raynor, 1998). Furthermore, patients have the option of revisiting information, and exercising their choice by choosing whether or not to read it (McPherson et al., 2001). Written informational materials are one of the most frequently utilised methods of providing information to patients (Kenny et al., 1998). However, within those interventions designed to improve heart failure management, written information usually forms part of a broader intervention incorporating a number of different approaches. In such interventions it has been impossible to isolate the effects of the booklet intervention and, therefore, very little evidence exists about the effectiveness of written materials to improve patient outcomes in heart failure. Indeed, only a single study was found which evaluated a written intervention only (Serxner, Miyaji & Jeffords, 1998). Heart failure patients receiving repeat mailings of generic patient information about their illness and its management, reported greater confidence, dietary and weight behaviour changes, less forgetfulness in taking medications, and fewer readmissions compared to the usual care group (Serxner et al., 1998). Due to the paucity of literature on written interventions for heart failure, insights could be gained from research conducted with other patient populations. The influence of written information on knowledge, behaviour change, and health and psychological outcomes will now be discussed.

Knowledge: A recent comprehensive review of patient-focused interventions concluded that written information produced improvements in health knowledge and recall (Coulter & Ellis, 2006). Similar results were also reported in a review which evaluated different methods of information delivery to cancer patients (McPherson et al., 2001): and a meta-analysis of psycho-educational care found that written materials significantly enhanced cancer patients' knowledge (Devine & Westlake, 1995). However, improvements in patient knowledge are not always achieved. Raynor and colleagues (2007) systematically reviewed the effectiveness of written information materials about individual medicines, and concluded that most studies failed to increase patients' knowledge. In addition, Harris, Smith, and Veale (2005) reported that printed educational materials to facilitate shared management in chronic illness only achieved limited effectiveness in improving patients' knowledge. It is worth noting that both Raynor and colleagues (2007), and Harris and colleagues (2005), identified that the effectiveness of written interventions to improve patient outcomes relied on their quality. Indeed, Harris et al (2005) reported that the majority of written materials in their literature review scored very low on the quality criteria. This finding may partly explain why the materials evaluated in this review, have not been shown to effectively influence patient outcomes.

Behaviour change: An extensive review of patient-focused interventions concluded that the impact of written health information on behaviour is unknown (Coulter & Ellis, 2006). Raynor and colleagues (2007) reported that written materials providing information about individual medicines failed to improve adherence to instructions for medication taking. It is suggested in the literature that written materials have the potential to influence behaviour when they are of good quality, and the recipient is motivated to comply with the information provided (Raynor, 1998). It is proposed that written information can influence behaviour when it dispels concerns and misconceptions, and meets patients' information needs (Raynor, 1998). In these circumstances, the provision of information alone may provide individuals with the knowledge to perform health behaviours. There are examples in the literature where written information materials have demonstrated the ability to promote behaviour change. Written information booklets have reduced GP consultations for common childhood illnesses (Anderson, Morrell, Avery, & Watkins, 1980) and reduced re-consultation rates for patients with respiratory rates (Macfarlane, Holmes, & Macfarlane, 1997). Theory-based booklets have produced improvements in health behaviour (e.g. Kelley & Abraham, 2004; Hill, Abraham, & Wright, 2007). (See chapter 4, part II for a discussion of theory-based booklets).

Health and psychological outcomes: The literature has produced mixed findings for the potential of written information booklets to influence health and psychological outcomes. McPherson and colleagues' (2001) systematic review of information-giving interventions for cancer patients, found that the majority of studies were ineffective in influencing psychological indices. However, the authors noted that although psychological outcomes were evaluated, the aim of the majority of these interventions was to educate patients and not to reduce psychological distress. Sheard and Garrud (2006) found that written booklets reduced reports of pain, and improved health outcomes in elective surgical patients. Studies evaluating the effects of written information on anxiety have produced mixed results. Some studies have reported no difference in anxiety between control and intervention groups after the provision of patient information (Asilioglu & Celik, 2006), while others reported significantly less anxiety in patients who are provided with information booklets (Sheard & Garrud, 2006).

Overall the broader literature provides considerably more evidence for the effectiveness of written information in enhancing patients knowledge, whilst findings for behaviour and psychological and health outcomes remained inconclusive. It is worth noting however that written information materials did not consistently produce improvements in the outcomes reviewed. A notable finding to emerge from the literature is that the effectiveness of written information materials is dependent on its quality. Evaluations of patient information materials report that they often contain inaccurate information, address irrelevant topics, and have high readability levels (Coulter, Entwistle, & Gilbert, 1998). Recommendations have, therefore, been developed to promote the development of quality written materials (see chapter 7, section 7.4 for a discussion of these recommendations, Coulter et al., 1998; Payne, Large, Jarrett, & Turner, 2000).

3.5 Computer-Based Education

Advances in computer technology have generated interest in the field of patient education. Early research supports the effectiveness of computer-based programs in delivering patient education and influencing clinical and health outcomes (Lewis, 1999). Beranova and Sykes (2007) assessed the impact of computer-based education for patients with coronary heart disease (their review also included 2 heart failure studies), and concluded that these interventions significantly increased knowledge when compared to standard education.

The suitability of computer-based education to deliver information to patients relies solely on their ease of use by the intended patient population. Heart failure patients are generally older and, therefore, research into the application of such interventions among this group needs to establish how proficient older adults are with information technology systems. Only 14% of heart failure patients aged 51 to 92 had some experience with computers (Stromberg, Ahlen, Fridlund, & Dahlstrom, 2002). A handful of studies in a review by Lewis (1999) reported that older patients were satisfied with computer-based learning technologies (Ogozalek, 1993; Luker & Caress, 1991; Leirer, Morrow, Pariante, & Sheikh, 1988; Rippey et al., 1987). However, visual deficits among some of the participants led to increased difficulty in using computer programs (Ogozalek, 1993). In addition, other programs have utilised methods such as touch screens (e.g. Stromberg et al., 2002; Fieler & Borch, 1996), or modified keyboards (e.g. Stromberg et al., 2002; Luker & Caress, 1991), to simplify interventions.

Computer-based education has been utilised to educate heart failure patients, albeit in a few studies. The first published study evaluated a Kodak photo-CD portfolio in conjunction with a nurse and pharmacist-led educational programme (Bjorck-Linne, Liedholm, & Israelsson, 1999). The CD intervention group showed significantly improved knowledge compared to those provided with standard education. Although the findings for this study were promising, the CD was evaluated as part of a multifaceted intervention and, therefore, the isolated effects of the CD alone were not established. In addition, patient knowledge was not assessed at baseline, and although randomisation was likely to reduce the possibility of differences existing between the groups, this possibility cannot be discounted (Bjorck-Linne et al., 1999).

Stromberg and colleagues (2002) found that the majority of heart failure patients (approximately 86%) preferred receiving information via a CD-ROM format, rather than booklets or videotapes. This study, however, used a research nurse to instruct and guide participants. Therefore, the question still remains as to whether such programmes can be used independently by older heart failure patients. A subsequent evaluation of this CD-ROM intervention found that it significantly improved knowledge in comparison to standard education. However, it did not improve quality of life or adherence to self-care behaviours (Stromberg, Dahlstrom, & Fridlund, 2006). Research suggests that computer-based interventions could be adopted to provide information and education to heart failure patients. However, methods such as touch screens, special keyboards, or instruction from health professionals, may be needed to increase their usability among older adults with limited computer experience.

3.6 Self-Management Interventions for Heart Failure

As discussed previously, heart failure patients tend to lack adherence to self-management. Patient interventions, therefore, have been developed and evaluated to improve patients' ability to self-manage their illness. The research indicates that multifaceted intensive self-management interventions can result in significant improvements in clinical outcomes (e.g. reduced hospital admissions and lower rates of mortality) and, consequently, have the potential to reduce health care costs (McAlister, Lawson, Teo, & Armstrong, 2001). However, the resources required for a multifaceted self-management intervention are beyond the remit of this study.

Patient education is an important component of heart failure management. McAlister and colleagues (2004) found that the majority of multifaceted self-management interventions incorporated an educational component. Within heart failure self-management, the purpose of patient education interventions is to increase patients' knowledge, and to promote their self-care abilities (Dracup et al., 1994). Stromberg (2002) identified a number of self-management interventions that utilised a strong educational component within their programmes. In the following section of this chapter, these trials and those of a similar nature will be reviewed, and their effects on clinical outcomes (readmissions, days in hospital, mortality), knowledge, adherence, self-care, and quality of life will be discussed. (Please see table 3 for an overview of the interventions).

3.6.1 Clinical Outcomes: Readmissions/Days in Hospital/Mortality

Cline and colleagues (1998) demonstrated that an intervention which provided patients with two hours of education prolonged time to first admission, and reduced hospitalisations by 36%, when compared to a control group. Similar effects have been reproduced by other multidisciplinary interventions on unplanned readmissions, and days in hospital (Stewart et al., 1999; Blue et al., 2001). One study found that a strong educational multidisciplinary intervention reduced mortality (Stewart et al., 1999).

However, other studies failed to report any significant effects on readmissions or days in hospital, following the intervention (Jaarsma et al., 1999; Ekman et al., 1998). It is worth noting that Ekman and colleagues (1998) associated the high drop-out rate and ineffectiveness of their intervention to its inaccessibility to heart failure patients. Patients in this study reported considerable difficulty in travelling to attend the intervention site due to their illness. The authors suggested that perhaps interventions delivered to patients within their own homes would be more suitable for older adults with moderate to severe heart failure

3.6.2 Knowledge, Self-care and Quality of Life

Self-management educational interventions have also demonstrated that they can increase knowledge (Rich et al, 1995), and self-care behaviours (Rich et al., 1995; Jaarsma et al., 1999). Nurse-directed interventions have increased medication adherence (Rich et al. 1995) and increased self-care behaviours (Jaarsma et al., 1999). The latter study, which also incorporated follow-up home visits, reported significant improvements in self-care behaviours between baseline and 9-month follow-up. However, deterioration in self-management was observed between the 1-month and 9-month follow-up (Jaarsma et al., 1999). This finding indicates that this intervention was unable to maintain improvements initiated in self-management behaviour. Multidisciplinary interventions which evaluated quality of life demonstrated improvements (Rich et al., 1995), no change (Cline et al., 1998), or short-term increases only (Stewart et al., 1999).

Table 3. *Characteristics and review of interventions which incorporate a strong educational component to improve heart failure patients' outcomes*

Study, sample and follow-up characteristics	Components of intervention	Outcomes evaluated	Effects of intervention
Rich et al. (1995) Older patients (70 years and older) at high risk of readmission 90 day follow-up	Intensive education delivered by a cardiovascular nurse in conjunction with a teaching booklet Individualised dietary assessment Reinforcement of information via home visits and telephone follow-up	Primary: Survival Secondary: Readmissions, days in hospital, quality of life, health care costs Additional: adherence, patient understanding	Trend towards a reduction in heart failure readmissions, improved quality of life and reduced health care costs. Significantly improved medication adherence and patient understanding
Ekman et al. (1998) Older patients (65 years and older) and NYHA[1] class of III-IV 6 month follow-up	Nurse directed intervention Individually structured care programme and tailored education Goal setting to improve adherence Specific forms for daily weighing and weekly medication Written guidelines for monitoring symptoms Reinforcement of information via telephone contact	Readmissions, survival, hospital days	No effect on readmission, survival or hospital days

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[1] NYHA is the New York Heart Association classification classifies the extent of heart failure (I-IV). Higher numbers indicate a more severe stage of heart failure.

Study, sample and follow-up characteristics	Components of intervention	Outcomes evaluated	Effects of intervention
Cline, Bjorck-Linne, Israelsson, Willenheimer, and Erhardt (1998) Patients aged 65 to 84. One year follow-up	Nurse follow-up Two 30 minute education sessions delivered during hospitalisation and an hour education session following discharge for patients and carers Use of patient diary Patient guidelines for self-management of diuretics Oral and video presentations to reinforce information Patients able to contact study nurse	Survival rate, time to readmission, hospitalisation and quality of life, cost analysis	No effect on survival rate, quality of life Time to first readmission significantly longer Trend to fewer days in hospital and reduced health costs
Jaarsma et al. (1999) Aged 50 or over and NYHA class of III or IV 1 and 9 month follow-up	Delivered by nurse and guided by nursing care plan General education including individualised information Education delivered prior to discharge and information reinforced at post discharge (home visit). Telephone contact by nurse	Self-care behaviours Self-care ability Readmission Use of health care resources	No effect on self-care ability, readmission and use of health care resources. Improved self-care, intervention group reported adherence with 14 of 19 self-care behaviours.

Study, sample and follow-up characteristics	Components of intervention	Outcomes evaluated	Effects of intervention
Stewart, Marley, and Horowitz (1999) 55 years and older 6 month follow-up	Single structured home visit delivered by nurse. Wide range of approaches used in intervention including information giving, remedial counselling and introducing regimens to improve adherence Telephone follow-up, patients could contact study nurse and additional home visits for patients with unplanned readmissions during follow-up period.	Survival Readmissions Days in hospital Quality of life	Reduced readmissions, fewer days in hospital and improved survival Significant improvements in quality of life only observed at 3 months
Blue et al. (2001) All patients admitted as an emergency to acute medical admissions 1 year follow-up	Nurse delivered intervention Home visits over a year that reduced in frequency over time and supplemented by telephone contact Patients provided with booklet which included personalised medical information	Survival Readmission Days in hospital	No effect on survival Fewer admissions and fewer days in hospital.

Study, sample and follow-up characteristics	Components of intervention	Outcomes evaluated	Effects of intervention
Koelling, Johnson, Cody, and Aaronson (2005) All patients from inpatient services 180 day follow-up	Usual care: provision of standardised discharge information (includes information about illness and management, list of medications, dosages and instructions for taking medication) Intervention included an addition hour long individual teaching session	Survival hospitalisation Adherence to self-care Quality of life	Less hospitalisation, improved survival and longer time to first readmission. Higher self-care scores, significantly greater proportion reporting daily weighing, following sodium restrictions and abstaining from smoking. No effect on quality of life
GESICA Investigatiors (2005) Grancelli et al. (2003) Participants 18 years and older and on the national multicentre chronic heart failure registry	Frequent telephone follow-up intervention delivered by nurses trained in heart failure management Information booklet provided to patients Telephone contact used to educate patients by clarifying and reinforcing content of information booklet. Telephone contact also used to monitor patients and information was tailored to their situation.	Admissions, mortality and quality of life	Reduced admissions for heart failure and improved quality of life. No effect on mortality.

3.7 Evaluation of Other Interventions for Heart Failure Management

The majority of interventions evaluated above delivered education to patients following discharge from hospital, and included follow-up comprising of home visits and telephone contact. However, an educational intervention delivered prior to hospital discharge without incorporating follow-up, also produced promising results (Koelling et al., 2005). This intervention provided patients with an hour long individual teaching session alongside usual care. Follow-up at 6 months revealed that patients in the intervention group decreased mortality rates, and stayed fewer days in hospital. Patients receiving the intervention also scored significantly higher on self-care measures, and at 1 month follow-up reported increased self-management (Koelling et al., 2005).

Interventions such as telemonitoring and telephone support have also been evaluated. A systematic review and meta-analysis assessing the effectiveness of these interventions indicated that telemonitoring[2] and telephone support significantly reduced mortality by 20%, hospital admissions by 21%, and had the potential to improve quality of life (Clark, Inglis, McAlister, Cleland, & Stewart, 2007). A telephone monitoring and support intervention, called DIAL, reduced cardiovascular admissions, and improved quality of life and self-management compared to usual-care patients (GESICA Investigators, 2005; Grancelli et al., 2003). This study recruited patients from outpatient clinics, and although this would represent a larger and less selective population of heart failure patients, these patients may have differed in their characteristics from those recruited from the hospital settings in the studies previously evaluated. Therefore, there is a possibility that a greater proportion of participants in the DIAL study were better able to perform self-care. These findings suggest that interventions, such as telephone support and short individual teaching, which require fewer resources and are more feasible to develop and deliver, may have the potential to influence heart failure patients' self-management of their illness.

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[2] Transfer of physiological data via telephone/digital cable in patient's home to health professionals.

3.8 Interventions to Improve Adherence to Self-management

A systematic review by van der Wal, Jaarsma and van Veldhuisen (2005) identified and evaluated interventions that employed adherence as an outcome measure. The review examined eight randomised studies and four non-randomised studies which generally incorporated education and counselling and, in some circumstances, telephone support and follow-up. Interventions which utilised a pharmacist were effective in improving patients' adherence to medication (e.g. Goodyer, Miskelly, & Milligan, 1995; Varma, McElnay, Hughes, Passmore, & Varma, 1999). Varma and colleagues (1999) reported that although self-reported adherence did not differ between the pharmacist intervention group and usual-care group, 43% of the patients in the intervention group (compared to 13% of patients in the control group) were adherent in filling in their prescriptions. However, a limitation of this study was that prescription data was only available for a small proportion of patients (n=23). Medication adherence was also improved by a multidisciplinary intervention incorporating a large educational component (Rich, Gray, Beckham, Wittenberg, & Luther, 1996).

The review by van der Wal, Jaarsma and van Veldhuisen (2005) identified interventions which were able to improve adherence to the lifestyle and self-monitoring behaviours required for effective self-care. For example, a nurse-led heart failure clinic intervention demonstrated improvements in daily weighing and fluid restriction (Stromberg, 2001). However, the influence of this intervention did not extend to 12 months follow-up, indicating that only short-term behaviour change was initiated. Another intervention, which involved frequent contact with a heart failure clinic and telephone contact, reported increases in self-reported dietary adherence, but did not influence medication adherence (Kasper et al., 2002).

Non-randomised studies also observed improvements in patients' adherence (van der Wal, Jaarsma & van Veldhuisen., 2005). An intervention, which incorporated an educational visit, food frequency questionnaires, measurements of self-efficacy and reinforcement of information by structured telephone support, resulted in decreased self-reported sodium intake in patients receiving the intervention (West et al., 1997). Likewise, a nutritional intervention which included dietary education from a dietician, monthly nutrition classes, nutritional assessment, and individual dietary goals, significantly decreased sodium and fluid intake at 2 to 3 month follow-up, compared to baseline (Kuehneman, Saulsbury, Splett, & Chapman, 2002). In addition, Hershberger and colleagues (2001) reported significant improvements in daily weighing from a nurse-led intervention delivered in a heart failure clinic. The literature reviewed indicates that a number of interventions are potentially available to promote heart failure self-management. These interventions demonstrate the potential to reduce hospitalisations, improve knowledge, and increase self-management. All the interventions, however, utilised different approaches, resulting in very little understanding/identification of the components within the interventions, which were more likely to influence patients' behaviour.

3.9 Chapter Summary

Patients require an understanding about their illness and its management in order to successfully self-care. Research has indicated that patients lack knowledge, and adherence to self-management is low. Indeed, the literature seems to imply that very few heart failure patients attain an advanced level of self-care. Research further suggests that heart failure patients do not feel adequately informed, are unsatisfied with information provision, and have unmet informational needs (e.g. NCC-CC, 2003; Rogers et al., 2000; Buetow & Coster, 2001). Information provision is generally given in a verbal form, where factors within the consultation process may hinder the successful transmission of health information. The underestimation by health professionals of heart failure patients' information needs, and their ability to cope with information may account for the inadequate provision of information to patients (e.g. Frattini et al., 1998; Hagenhoff et al., 1994; Wehby & Brenner, 1999). The literature indicates that heart failure patients are unlikely to request further information (Rogers et al., 2000), and lack of knowledge may impede their awareness of informational deficits (Buetow & Coster, 2001). Furthermore, even when information within the consultation does succeed in meeting patients' informational needs, patients may encounter difficulty retaining and/or recalling information (e.g. Cline et al., 1999), or have difficulty assimilating information due to reduced cognitive capacity, short-term memory loss, or confusion (Rogers et al., 2000).

Written information can be utilised to supplement and reinforce verbal information. Compared to verbal information written information presents several advantages including: not being as easily forgotten (e.g. Ley & Morris, 1984; Raynor, 1998), and allowing patients to select from, and revisit, information (e.g. McPherson et al., 2001). Written materials can lead to improvements in knowledge (Coulter & Ellis, 2006), and has the potential to influence behaviour (e.g. Raynor, 1998; Macfarlane et al., 1997) and improve health and psychological outcomes (e.g. Sheard & Garrud, 2006). However, written information is not able to consistently produce changes in chosen outcomes (e.g. Raynor et al., 2007; McPherson et al., 2001; Asilioglu & Celik, 2004). The ineffectiveness of some written materials to improve patient outcomes may be attributed to their poor quality (Harris et al., 2005; Coulter et al., 1998). Therefore, recommendations for producing written health information should be consulted and incorporated during the development of patient education materials. In practical terms, written information materials offer an option that is feasible for development and wide dissemination even within contexts where resources may be limited.

Computer-based interventions in heart failure have the potential to improve knowledge (Stromberg et al., 2006). The usability of computers may be improved among older adults with limited computing experience by the use of touch screens, simple key pads or the provision of instruction by a professional. However, the extra resources required to provide additional support and guidance to older adults in the use of these programmes, would increase the resources and costs involved in implementing a computerised intervention.

Interventions that incorporate a strong educational component decreased readmissions, days in hospital, mortality, and increased knowledge and adherence. However, these improvements were not demonstrated in all studies (e.g. Jaarsma et al., 1999; Ekman et al., 1998; Rich et al., 1995). Research indicated that patients with moderate to severe heart failure experience great difficulty travelling to receive interventions delivered in health care settings (Ekman et al., 1998). Therefore, interventions that are deliverable within the home setting may be more accessible to patients with severe or moderate heart failure. Interventions designed to improve adherence did demonstrate some success (e.g. Rich et al., 1996; Stromberg, 2001; Hershberger et al., 2001). However, in some instances improvements in adherence were short-term (Stromberg, 2001), and not all adherence behaviours targeted by interventions were influenced (Kasper et al., 2002). Compared to more multifaceted and resource-intensive interventions, simpler interventions also demonstrated improvements in outcomes. An intervention delivered within the hospital setting, prior to discharge and with no telephone follow-up, led to improvements in self-management (Koelling et al., 2005): and a centralised telephone follow-up study improved self-management, and reduced readmissions (GESICA Investigators, 2005). This demonstrated that interventions which are less resource-intensive to develop and deliver, may also have the potential to improve patients' self-management.

The majority of interventions were investigated as a whole, and, therefore, it is difficult to establish the contribution of specific components, and to identify which components produced greater improvements in outcomes (e.g. van der Wal, Jaarsma & van Veldhuisen., 2005). Thus, very little is known about how interventions actually influence patient behaviour (Molloy, 2005). Studies generally failed to incorporate a theoretical framework for the development and evaluation of interventions. Therefore, although significant improvements in end-points such as survival and hospitalisations were produced, it is impossible to identify what these outcomes are attributed to. It can only be inferred from such studies that a change in patient behaviour accounted for these types of changes in outcomes. Interventional studies which evaluated outcomes such as patients' adherence, were unable to identify the potential mediators that may have resulted in the outcomes observed following the intervention. The literature as it currently stands, therefore, provides a very limited knowledge base which can inform future research.

3.10 Implications for this Research Programme

Multifaceted interventions require a substantial amount of resources and finance, and traditional one-to-one teaching and home visits would require space, resources, and the expertise and time of health professionals. These interventions, therefore, would be not feasible within the limited resources available for this study. Patient education methods, such as written and computerised interventions, have demonstrated the potential to influence a range of outcomes, and have the advantage of being less resource-intensive and, therefore, more feasible. The development of techniques, such as touch screens and special keyboards, need to be incorporated in computer-based approaches, in order to increase their usability among the predominantly older heart failure patient population. To design such a computerised intervention would entail the input of specialised professionals and financial resources, which are beyond the remit of a PhD study.

In comparison, written information materials are more cost-effective, have the advantage of being easy to implement in health care services, and can be distributed to patients in their own homes. Furthermore, even if information booklets have a limited effect, they can be easily combined with other types of support in the clinical setting, such as one-to-one education with a nurse. The heart failure literature has an insufficient evidence-base to ascertain the effectiveness of written information materials on patient outcomes. It is, therefore, important to establish whether a booklet intervention alone can produce measurable improvements in heart failure patients' knowledge and self-management. This research programme aims to develop an informational booklet to provide patients with information about their illness and its self-management, and to evaluate whether this booklet is able to successfully influence patient outcomes.

A notable finding from the literature reviewed was that interventions did not draw upon models of behaviour change in their development and evaluation. Previous research has, therefore, been unable to provide guidance on the mechanisms of change, or predictors of behaviour which actually need to be targeted in interventions. This research programme aims to develop a booklet promoting heart failure self-management, which will be informed by the Theory of Planned Behaviour. This booklet will differ from atheoretical written materials, as it will include messages that target the cognitive predictors of behaviour identified by psychological models of behaviour change. This development in written patient education is discussed in greater detail in the following chapter.

3.11 Conclusions

It has been shown that heart failure patients lack knowledge, and that patients' performance of self-management is sub-optimal at best. While a range of interventions are available, the majority are not feasible within the resources available for this research programme. Written interventions can be easily incorporated into clinical practice, and provide a cost-effective alternative. This research programme will develop a written information intervention to improve knowledge and promote heart failure self-management. This research area could benefit from the use of health psychology theoretical approaches to identify potential predictors of behaviour, which can then be targeted in interventions, and which will extend our understanding about the effects of interventions on patients' self-management. This research programme will, therefore, utilise psychological models of behaviour change to inform the development and evaluation of the written information intervention for heart failure self-management.

Chapter Four: The Theory of Planned Behaviour

4.1 Introduction

This chapter will provide a review of the Theory of Planned Behaviour, the main theoretical framework used in this thesis. At the outset of this thesis, it was envisaged that a health professional intervention would be developed to implement guideline recommendations. However, a patient intervention was deemed more appropriate after evaluation of the findings from the first study. This chapter, therefore, is separated into two parts. The first part describes the Theory of Planned Behaviour (TPB) and its predecessor the Theory of Reasoned Action (TRA), and evaluates the usefulness of these models in the prediction of health professional behaviour. The second part discusses the application of the TPB to behaviour change interventions. In particular, studies which have utilised the TPB as the theoretical framework in the development of written interventions are discussed. This section provides the background to the theory-based booklet developed in this research programme to promote heart failure self-management.

Part I

4.2 Theory-Based Approaches to Understanding Health Professional Behaviour

As discussed previously, health professionals do not consistently practice according to clinical guidelines. A number of implementation interventions have been developed which promote clinical behaviour change, and in some instances these have been successful in achieving their aims. However, due to the atheoretical design of previous research, very little is known about the mechanisms through which implementation interventions influence behaviour. Researchers in this field are directing their attention to psychological models of behaviour change to improve understanding about clinical behaviour. These models identify modifiable factors which influence behaviour and could be targeted by interventions. It is hoped that these models may "bridge the gap between clinical guidelines and clinicians' behaviour" (Bonetti et al., 2003). Adopting a theoretical framework in implementation science provides several benefits. Most importantly, it will enable investigators to gain an insight into the mediators involved in changing clinical behaviour, and provide a much needed insight into the reasons why an intervention has achieved change or not (e.g. The Improved Clinical Effectiveness through Behavioural Research Group (ICEBeRG), 2006; Michie et al., 2005; Bonetti et al., 2003).

Several psychological models of behaviour change exist that have generated considerable interest and a substantial amount of literature. The majority of research using these models has focused on the behaviour of patients or healthy populations. There is a need, therefore, to establish whether these models can be utilised to understand the factors that predict the behaviour of health professionals. This line of enquiry is necessary as there may be differences in the cognitive processes that underlie the "purpose of protecting one's own health, compared to behaviours that are instigated to protect or enhance the health of someone else" (Walker, Grimshaw, & Armstrong, 2001, p.348).

The majority of behaviour change models are motivational or multi-stage in focus. Motivational models (e.g. Health Belief Model, Protection Motivation Theory, Social Cognitive Theory, TRA and TPB) typically set out to identify the variables that underlie decision-making, and assess their ability to predict behaviour. Multi-stage models (e.g. Transtheoretical Model, Health Action Process Approach) propose that the influences on behaviour vary according to the different stages in the model. Both sets of models could prove useful in the prediction and explanation of clinical behaviour change. However, the measures which classify individuals into stages of behaviour change in multi-stage models require further development (Armitage & Conner, 2000). Motivational theories give a clearer understanding of the social cognitive determinants of intention, particularly for theories such as the Protection Motivation Theory and the TPB (Armitage & Conner, 2000). Furthermore, motivational theories are able to predict behaviours at single points in time (Armitage & Conner, 2000). This study is not focused on the process of change over time; therefore, motivational theories would be more useful in this study for identifying the factors that influence health professionals' intention or actual behaviour.

In comparisons of the different types of motivational models, the TPB has emerged as the superior predictor of intention and behaviour (Conner & Norman, 1994; Quine, Rutter, & Arnold, 1998; Weinstein, 1993). The TPB and its predecessor the TRA, unlike other motivational theories, have been employed to understand a wide range of behaviours, and not solely patient health behaviours. These two models have also been more readily applied to the prediction and explanation of health professional behaviour. The main distinction between the TPB and TRA is that the TRA is applicable to behaviours directly under the 'volitional control' of an individual. The TPB was extended to include 'perceived behavioural control'. The addition of this construct improved the model's ability to predict behaviours that may not be under an individual's control. It would, therefore, be interesting to compare these two models to determine not only which model is more successful in the explanation and prediction of clinical behaviour, but also whether 'perceived behavioural control' is an important factor in the decision-making of health professionals.

The aim in the first part of this chapter is to provide an overview of the TRA, and the TPB, and to review the previous research employing the TRA and TPB to predict and explain clinical behaviour. However, while this chapter will touch upon some of the debates or issues that have emerged from the application of these models, it will not provide a full account of all these debates. Only those debates relevant to the utilisation of these models to the prediction or explanation of clinical behaviour will be discussed. The usefulness of the components of the models in explaining behavioural intention and the actual behaviour of health professionals will be discussed. In addition to the major components of the model, several authors have suggested a number of additional factors which they believe will increase the predictability of intention and/or behaviour for certain clinical behaviours. These additional constructs will also be evaluated in this chapter.

4.3 *The Theory of Reasoned Action*

Fishbein and Ajzen developed the innovative concept of concentrating on behavioural intention as the immediate antecedent to behaviour. Previous research had generally focused on the relationship between attitudes and behaviour, resulting in a large body of research which revealed that attitudes do not always predict behaviour (Wicker, 1969). It soon emerged that in order to predict behaviour as accurately as possible, other factors other than attitudes, had to be considered.

According to the TRA, intention is a measure of the likelihood that a person will engage in a given behaviour (Ajzen & Fishbein, 1980). The TRA claims that intention is always the primary and best predictor of one's subsequent behaviour (Ajzen & Fishbein, 1980; Fishbein & Ajzen, 1975), and the strength of intention will determine the likelihood of that behaviour being performed (Ajzen & Madden, 1986). The model is based on the premise that individuals who intend to perform a behaviour are more motivated to try, and, therefore, more likely to successfully carry out the behaviour. Figure 1 presents a diagram of the TRA.

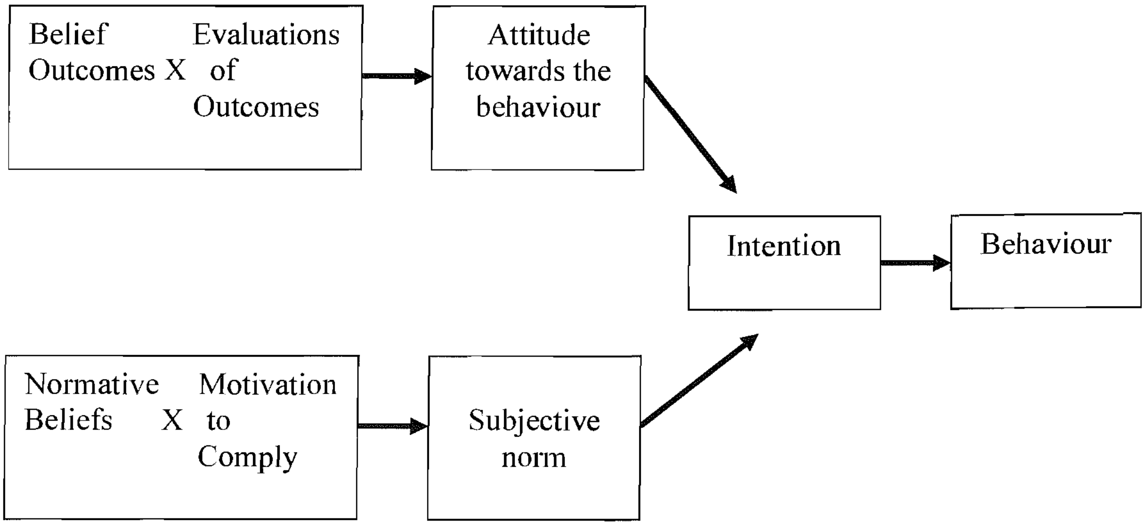

Figure 1. The theory of reasoned action.
Adapted from Ajzen and Fishbein (1980).

The model consists of two main constructs; attitude and subjective norm that jointly predict behavioural intention, the immediate antecedent of behaviour (Ajzen & Fishbein, 1980). Attitudes are an individual's overall evaluation of whether the behaviour is deemed favourable or unfavourable (Ajzen & Fishbein, 1980). The TRA states that attitudes arise from behavioural beliefs which comprise of belief outcomes and outcome evaluations. Belief outcomes refer to the consequences of carrying out the behaviour, and outcome evaluations are an individual's evaluations of the range of consequences possible from performing the behaviour. A measure of the strength of attitude towards a behaviour is obtained by multiplying 'belief outcome' by 'evaluation of the outcome'; the resulting products are then summed across all salient behavioural beliefs.

Subjective norm is an individual's perception of social pressure to perform the behaviour. Subjective norm is a function of normative beliefs and motivation to comply. Normative beliefs are based on the perceptions and possible reactions (approval or disapproval) of significant others towards the desired behaviour. Motivation to comply is a set of beliefs based on an individual's motivation to comply with the views of significant others (Fishbein & Ajzen, 1975). A measure of the strength of subjective norm is obtained by multiplying normative beliefs with motivation to comply; the resulting products are summed across all salient referents. The model states that external variables (e.g. demographic variables, self efficacy and risk) influence intention through the formation of attitudes and subjective norms (Fishbein & Middlestadt, 1989).

The relative influence and importance of subjective norms and attitudes will vary depending on the individual and behaviour. This will in turn influence the strength of the intention and the subsequent probability of performing the behaviour (Ajzen & Fishbein, 1980). Within the TRA, both subjective norm and attitudes are weighted in order to reflect the importance of the constructs to an individual (Ajzen & Madden, 1986). According to the TRA, behaviour is more likely to occur when an individual positively evaluates the outcome of behaviour, believes that significant others want them to perform the behaviour, and is motivated to comply with these significant others. Using this model, a health professional would implement a guideline if they evaluate it favourably (attitude) and believe that people important to them think that they should implement it (subjective norm).

The TRA is restricted to volitional behaviours. Only when a behaviour is under an individual's volitional control can an association between intention and behaviour be achieved. The TRA is based on the premise that behaviours of social relevance are under an individual's volitional control. An individual can, therefore, decide at will whether to perform the behaviour or not (Ajzen & Madden, 1986). Behaviours that require additional skills and resources or external opportunities deemed beyond the control of an individual, are outside the conditions established for this model (Sheppard, Hartwick, & Warshaw, 1988). In these circumstances, the TRA would be insufficient. This raises questions about the applicability of the TRA, as even the most mundane behaviours are sometimes reliant on factors beyond one's control (Ajzen & Madden, 1986).

4.4 Application of the TRA to health professional behaviours

Several studies were identified that used the TRA to predict or explain health professional behaviours. See table 4 for an outline of these studies.

4.4.1 Attitude

Attitude was found to be a significant predictor for all the health professional behaviours, with the exception of the documentation behaviour of nurses (Renfroe, O'Sullivan, & McGee, 1990). Attitude exerted a greater influence than subjective norm on physicians' intention to prescribe emergency contraception (Sable, Schwartz, Kelly, Lisbon, & Hall, 2006), nurses' intentions to use physical constraints (Werner & Mendelsson, 2001), nurses' intentions to adopt caring behaviours towards self-poisoning patients (McKinlay, Couston, & Cowan, 2001), and glove use by healthcare workers (Levin, 1999). Behavioural beliefs demonstrated the ability to discriminate between high/medium and low intenders to prescribe emergency contraception (Sable et al., 2006), and between nurses who adopted a more positive and less positive behavioural orientation towards self-poisoning patients (McKinlay et al., 2001).

4.4.2 Subjective Norm

Subjective norm was found to be a significant predictor for all the health professional behaviours, although only indirect subjective norm influenced physicians' prescriptions of emergency contraception (Sable et al., 2006). Attitudes generally are found to exert a greater influence on behavioural intention compared to subjective norms (O'Keefe, 1990; Conner & Norman, 1996). However, a number of studies reported the opposite (Lambert et al., 1997; Millstein, 1996; Renfroe et al., 1990). Despite great variation in the types and cost of antibiotics, Lambert and colleagues (1997) reported that normative considerations exerted a greater influence on intention to prescribe oral antibiotics than attitudinal considerations for all but one of the seven drugs investigated in their study. The authors suggested that the care management setting within which the physicians practised may have contributed to this finding. Physicians were not autonomous decision makers and management usually undertook decision-making. Consequently, the views of significant others, including the decisions of management, would have a considerable influence on physicians' prescribing behaviour.

Table 4. *Applying the TRA to predict behavioural intention and behaviour for health professional behaviours*

Authors	Behaviour	Significant predictors of behaviour	Variance in intention	Variance in behaviour	Additional variables
Sable et al. (2006)	Prescription of emergency contraception by physicians	Attitude[1] Indirect subjective norm	Not reported	No measurement	None
Werner and Mandelsson (2001)	Use of physical restraints by nurses on older people	Attitude[1] Subjective norm Moral obligation	48%	No measurement	Moral obligation
McKinlay et al. (2001)	Nurses and self-poisoning patients	Attitude[1] Subjective norm	66%	No measurement	None
Bunce and Birdie (1998)	Doctors request for autopsy. Investigation of the differences between senior doctors with a high level of control in their job and junior doctors with less control in their jobs.	*High job control* Attitude Subjective norm[1] *Low job control* Attitude[1] Subjective norm	*High job control* 61% *Low job control* 39%	No measurement	

[1] Most predictive of intention

Authors	Behaviour	Significant predictors of behaviour	Variance in intention	Variance in behaviour	Additional variables
Lambert et al. (1997)	Physicians prescribing behaviour	Attitude Subjective norm[1]	37%-81%po	TRA components not predictive of behaviour	None
Millstein et al. (1996)	Physicians provision of sexually transmitted disease education to adolescent patients	Attitude Subjective norm	15%	37% (self-report)	None
Levin (1999)	Glove use by healthcare workers	Attitude[1] Subjective norm	41%	70% (self-report)	None
Renfroe et al. (1990)	Documentation behaviour of nurses	Subjective norm	41.6%	15.2% (sample of medical notes)	None

[1] Most predictive of intention

4.4.3 Extensions to the Theory of Reasoned Action

The TRA is considered a very simple model and, therefore, attempts have been made to extend it to improve its predictability. Werner and Mandelsson (2001) included moral obligation to improve understanding of nurses' intention to use physical restraints on older people. The authors believed that nurses may encounter ethical dilemmas when making decisions about this type of behaviour. Moral obligation was found to make a small but significant contribution to nurses' intention to use physical restraints, adding to the prediction of intention by the TRA.

4.4.4 Other Influences on the Constructs within the Model

Demographic and professional: Another area of interest in the study of health professional behaviour is whether demographic and professional variables relate to the constructs within the TRA. This type of investigation provides insight into the impact of experience and training on the behavioural intention of health professionals. Sable and colleagues (2006) found demographic variables exerted no influence on doctors' prescribing behaviour. However, Werner & Mandelsson (2001) reported that older age was significantly associated with a weaker intention to use physical restraints, and education level was negatively related to attitude towards using physical restraints and to moral obligations. This indicates that nurses with higher levels of education had less positive attitudes and less strong moral obligations to use physical restraints.

Situational: Research has also investigated whether the characteristics of a situation influences the strength of behavioural intention. Nurses' behavioural intentions to use physical constraints was influenced by the situation (Werner & Mandelsson, 2001). Nurses had greater intention to use restraints with patients who refused to eat, removed feeding tubes, or had experienced numerous falls. In contrast, nurses had less intention to use restraints with wandering patients and with patients who would enter the nursing station and take medications. This indicates that behavioural intention to perform a specific behaviour can change due to small variations in the circumstances in which the behaviour is to be performed.

4.5 The Theory of Planned Behaviour

The theory of planned behaviour (Ajzen, 1991; Ajzen, 1985) extends the TRA by including a third predictive construct, namely perceived behavioural control (PBC). It became apparent that attitudes and subjective norms alone (TRA) were insufficient to explain behaviours not under volitional control. In such circumstances, even if an individual held a favourable attitude, and believed that important others approved the behaviour, lack of resources or opportunity could lead to a weak behavioural intention being formed. The performance of behaviour, therefore, depended on motivation and adequate control over the behaviour. Within the TPB, attention is given to the factors that may hinder or promote performance of behaviour by the inclusion of PBC (Ajzen, 1988). PBC is influenced by beliefs regarding the perceived ease or difficulty of performing a behaviour, reflecting past experience, experiences of acquaintances and friends, as well as anticipated barriers and facilitators (Sideridis, Kaissidis, & Padeliadu, 1998; Ajzen & Madden, 1986). Beliefs about resources and opportunities may also be viewed as underlying PBC (Ajzen & Madden, 1986). Behavioural control is on a continuum from complete control to minimum control, with most behaviours falling somewhere in the middle (Ajzen, 1985). Figure 2 presents a diagram of the TPB.

The TPB states that PBC arises from control beliefs and perceived power. Control beliefs are an individual's perception of factors that may facilitate or inhibit the performance of behaviour. Control beliefs comprise both internal (e.g. information, personal deficiencies, skills, abilities, emotions) and external (e.g. opportunities, dependence on others, barriers) factors. Perceived power refers to the ability of a particular control factor to facilitate or inhibit performance of the behaviour. An individual's beliefs about the facilitators and inhibitors are multiplied with the beliefs about the 'perceived power' to determine the strength of PBC.

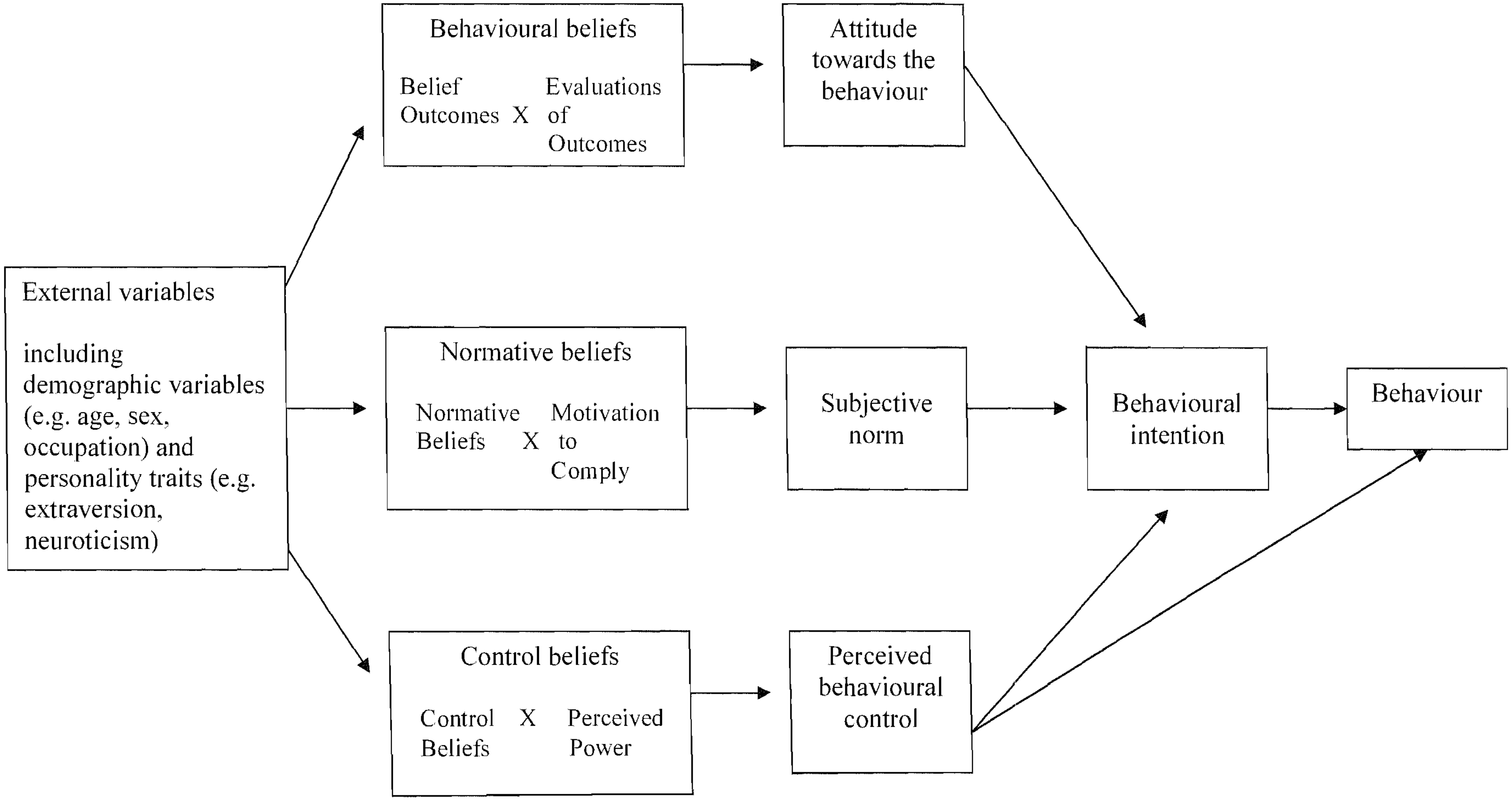

Figure 2. The theory of planned behaviour

Adapted from Conner & Sparks (1996)

PBC exerts both a direct and indirect effect through behavioural intention to influence behaviour. PBC may exert a direct effect on behaviour, but only if an individual's perceived control is an accurate reflection of actual control over the behaviour (Ajzen, 1991). Thus, the TPB proposes that intention is predicted by attitudes, subjective norm and PBC, and behaviour is predicted by behavioural intention and PBC. As with the TRA, the importance of attitude, subjective norm, and PBC in the prediction of intention, is expected to vary across behaviours and situations (Ajzen, 1991). According to the TPB, the more favourable an individual's attitude and subjective norm towards a behaviour, and the greater the PBC, the stronger the individual's intention to perform the given behaviour (Ajzen, 1991).

PBC has been found to improve the prediction of intention and behaviour (Conner & Sparks, 1996; Schifter & Ajzen, 1985; Ajzen, 1991; Ajzen & Madden, 1986). Ajzen (1991) has stated that 'perceived behavioural control should become increasingly useful as volitional control over behaviour declines' (p. 185). Madden, Ellen and Ajzen (1992) assessed the effectiveness of the TRA and TPB to predict ten behaviours that varied in the degree of control that participants would feel over the behaviour. It was shown that, for behaviours that were highly controllable, there were slight or non-existent differences between the TRA and TPB in predicting behavioural intention. However, for behaviours not under volitional control, the addition of perceived control significantly improved the prediction of behavioural intention for these behaviours. This finding is expected, as behaviours that are less under control are more likely to be affected by external controls (Netemeyer, Burton, & Johnston, 1991; Richard & Dedobbeleer, 1994).

4.6 Application of the TPB to Health Professional Behaviour

Several studies were identified that used the TPB to predict or explain health professional behaviours. See table 5 for an outline of these studies.

4.6.1 Attitudes

Attitude was found to be a significant predictor of all but five of the behaviours investigated. This suggests that on most occasions the favourable or unfavourable evaluations that health professionals held about their clinical behaviours significantly contributed to the formation of behavioural intention. In Watson and Myers (2001) study attitudinal considerations were found to exert a greater influence compared to subjective norm and PBC for nurses' intention to use gloves during clinical practice. Edwards and colleagues (2001) uncovered the complexity of attitudes held by health professionals regarding clinical behaviours. It was discovered that although nurses held overall positive attitudes towards administering opioids for pain relief, they also held some negative behavioural beliefs. As both direct and indirect attitude were significant predictors of behavioural intention, these negative behavioural beliefs may explain nurses' reluctance to administer opioids.

In addition, qualitative data was found to support quantitative findings produced from the application of the TPB. Liabsuetrakul, Chongsuvivatwong, Lumbiganon, and Lindmark (2003) investigated why obstetricians continued to administer multiple doses of antibiotics after a caesarean section, when a single dose had been proven and reported to be effective. Attitude was found to be a significant predictor in obstetricians' behavioural intention to use a single dose regimen, but was not found to be predictive of the other four aspects of prophylaxis use. Qualitative interviews conducted as part of this study found that although obstetricians held positive attitudes towards antibiotic prophylaxis, they held negative views towards the single dose regimen. Obstetricians feared the consequences of post-caesarean infections and commented that they would feel 'guilty' if they administered a single dose regimen, and the patient developed an infection. Furthermore, Walker and colleagues (2001) found that behavioural beliefs were able to distinguish between GPs who did or did not intend to prescribe antibiotics for patients with sore throats. GPs who intended to prescribe antibiotics were more likely to agree that antibiotics were cost-effective and could reduce the risk of minor complications.

Table 5. *Applying the TPB to predict the behavioural intention and behaviour for health professional behaviours*

Authors	Behaviour	Significant predictors of intention	Variance in intention	Variance in behaviour	Additional variables
Foy et al. (2005)	Assessment appointment referral and contraceptive supplies prior to discharge following abortion	*Assessment* Subjective norm[1] *Contraceptive* PBC[1]	*Assessment* 27% *Contraceptive* 34%	*Assessment* Intention[2] and PBC 15% *Contraceptive* Not predictive	None
Legare et al. (2005)	Prescription of hormone therapy by GPs and gynaecologists	Power of control beliefs[1] Moral norm Role belief	Not reported	No measurement	Moral norm Role belief
Puffer and Rashidian (2004)	Nurses and offering smoking cessation advice	Attitude PBC	40%	No measurement	Past behaviour Demographic variables
Tabak and Ozon (2004)	Nurses' and patients privacy	Attitude	13%	PBC[2] and attitude 15% (self-report)	Demographic variables

[1] Most predictive of intention
[2] Most predictive of behaviour

Authors	Behaviour	Significant predictors of intention	Variance in intention	Variance in behaviour	Additional variables
Liabsuetrakul et al. (2003)	Intention to comply with five aspects of antibiotic prophylaxis	*Overall* Subjective norm *Five aspects* Subjective norm Attitude for single dose only	*Overall intention* 56% *Five aspects* 25%-70% (administration after cord clamping only non-significant- 25%).	Medical records Correlation between intention and behaviour ranged from 0.16 to 0.50	None
Jenner, Watson, Miller, Jones, and Scott (2002)	Hand hygiene among health care workers	Attitude Personal responsibility[1]	79% of cases correctly classified	Intention[2] and PBC[2] 87% (self-report)	Personal responsibility Barriers

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[1] Most predictive of intention

[2] Most predictive of behaviour

Authors	Behaviour	Significant predictors of intention	Variance in intention	Variance in behaviour	Additional variables
Limbert and Lamb (2002)	Guideline for management of acute asthma Guideline for use of antibiotics	Acute asthma Subjective norm[1] Attitude PBC Antibiotics Attitude[1] PBC Subjective norm	Acute asthma 58% Antibiotics 52%	No measurement	None
Edwards et al. (2001)	Nurses administration of opioids for pain relief	Attitude Subjective norm PBC[1]	39.1%	No measurement	None
Watson and Myers (2001)	Nurses use of gloves	Attitude[1] PBC Amount of anticipated contact with blood	45%	Intention and perceived time availability 60% (self-report)	Perceived barriers

[1] Most predictive of intention

[2] Most predictive of behaviour

Authors	Behaviour	Significant predictors of intention	Variance in intention	Variance in behaviour	Additional variables
Walker et al. (2001)	GPs prescription of antibiotics for sore throat	Attitude Control beliefs	48%	No measurement	Past behaviour
O'Boyle, Henly, and Larson (2001)	Hand hygiene in nurses	Subjective norm Control beliefs	56%	Intention did not predict behaviour (observed behaviour)	Intensity of activity
Godin, Naccache, Morel, and Ebacher (2000)	Nurses adherence to universal precautions for venipunctures	Perceived barriers[1] Subjective norm Personal normative belief	68%	Intention[2] and PBC 28% (self report)	Personal normative belief Role belief Habit and past behaviour
Levin (1999)	Glove use in healthcare workers	Attitude PBC	74%	Intention 66% (self report)	Perceived risk

[1] Most predictive of intention

[2] Most predictive of behaviour

Authors	Behaviour	Significant predictors of intention	Variance in intention	Variance in behaviour	Additional variables
Conner and Hayood-Everett (1998)	GP referral of Asians and non-Asians to mental health services	Asians Normative beliefs Motivation to comply Non-Asians Outcome beliefs	*Asians* 24% *Non-Asians* 26%	No measurement	Past behaviour
Bunce and Birdie (1998)	Doctors request for autopsy-differences between high and low job control	High job control Attitude Subjective norm[1] Low job control A Subjective norm[1] PBC	High job control 61% Low job control 43%	No measurement	Past behaviour

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[1] Most predictive of intention

[2] Most predictive of behaviour

Authors	Behaviour	Significant predictors of intention	Variance in intention	Variance in behaviour	Additional variables
Millstein (1996)	Physicians provision of sexually transmitted disease education to adolescent patients	Attitudes Subjective norm PBC[1]	27%	Intention and PBC 39% (self-report)	None
Nash, Edwards, and Nebauer (1993)	Nurses intention to conduct pain assessments	Attitude Subjective norm PBC[1] (only significant)	21%	No measurement	None

[1] Most predictive of intention
[2] Most predictive of behaviour

4.6.2 Subjective Norms

The role of subjective norms in explaining health professional behaviours using the TPB represented a very different picture from the findings discussed earlier using the TRA. About half of the studies reviewed found that subjective norm significantly contributed to behavioural intention (Liabsuetrakul et al., 2003; Edwards et al., 2001; Foy et al., 2005; O'Boyle et al., 2001; Conner & Heywood-Everett, 1998; Millstein, 1996). Subjective norm was the only significant predictor of obstetricians' behavioural intention to use antibiotic prophylaxis, and was consistently a significant predictor for all five aspects of antibiotic prophylaxis use investigated (e.g. whether or not antibiotics were used, whether single or multiple doses were given) (Liabsuetrakul et al., 2003). During qualitative interviews, obstetricians mentioned that they were informed during medical training of the evidence that a single dose was as effective as multiple doses. However, during residency training they observed the behaviour of other obstetricians who gave multiple doses. They subsequently chose to do the same and had not changed their practice since, thus explaining why obstetricians' behaviour was strongly influenced by subjective norms.

Subjective norm was also a significant predictor of nurses' intention to administer opioids for pain relief (Edwards et al., 2001). The majority (80%) of nurses perceived that significant others thought that they should administer opioids to patients in pain. However, variation was found in the nurses' reported motivation to comply with the wishes of referents. Nurses were more likely to comply with the wishes of patients (94%) and medical staff (86%), than with those of their colleagues (68%) and patients' families (54%). Therefore, within this setting, the influence of patients and medical staff was greater on nurses' behavioural intention to administer opioids for pain relief.

A number of studies have supported previous findings in the literature which indicate that social influence is less important than attitude or PBC in predicting behavioural intention (Godin & Kok, 1996), and is the weakest component of the TPB. In some research this has resulted in the removal of the subjective norm construct from analysis (e.g. Sparks, Shepherd, Wieringa, & Zimmermans, 1995), as was found in some studies predicting health professional behaviour (e.g. Puffer & Rashidian, 2004; Levin, 1999). Puffer and Rashidian (2004) suggest that the tensions between current clinical practice and recommendations from a guideline, may influence the role that subjective norms play in determining behavioural intention. They suggest that subjective norm and behavioural intention were not correlated in their study because the guideline they investigated was not controversial. The authors propose that the views of others (subjective norm) are more likely to be influential when a guideline provokes disagreement. It does appear that in using the TPB to investigate the intention of health professionals to perform behaviour, subjective norms are either likely to have a very significant effect on behavioural intention, or a very limited to non-existent effect. The circumstances in which either could occur have yet to be fully investigated.

4.6.3 Perceived Behavioural Control (PBC)

This construct was found to be fairly successful in the prediction of clinical behaviour. The influence of PBC is potentially very important, especially as it can directly influence behaviour provided it is an accurate representation of control. Bunce and Birdie (1998) demonstrated that the effects of PBC were more prominent in junior doctors' intention to order autopsies than among more senior doctors with greater autonomy. This supports the underlying assumption of the TPB that the importance of PBC increases as volitional control over a behaviour decreases (Madden et al., 1992). Millstein (1996), compared the predictive ability of both the TRA and TPB, and found that the inclusion of PBC reduced the relative predictive abilities of both subjective norm and attitude. In this study, the perceived control that physicians' felt over performing the behaviour was greater, compared to the social influences or their attitudes towards the behaviour. Nash, Edwards, and Nebauer (1993) and Walker and colleagues (2001) found that PBC could distinguish between health professionals who were 'intenders' or 'non intenders'. Walker and colleagues (2001) reported that there were significant differences in the control beliefs of GPs who did or did not intend to prescribe antibiotics for sore throat. It was found that doctors who intended to prescribe antibiotics were more likely to prescribe on the request of a patient. The addition of PBC within the TPB highlighted the importance of perceived control on health professionals' behavioural intention for a variety of behaviours.

Foy and colleagues (2005) found that PBC was the best predictor of clinical staff intention to offer contraceptive supplies, prior to discharge to women following an abortion. Interviews conducted with health professionals found that most responses related to PBC were organisational constraints such as limited time and resources.

These findings have practical implications in the implementation of guidelines. The construct of PBC could be useful in identifying potential barriers to changing behaviour in accordance with clinical recommendations.

4.6.4 Constructs Added to Improve the Predictive Ability of TPB

Ajzen (1991) proposed that the TPB could be extended by the inclusion of additional predictors. It is the intention here to present the additional predictors utilised by researchers in this field and to discuss their contribution to the prediction of behavioural intention.

Moral constructs and responsibility: Ajzen (1991) suggested that in certain circumstances constructs such as moral obligation or responsibility, may exert an influence on intention alongside the other constructs of the model, thus adding to the predictive ability of the model. Legare and colleagues (2005) investigated the influence of moral norm on physicians' intention to prescribe hormone therapy. Moral norm was conceptualised as a physician's personal convictions, sense of guilt, and ethics. This construct significantly contributed to the prediction of intention, suggesting that physicians' personal values might promote a decision to prescribe hormone therapy.

Perceived responsibility was added to the TPB as a potential predictor of health care workers' intention to perform hand hygiene behaviours (Jenner, Watson, Miller, Jones, & Scott, 2002). The authors described perceived responsibility as 'the locus of responsibility for maintaining both one's own health and the health of others' (Jenner et al., 2002). The authors predicted that health care workers who perceived themselves as being responsible for the prevention of cross-infection were more likely to engage in hand hygiene behaviours. The contribution of perceived responsibility towards behavioural intention was significant and independent of attitude, subjective norm, and PBC.

Role belief: Role belief refers to the perceptions of behaviour expected from groups in society (Triandis, 1977). It specifically relates to beliefs concerning what someone like them would do (Legare et al., 2005). Role belief was found to significantly predict the intention of doctors to prescribe HRT (Legare et al., 2005).

Perceived Barriers: Two studies used the construct of barriers as an extension to the TPB in explaining hand hygiene behaviours (Jenner et al., 2002; Watson & Myers, 2001). The barriers construct has been found to improve the predictive value of the TPB (Basenquist, 1992; Horne, 1994; Hounsa, Godin, Alihonou & Valois, 1993). Perceived barriers (e.g. time availability, number and location of sinks) were found to classify another 7% of hand hygiene cases correctly (Jenner et al., 2002). However, the results were not significant, and none of the barriers (e.g. time availability, number or location of sinks) significantly correlated with intention or were predictive of intention (Jenner et al., 2002). In contrast, Watson and Myers (2001) reported that the perceived barriers of amount of blood anticipated, and time constraints, explained a further 3.5% of nurses' behavioural intention to wear gloves for hygiene purposes, with this reaching significance for the barrier blood anticipated.

From a theoretical perspective, external control factors such as perceived barriers would form part of PBC (Conner & Norman, 1996). This was supported by findings that two of the barriers in the study by Jenner and colleagues (2002), and one of the barriers in the study by Watson and Myers (2001), were significantly correlated with PBC. However, the significant contribution of the barrier anticipated contact with blood was not found to be correlated with PBC (Watson & Myers, 2001) and, therefore, exerted an influence on intention independently of PBC. This could, therefore, indicate that the construct of PBC might be insufficient to explain all barriers that may influence health professional behaviour.

Perceived risk: Perceived risk was used as an additional predictor to extend the TPB for predicting the behavioural intention of glove use in health care workers (Levin, 1999). Perceived risk is defined as the evaluation of an individual's personal degree of risk as compared to others. This construct could be a useful predictor for glove use, as any situation involving the potential for blood or body fluid exposure could lead to catching a blood borne disease. Perceived risk was a significant predictor of glove use intention although the contribution made was minimal. Thus, health care workers who perceived themselves to be at less risk for blood borne diseases were less likely to report wearing gloves.

Past behaviour: There has been considerable debate about the influence of past behaviour on current or future behaviour. It has been suggested that many behaviours are determined by one's past behaviour (Sutton, 1994), and a number of studies have found past behaviour to significantly predict future behaviour (e.g. Mullen, Hersey, & Iverson, 1987; Godin, Valois, & Lepage, 1993). However, according to the TPB, past behaviour should be encapsulated within the concept of PBC (Ajzen, 1991). The influence of past behaviour was investigated on nurses' intention to offer smoking cessation advice (Puffer & Rashidian, 2004), GPs' behavioural intention to prescribe antibiotics for sore throat (Walker et al., 2001), doctors' request for autopsy (Bunce & Birdie, 1998), and GPs' referral of Asian and non-Asian patients to mental health services (Conner & Haywood-Everett, 1998). Past behaviour was not found to be a significant predictor of nurses' intention to offer smoking cessation advice (Puffer & Rashidian, 2004). This fully supports the TPB, which proposes that all influencing factors will impact on behavioural intention via the constructs in the theory. In contrast, the proportion of variance explained by the TPB in the behavioural intention of GPs to prescribe antibiotics significantly increased, when a measure of past behaviour was included (Walker et al., 2001). The influence of past behaviour on intention has been found to vary according to differences in patient's characteristics, or in health professionals' level of experience. For instance, past behaviour significantly increased the variance explained for intention to refer Asian patients to mental health services, but not for non-Asian patients (Conner & Haywood-Everett, 1998). In addition, past behaviour independently predicted intention to request an autopsy among senior doctors; this, however, was not the case with lower grade doctors (Bunce & Birdie, 1998). The authors suggest that perhaps a greater level of habitual behaviour existed for doctors in more senior roles (Bunce & Birdie, 1998). These findings provide evidence that past experience may be important in predicting future intention to perform clinical behaviours.

4.6.5 Other Influences on the Constructs in the Model

According to the TPB, factors such as demographic characteristics would influence intention and behaviour by influencing the determinants of behaviour (Ajzen, 1991). Puffer and Rashidian (2004) found that demographic characteristics did not independently contribute to the behavioural intention of nurses to offer smoking cessation advice, thus providing support for this assumption. In contrast, Tabak and

Ozon (2004) discovered that several demographic factors correlated with attitude, such as 'number of hours worked', 'educational level', and 'professional seniority'. These findings indicate that the constructs of the TPB may differ on many professional characteristics. This is a pertinent finding, as it suggests that contrasting interventions may be required to target health professionals with different professional profiles when implementing guidelines.

4.7 Comparisons of the TRA and TPB

A number of studies were conducted to determine which model had the greatest predictive power. Bunce and Birdi (1998) compared the capacity of the TRA and TPB to predict intention to order autopsies among doctors with varying levels of job control. The authors reported that the inclusion of PBC significantly improved the amount of variance explained in junior doctors' intention (lower job control), while this effect was not observed for more senior doctors with greater autonomy. This supports previous findings which demonstrate that the differences between the TPB and TRA are slight or non-existent for behaviours with higher controllability (Madden et al., 1992). Millstein (1996) compared the ability of the TPB and TRA to predict physicians' behaviour with regard to educating adolescent patients about the transmission of HIV and other sexually transmitted infections. This study found the TPB model to be significantly superior, as it explained an additional 12% of variance in behavioural intention. Likewise, Watson and Myers (2001) reported that the TPB had greatest predictive power when explaining the behavioural intention of nurses' glove use. However, Levin (1999) compared the ability of three theoretical models, the TRA, TPB, and TPB extended with perceived risk, to predict the behaviour of glove use among health care workers. This study found that all three models provided a good fit for the data, with the TPB extension producing the overall better fit for the data. However, this study did not find that the TPB extended model explained significantly more variance than the TRA and TPB.

4.8 Using the TRA and TPB to predict behaviour

Within the TRA and TPB, intention is the most immediate and important predictor of behaviour. However, intentions are not perfect predictors of behaviour. Several meta-analyses of empirical studies employing the TRA have shown that it predicts on average 19 to 38 per cent of the variance in behaviour (Sutton, 1998). Only a few studies incorporating the TRA measured behaviour, and of these the variance explained ranged from 15.2% to 70% (see table 4). Two studies managed to collect data for actual clinical behaviour (O'Boyle et al., 2001; Renfroe et al., 1990). Renfroe and colleagues (1990) predicted a smaller amount of variance in behaviour compared to self-report measures, and O'Boyle and colleagues reported that intention did not account for hand hygiene behaviours in nurses. It is worth noting that often the percentage of variance explained in TPB studies adopting self-report measures of behaviour is greater compared to those employing objective measures (Armitage & Conner, 2001).

Two separate meta-analyses concluded that intention and PBC account for 27% (Armitage & Conner, 2001) and 34% (Godin & Kok, 1996) of the variance in behaviour. A small number of studies have investigated the prediction of actual clinical behaviour by intention and PBC. Watson and Myers (2001) found that their extended TPB model explained 60% of the variance in self-reported glove use in nurses, with intention and barrier regarding time availability, being significant predictors of behaviour. Although a direct path between PBC and behaviour was not found, the barrier of time availability was highly correlated with PBC, leading the authors to suggest that the barrier should be considered a measure of PBC. This study, therefore, supported the model of the TPB. Similarly, Jenner and colleagues (2002) found that intention and PBC were significant predictors of hand hygiene behaviours among health care workers.

However, not all the studies have fully supported the TPB, Levin (1999) reported that only intention was a significant predictor of self-reported glove use among health care workers, while Foy and colleagues (2005) found that PBC was the strongest predictor of unit compliance for clinical staff offering assessment appointments to women after an abortion. Clinical staff reported that organisational factors were the greatest barrier to implementing this guideline, thus supporting this finding. Regarding the second guideline that Foy and colleagues (2005) considered, neither intention nor PBC were found to predict unit compliance for offering contraceptives to women before discharge. O'Boyle (2001) also reported that intention was not predictive of observed hand hygiene behaviour; however, a measure of intensity of activity which quantified the activity of the nursing unit significantly predicted behaviour. The authors suggested that hand hygiene adherence was not determined by internal motivational factors. Overall, the findings for the predictability of actual behaviour by intention and PBC were mixed and consequently no firm conclusions could be drawn from the results.

4.9 Summary

The body of literature addressing the value of the TRA and TPB in predicting and understanding the behaviour of health professionals is continually growing. The literature reviewed in this chapter provides support for the applicability of the TRA and TPB to the prediction of health professional behaviour. Attitude and subjective norm were found to be significant predictors of all the behavioural intentions investigated using the TRA. For the TPB, attitude was a significant predictor for the majority of professional intention, and PBC was important for many of the behavioural intentions investigated for a variety of different professional behaviours. However, the picture for the construct of subjective norm was more mixed. These findings may be explained by previous research which has identified subjective norm as the weakest component of the TPB, and less important than PBC and attitude (Godin & Kok, 1996). Nonetheless, in some studies subjective norm was found to be the strongest predictor of behavioural intention, indicating that for some clinical behaviours social influence is very important (e.g. Liabsuetrakul et al., 2003; Edwards et al., 2001; Foy et al., 2005; Millstein, 1996). Further support for the applicability of the TRA and TPB in the prediction of health professional behaviour was provided by the ability of the models to identify differences in salient beliefs between groups of health professionals who were 'intenders' or 'non-intenders' (Walker et al., 2001; Nash et al., 1993; McKinlay et al., 2001). No firm conclusions can be drawn about the impact of different additional predictors added to the TPB, as they have only been investigated in a limited number of studies. On occasion, the additional predictors were found to improve the predictability of the model. However, even within the few studies investigating similar predictors, such as past behaviour and perceived barriers, the findings have been inconsistent.

The complexity of changing health professional behaviour was highlighted by the discovery of some interesting, albeit preliminary findings. The constructs of attitude, subjective norm, and PBC were found to differ in strength among different types of health professionals. This finding, if confirmed in subsequent research, has implications for the development of interventions to implement guidelines. Perhaps different components of an intervention need to target the various psychological factors, influences, and barriers that may be encountered by different types of health professionals within the same healthcare setting. The picture for implementing guidelines is complicated further by findings that the constructs of the TPB and TRA differed on some demographic (e.g. age) and professional (e.g. educational) variables (Werner & Mandelsson, 2001; Tabak & Ozon, 2004). This suggests that interventions may also have to take into consideration variations in the education, experience, and demographic characteristics among staff in the healthcare setting.

Consideration must be given to the factors that may have influenced the reliability of the findings. It was very difficult to compare studies of professional behaviour as they were conducted across multiple professional groups and medical specialisms. Even the four studies investigating hand hygiene behaviour (Levin, 1999; O'Boyle et al., 2001; Watson & Myers, 2001; Jenner et al., 2002) differed in the populations studied and the findings produced. The countries within which the studies had taken place were also diverse, including America, Australia, UK and Thailand. Walker and colleagues (2001) found that attitude and perceived control were significant predictors of intention in predicting doctors' prescribing behaviour, contradicting findings by Lambert and colleagues (1997), that social normative factors exerted greater influence on physicians' prescribing behaviour. The variability in these findings may be attributable to the very different health care settings in which the studies took place. Lambert and colleagues (1997) conducted their study in a care management setting where decision-making about clinical matters was undertaken by management, thereby reducing the autonomy of health professionals. Therefore, it was likely that the results of this study would differ from those of Walker and colleagues (2001) which took place within a primary care setting of the UK, where GPs have greater autonomy, increasing the likelihood that their behaviour will be influenced by motivational factors.

A common methodological challenge evident in guideline implementation research is the availability of data on actual clinical behaviour. Relatively few of the studies were able to measure actual behaviour, therefore, most relied on self-report measures. The very nature of self-report measures in itself raises concerns. Previous research has indicated that they may result in an overestimation of intention and behaviour (Abraham, Clift & Grabowski, 1999), and often the variance explained in behaviour among studies using self-report measures is greater (Armitage & Conner, 2001). However, even when performance data can be obtained it is often less than desirable. Foy and colleagues (2005) found that performance data was only available at the organisational level and not the individual level. It is thus unlikely that the studies discussed in this chapter were able to accurately investigate the relationship between behaviour and its most immediate predictors.

4.10 TPB and Factors Influencing Health Professionals' Communication of the Management Plan

The studies within this chapter have provided some evidence of the power of the TPB to predict the behaviour of health professionals. It is extremely likely that the implementation of guidelines will be influenced by non-motivational factors such as time, skills, and resources. Therefore, the TPB would be more able than the TRA to account for these influences. The construct of PBC has already proven its ability to take into account external constraints such as organisational factors and resource implications (Foy et al., 2005). However, the aim of the first qualitative study in this research programme was not to investigate the predictive power of the TPB, but to use the TPB as a framework for identifying the salient beliefs of health professionals towards the NICE guidelines for heart failure management, and the guideline 'communicating the management plan' to patients. The identification of these salient beliefs along with barriers would then inform the design of an intervention to implement the heart failure guideline recommendations.

Part II

4.11 TPB and Behaviour Change

This part of the chapter discusses the application of the TPB to behaviour change interventions, and reviews studies which have utilised the TPB as a theoretical framework in the development of written information interventions. Previous research into heart failure interventions and written information interventions has been atheoretical, resulting in very little insight into the strategies that are most successful in improving patient outcomes. The UK Medical Research Council (MRC) recommends the establishment of a theoretical basis for the development and evaluation of interventions (MRC, 2000). The TPB provides a theoretical framework which identifies modifiable factors that influence behaviour and could be targeted in interventions. A number of stages have been proposed for the development of an intervention based on a social cognition model. These stages include: (1) definition of target behaviour and population; (2) identification of modal salient beliefs; (3) establishment of the relative contribution of components in the model; (4) identification of beliefs that distinguish between intenders and non-intenders, and (5) development of intervention based on previous stages and evaluation (Sutton, 2002; Fishbein & Ajzen, 1975). According to the TPB, behaviour change occurs by influencing the underlying attitudinal, normative and control beliefs of the behaviour. The stages described above identify the beliefs that are most predictive of the target behaviour, and ultimately the beliefs that could be targeted in interventions.

However, very few studies adopt the TPB as a basis for an intervention (Hardeman et al., 2002). At the time of commencing this study, a systematic review of TPB interventions identified only 12 interventions based on the theory, four of which were found to change behaviour (Hardeman et al., 2002). The review was unable to identify strategies that could be used to influence the components of the theory. Indeed, Michie and Abraham (2004) stated that there is a lack of evaluated strategies identified as promoting behaviour change within the framework of the TPB. Persuasive communication has been proposed as a strategy by the founders of the TRA for influencing the beliefs underlying behaviour (Fishbein & Ajzen, 1975), and this method along with information giving were the most frequently adopted in TPB interventions (Hardeman et al., 2002). This research programme proposes to develop a theory-based booklet. The TPB could potentially be very useful in the development of written interventions designed to influence behaviour. The application of the TPB to written information interventions therefore will be discussed below.

4.12 TPB-based Written Information Interventions

Written information should, in addition to improving knowledge, attempt to positively influence attitudes and behaviour (Weinman, 1990). Evaluations of health promotion leaflets to promote safe sex, or reduce alcohol consumption, concluded that the majority of booklets did not incorporate messages targeting the modifiable cognitive predictors identified in research (Abraham, Krahe, Dominic, & Fritsche, 2002; Abraham, Southby, Quandte, Krahe, & van der Sluijs, 2007). Thus, the development of health education materials is not driven by developments in psychological research about the predictors of behaviour. Written information booklets could incorporate messages targeting the underlying attitudinal, normative and control beliefs underlying health behaviour. A small number of studies have utilised the TPB as the principal framework for the development and evaluation of written interventions, see table 6 for examples.

Table 6. *An overview of written interventions informed by the TPB*

Study, target behaviour and population	Intervention	Outcome
Hill, Abraham, and Wright (2007) Increasing exercise among adolescents	Persuasive text targeting attitude, normative beliefs, and PBC. Groups evaluated: (1) leaflet (2) leaflet plus extrinsic reward (3) leaflet and implementation intentions (4) control group	Each leaflet group increased behaviour compared to the control group. Improvements in intention, attitude, normative beliefs, and PBC for all leaflet groups. Change in behaviour partially mediated by intention and to a lesser extent PBC. Change in intention partially mediated by attitude, normative beliefs, and PBC.
Murgraff, Abraham, and McDermott (2007) Reduce risky single occasion drinking among moderate drinking students	Leaflet like intervention targeting attitude, subjective norm, and self efficacy. Also included implementation intentions	No change in behaviour or TPB components. Post hoc analysis found that action-specific self efficacy increased in males identified as risky single occasion drinkers at baseline. Small reduction in alcohol consumption in women identified as risky single occasion drinkers at baseline.

Study, target behaviour and population	Intervention	Outcome
Chatzisarantis and Haggis (2005) Increase physical activity in adolescents	Persuasive text targeting behavioural beliefs	Increased attitudes and intention. Change in intention mediated by attitude. Did not influence behaviour.
Kelley and Abraham (2004) Healthy eating and physical activity among older adults	Persuasive text targeting PBC and intention Also included Cognitive dissonance theory, Oettingen's theory of goal generation and goal setting	Increased PBC, intention and behaviour for healthy eating and physical activity. Change in healthy eating behaviour partially accounted for by intention. Change in physical activity behaviour not accounted for by intention or PBC. Gains in healthy eating and physical activity attributed to goal setting.
Armitage and Conner (2002) Reduce fat intake in hospital workers	Two different persuasive messages (1) targeting behavioural beliefs (2) targeting control beliefs targeted beliefs that could distinguish between intenders and non-intenders	Change in behaviour but only for participants with a high fat intake. The TPB could not account for this change in behaviour. Neither intervention influenced the components of the TPB.

Study, target behaviour and population	Intervention	Outcome
Quine and Rutter (2001) Quine, Rutter, and Arnold (2002) Increasing use of protective helmets in school-age cyclists	Targeted normative, behavioural and control beliefs. Targeted beliefs that could distinguish between intenders and non-intenders. Though listing also included to allow participants to elaborate on the message. This involved participants listing advantages, significant others who approved of the behaviour and ways to deal with barriers.	Improvements in underlying beliefs and an increase in intention and behaviour. Changes in behaviour accounted for by changes in beliefs.
Hoogstraten, de Hann, and ter Horst (1985) Return dental care application and health insurance members	Targeted behavioural beliefs	No behaviour change but attitudes increased. Behaviour was higher in the group which did not receive a persuasive message.

The results of the studies in table 6 indicate that written interventions based on the TPB have the potential to influence behaviour and/or the determinants of behaviour. Of the studies which conducted mediational analysis, the TPB was found to partially account for the changes in intention and behaviour (Kelley & Abraham, 2004; Hill et al., 2007). However, in one instance the TPB was unable to account for the behaviour change resulting from the intervention (Armitage & Conner, 2002). The authors suggest that behaviour change could be attributed to other effects of the leaflet not identified by the TPB. Two interventions produced improvements in the determinants of behaviour but not in actual behaviour (Chatzisarantis & Hagger, 2005; Hoogstraten et al., 1985). A plausible explanation for this finding is that the written interventions did not influence the volitional factors that translate intentions into actions (see below for further discussion). Chatzisarantis and Haggis (2005) compared the presentation of persuasive messages targeting either salient or non-salient behavioural beliefs for physical activity. Their study found that participants receiving persuasive messages targeting salient behavioural beliefs reported more positive attitudes and intentions. This suggests that written information targeting salient beliefs may be more effective than atheoretical written information in influencing the cognitive predictors of behaviour.

In a number of studies, the TPB was augmented by other strategies such as implementation intentions, goal setting, extrinsic rewards, and thought listing. The founders of the TRA and TPB state that the TPB is primarily a motivational model which concentrates on producing a desired intention (Ajzen & Manstead, 2007; Fishbein & Ajzen, 2005). However, motivation to perform a behaviour does not automatically lead to behaviour enactment (e.g. Orbell & Sheeran, 1998). The distinction, therefore, between a motivational and volitional phase would be advantageous (Heckhausen, 1991). The motivational phase, as already discussed, leads to the formation of an intention to perform a desired behaviour. To fully understand behaviour, post-intentional processes also referred to as the volitional phase must also be considered. The volitional phase requires individuals to develop strategies and plans which promote the enactment of behaviour (Gollwitzer, 1993; Heckhausen, 1991). Therefore, the use of other strategies such as implementation intentions could be used to facilitate the enactment of intention, when intentions alone are insufficient to promote behaviour (Ajzen & Manstead, 2007; Fishbein & Ajzen, 2005). Implementation intentions focus on the intention-behaviour gap (Ajzen & Manstead, 2007), and consist of plans of action which specify when, where, and how a particular behavioural intention will be enacted (Gollwitzer, 1999). Milne, Orbell, and Sheeran (2002) found that supplementing a motivational intervention based on the Protection Motivation Theory, with implementation intentions, increased exercise participation behaviour beyond the effects produced by the motivational intervention alone. However, within the TPB written intervention studies, implementation intentions did not influence behaviour or produce effects beyond those of comparison leaflet interventions (Hill et al., 2007; Murgraff et al., 2007). Nonetheless, the literature has provided ample evidence that implementation intentions can be effective in achieving goals and producing behaviour change (see Orbell & Sheeran, 2002; Gollwitzer & Sheeran, 2006). Implementation intentions can also be easily utilised in written interventions, and have the potential to assist individuals who have been unable to translate their intentions into behaviour. Kelley and Abraham (2004) identified goal setting in their booklet intervention as facilitating the enactment of intentions. It is suggested that goal theories could enhance the predictive ability of the TPB, and that PBC may be partly determined by levels of planning (Abraham & Sheeran, 2003). Therefore, including recommendations for goal setting or providing goal setting prompts in written interventions may improve their effectiveness.

As already outlined, the TPB provides little guidance on how to change the underlying beliefs predicting behaviour. However, persuasive communication has been suggested as a method to change beliefs (Ajzen & Manstead, 2007; Fishbein & Ajzen, 1975). Models such as the Elaboration Likelihood Model (Petty & Cacioppo, 1986) identify central and peripheral routes to information processing. The latter relies on the evaluation of information according to the characteristics of the message, such as credibility and source. However, the central processing route is used when readers are motivated to think about the information presented, and can lead to attitude change. Developers of TPB booklets have, therefore, utilised methods such as thought listing and extrinsic rewards to encourage readers to engage with the content of the material, thereby promoting systematic processing. The utilisation of an extrinsic reward (quiz and prize) in the study by Hill and colleagues (2007) did not produce any effects on the TPB components over and above the theory-based leaflet alone. However, the adoption of a similar strategy, alongside a leaflet targeting identified predictors of condom use, produced more positive changes in the cognitive antecedents of condom use compared to the leaflet alone and no leaflet groups (Krahe, Abraham, & Scheinberger-Olwig, 2005). Written interventions based on the TPB have the potential to influence behaviour and the cognitive determinants of behaviour. Additionally, written interventions can also incorporate volitional and persuasive techniques to further enhance the effectiveness of these interventions.

4.13 TPB Written Intervention to Promote Heart Failure Self-management

Previous research in heart failure has identified that patients' self-management of heart failure is sub-optimal (van der Wal, Jaarsma, & van Veldhuisen, 2005). No previous literature has adopted the TPB to predict heart failure self-management behaviours. However, the theory has already accumulated considerable support in its ability to predict and understand behaviour (e.g. Armitage and Conner, 2001; Godin & Kok, 1996). Furthermore, the TPB has been adopted to predict behaviours such as regular physical activity and strength training in older adults (Dean, Farrell, Kelley, Taylor, & Rhodes, 2007; Courneya, 1995), physical activity and healthy eating after a cancer diagnosis (Andrykowski, Beacham, Schmidt, & Harper, 2006), dairy product consumption by older adults (Kyungwon, Reicks, & Sjoberg, 2003), and consuming a low fat diet (Povey, Conner, Sparks, James, & Shepherd, 2000). These behaviours are similar to those which need to be adopted in heart failure self-management. Heart failure patients have been found to be unaware that certain behaviour changes are required within the self-management regimen (van der Wal, Jaarsma & van Veldhuisen; Ni et al., 1999). Therefore, it cannot be assumed that patients receiving the booklet intervention will have formed an intention to perform self-management behaviour. The TPB, which is primarily a motivational theory, would enable the booklet to target salient beliefs and amenable factors, identified by the model, to encourage patients who have not formed a strong intention to change behaviour to do so. Moreover, strategies such as implementation intentions and goal setting could supplement the TPB intervention to assist patients who have formed intentions to perform self-management, but have not translated these into behaviour. Further research is needed to evaluate written information informed by the TPB, to test whether effects produced by theory–based booklets are beyond those observed for atheoretical written information. This thesis is the first to apply the TPB to written information promoting the self-management of heart failure.

4.14 Chapter Summary

After reviewing the literature, it is proposed that the TPB is the most useful theory to gain further insights into the motivational factors influencing health professional behaviour. This research programme will, therefore, utilise this theory to gain an insight into the beliefs and barriers identified by health professionals, in implementing the NICE guidelines for heart failure management, and communication of the management plan to patients. The TPB has also proved to be a useful framework to adopt in the development of written information interventions. This research programme will, therefore, also utilise the TPB to develop a theory-based written booklet intervention to promote self-management in heart failure patients.

Chapter Five: Methodological Chapter

5.1 Introduction

This chapter outlines, discusses, and justifies the use of the methodological approaches employed in the empirical work that follows. Both quantitative and qualitative approaches were considered appropriate within this research programme. Therefore, it is necessary to discuss the issues related to adopting a mixed methods programme of research. The final sections of this chapter focus on the particular methodologies employed within this research programme.

5.2 Mixing Qualitative and Quantitative Methodologies

Health psychology researchers have a variety of research methodologies at their disposal, encompassing both qualitative and quantitative paradigms. The combination of these methods would be useful for health psychology research (Abraham & Hampson, 1996). However, the prospect of combining qualitative and quantitative methods has resulted in considerable debate. This debate stems from differences in ontology (nature of reality), epistemology (nature of knowledge about reality) and methodology between the two paradigms. Some of these differences are outlined below.

Quantitative methodologies stem from the ontological position of the existence of one truth and one objective reality which is separate from the observer. This independent reality is knowable (realist) and can be measured and explained scientifically. Quantitative research attempts to present a static reality by quantifying and measuring psychological characteristics in an attempt to develop universal laws. The researcher is an objective observer who does not influence, and is not influenced by, the phenomenon being studied. In contrast, qualitative methodologies stem from the ontological perspective of the existence of multiple truths and realities, which are constructed by people. Therefore, many realities exist and are knowable through our conceptual frameworks (relativist). The emphasis in qualitative research is on the exploration of the process and meanings created by people of a dynamic reality. This method does not claim that findings are universal and replicable. The researcher is used as an instrument to collect information and participates and/or becomes immersed in the phenomenon being studied. The findings created are developed mutually between researcher and the researched, and these multiple perspectives are included in the findings.

Many diverse views exist about the possibility of mixing methods from these paradigms. These views vary from the philosophical to the technical level. At the philosophical level, purist support the 'incompatibility thesis' and argue that research approaches are so closely bound to their mutually exclusive epistemological positions, that any talk of combining or mixing the approaches is pointless (Smith, 1983; Smith & Heshusius, 1986). Researchers who regard both methodologies as useful may also consider the paradigms as incommensurable (e.g. Masse, 2000). This perspective represents a top-down approach to viewing research methods and suggests that differences at the ontological level also filter down to the research tools and methods associated with the approach (Morgan, 2007). Thus, the choice of methods for a research study begins with the chosen ontological position and this determines the design and research tools to be utilised.

The dichotomous representation of methodologies has been challenged by those who suggest that it obscures the diversity of methods available within each paradigm and is a barrier to their integration (Hammersley, 1992). This view stresses that research methodologies do not just fall neatly into the two paradigms but instead involve a range of positions which are not parallel and do not differ in kind but emphasis (Hammersley, 1996). Indeed, it has been proposed that methodologies could be placed on a continuum of research objectives (Casebeer & Verhoef, 1997).

Decisions to employ a research method are not always based on their philosophical underpinnings. Instead researchers may select a method for technical or practical reasons (e.g. resources available) (Sale, Lohfeld, & Brazil, 2002; Hammersley, 1996). Pragmatists argue that both methods can be used in a single study. Pragmatism is not committed to one paradigm, but instead focuses on the most appropriate methods for the investigation. From this perspective, the research question drives the decisions for the methods to be employed (Tashakkori & Teddlie, 2003), and those most suited are selected. This approach advocates the precedence of technical decisions, and views research methods as tools to aid understanding of the world. At this technical level, the combination of both approaches becomes a possibility. This is the stance that I take in this thesis. It must be noted that the technical position does not suggest that philosophical issues are unimportant, but that they should be marginalised (Bryman, 2006). Indeed philosophical issues should not be overlooked, as this may lead to philosophical assumptions being violated (Yardley & Bishop- in press). For example, researchers may employ research methods incorrectly, or conclude their findings in a manner which conflicts with the philosophical assumptions of the method.

Mixing methods enables the researcher to benefit from the different strengths of each approach, balance out their weaknesses, and facilitates a more comprehensive account of the research phenomenon (Sale, et al., 2002). Foss and Ellsefen (2002) suggest that a mixed methodology provides knowledge at macro and micro levels. The researcher can benefit from the broader view provided by quantitative methods, and the deeper insight provided by qualitative methods, thereby, producing two different but non-competing types of knowledge.

'Mixed methods' has been defined as 'research designs using qualitative and quantitative data collection and analysis techniques in either parallel or sequential phases' (Tashakkori & Teddlie, 2003, p.11). Hammersley (1996) proposes three ways in which research methods can be mixed:

1. Triangulation: Here, the findings from qualitative and quantitative methods are checked against each other to help confirm and validate research findings. For example, findings from a questionnaire may be compared to findings from ethnographic observation.
2. Facilitation: Here, one method acts as a foundation/preliminary stage for another method. For example, findings from qualitative interviews may assist in generating hypotheses for a quantitative study.
3. Complementary: Here, both approaches produce information which complements one another. For example, quantitative research may confirm causal relationships and qualitative research could provide insight into these relationships in a natural setting.

Mixed designs should only be used when necessary and appropriate and not due to the perception that using more and different methodologies is better (Barbour, 1998). Criteria have been established to guide researchers wishing to adopt mixed designs, ensuring that the approach is justified and well explained. Leech and Onwuegbuzie (in press) propose that mixed methods designs are a function of three dimensions:

1. Level of mixing- whether methods are partially or fully mixed. Fully mixed designs incorporate qualitative and quantitative components across the research objectives, type of data, type of analysis, and type of interference. Partially mixed designs are those that only mix methods at one stage of the research process, for example at the interpretation stage.
2. Time orientation- whether methods are conducted sequentially or concurrently
3. Emphasis- whether methods used are equal in status, or one is more dominant than the other, for addressing the research question.

A number of typologies have been developed as a means of guiding researchers to identify appropriate mixed method research designs. There is a distinction in the literature between mixed model or mixed method designs. Mixed model designs combine methods within and across the research process, whereas mixed method designs comprise of phases where different methods are used. In regards to this thesis, the level of mixing was consistent with a mixed method design. This research programme consisted of mini studies which answered different research questions. It was not the intention at any stage in this thesis to mix methods to address a particular research question. From the typology of mixed methods developed by Leech and Onwuegbuzie (in press), the research design used in this thesis most closely resembles a partially mixed sequential dominant status design.

In regard to time orientation, a sequential framework was adopted during this research programme, as different research questions and objectives were important during different stages of the research programme. During this thesis an intervention strategy to communicate information about heart failure to patients was chosen, designed, and modified according to patient feedback, and then evaluated in a RCT. The research objectives in this thesis were:

1) To explore the views, and beliefs, and barriers of health professionals to the implementation of the NICE guidelines for heart failure, and the communicating the management plan guideline
2) To develop a theory-based booklet intervention to promote heart failure self-management which took into account heart failure patients beliefs' and recommendations
3) To evaluate the effectiveness of the theory-based booklet on patient outcomes

The different objectives during the thesis lent itself to different methodologies. The overarching aim of this thesis was to answer the question 'Are theory-based patient education materials more effective in improving patient knowledge, and influencing the cognitive predictors of behaviour?' Therefore, the final quantitative study which addresses this research question takes precedence. With regards to emphasis, the quantitative approach in this thesis is the dominant method. A post-positivist lens was, therefore, appropriate for this thesis as the quantitative data was prioritised.

Qualitative methods were used for the first and second research objectives. Thematic analysis was chosen to analyse the qualitative data, as a more abstract and subjective interpretation offered by grounded theory and interpretative phenomenological analysis would not be useful for the practical purpose of guiding the selection and development of an intervention. The advantage of qualitative methods is that research does not begin with a set of predetermined possibilities. Little previous research had investigated doctor-patient communication in heart failure and the application of theory to heart failure self-management. Therefore, qualitative methodology enabled a wider exploration of the research topic, with participants able to provide a range of different views. Within this research programme, the two qualitative studies formed the basis for the theory-based intervention.

The sequential framework enabled a process of facilitation where research questions addressed in one phase of the study then contributed to the knowledge base in another phase of the study. For example in this thesis, the justification for developing a theory-based booklet was drawn from findings in the first study, while the findings from the second study were used to optimise the theory-based booklet tested in the final study.

5.2.1 Qualitative Methods Used in the Research Programme

The TPB was used in this research programme to develop an intervention. This required a different methodology from conventional studies which have used the TPB to predict intention and behaviour. The TPB was used in interview format for the first study to identify health professionals' views. This enabled participants to present their personal views and allowed greater exploration without being limited to the components of the model. This first qualitative study provided an understanding of the healthcare context, and factors and processes which facilitated or inhibited the implementation of clinical guidelines. This led to an understanding of current service provision, and laid the foundations for the development of the intervention. The importance of qualitative work before designing an intervention is discussed in the literature (see Eccles, Grimshaw, Campbell, & Ramsay, 2003; Freemantle, Wood, & Crawford, 1998), as it enables idea generating. Furthermore, interventions based on an assessment of potential barriers are more likely to be effective (Grimshaw et al., 2001; Centre for Reviews and Dissemination, 1999).

There are a great variety of methods for data collection and analysis in qualitative research. Both focus groups and interviews could be appropriate methods of eliciting information about the views of patients and health professionals. While interviews gather data from individual participants, focus groups bring people together to discuss a particular topic. Focus groups generate data that is different from individual interviews; the very nature of people sharing and discussing their views enables a clearer insight into the cultural values and group norms that exist for the topic under discussion (Kitzinger, 1995). Focus groups have been utilised in research identifying health professionals' views (e.g. Barnes et al., 2006; Hanratty et al., 2002), and heart failure patients' views (e.g. Bosworth et al., 2004; Bennett, Cordes, Westmoreland, Castro, & Donnelly, 2000; Simpson, Farris, Johnson, & Tsuyuki, 2000). However, there were a number of practical issues that made interviews a more viable option for this research programme. Arranging a mutually convenient time for all interested health professionals could prove very problematic due to their limited availability and differing schedules. Also, finding a site to conduct the focus group could be costly, and requesting potential participants to travel to an external site for the study may discourage participation. Heart failure patients in particular have stated that they find it difficult to travel to hospital appointments, or attend heart failure management interventions delivered in a healthcare setting (see Rogers et al., 2000; Ekman et al., 1998). Alongside the practical difficulties of conducting focus groups, data generated from focus groups and interviews may differ. Meaning is created via the social process in focus groups (Wilkinson, Joffe, & Yardley, 2004). Thus, the group processes and social interaction shape the views presented by individuals. A consensus may emerge from the group, however, this may not be important to all members and may not be reflective of individuals' own views (Krueger, 1994). Moreover, in focus groups, health professionals may be unwilling to disclose honest views that conflict with the acceptable public response to evidence-based practice. Running focus groups within secondary care would result in health professionals with pre-existing relationships forming the groups. This might further hinder individuals from expressing views that may be professionally undesirable. Conducting interviews would allow individuals to discuss in-depth the issues that are most important to them, and provide a comprehensive view of the topic from their perspective without the influence of others. Interviews would also facilitate the expression of minority views that might not be presented in a focus group discussion. Therefore, interviews were seen as a more appropriate and practical method of data collection, and one which would not discourage busy health professionals and heart failure patients from participating.

Semi-structured interviews would be used because they encompass the advantages of both structured and open interviews. They have the advantage of being structured around an interview schedule, but also allow the interviewer some flexibility to ask for clarification or elaboration, and to pursue ideas generated in the interview. The structure of the interviews provides some comparability during data analysis, and the openness of the interviews enables the interviewee to express their views, experiences, and concerns (Arksey & Knight, 1999).

It is possible to analyse the data from interview transcripts in a number of ways. Approaches such as interpretative phenomenological analysis and grounded theory offer a more subjective or abstract interpretation of the data. This type of understanding would not prove so useful for the practical purpose of developing an intervention. The two most appropriate analyses for identifying both health professional and patient views would be content and thematic analysis. However, both methods have very different associated epistemologies. Although content analysis deals with qualitative data, it stems from the realist and positivist approach and is concerned with providing a numerical description of the text. Thematic analysis on the other hand is based on the interpretive and constructivist approach, and is concerned with indexing data. The main limitation of content analysis is that it ignores the context in which words occur (Joffe & Yardley, 2004). As a consequence, the analysis only provides information about the frequency with which words occur, and does not consider whether the meaning associated with the word was similar each time. Thematic analysis does take the contexts in which words occur into consideration, "adding the advantages of the subtlety and complexity of a truly qualitative analysis" (Joffe & Yardley, 2004). Furthermore, the researcher can decide whether consideration will be given to the frequency of themes, with more frequent themes being analysed in greater depth, or whether the focus of the analysis will be primarily on the meaning derived from particular contexts of thought. Thematic analysis, in this research programme, was used to describe the experiences and meanings of participants.

Qualitative methods were utilised for the identification of patients' salient beliefs regarding heart failure self-management. The TPB was used as the theoretical model to drive data collection and analysis. To obtain patients' salient beliefs, open ended questions were used according to the criteria proposed by Fishbein and Ajzen (1975). This enabled the identification of positive and negative outcomes (attitude) and the factors which hindered or facilitated the performance (PBC) of self-management behaviours. Content analysis is the chosen method in TPB studies for identifying the salient beliefs of people, and priority is given to the more frequently occurring salient beliefs (Godin & Kok, 1996). However, in this programme of research thematic analysis was used to identify heart failure patients' salient beliefs to self-management behaviours. This method was utilised because the purpose of identifying patients' salient beliefs in this study differed to the majority of other TPB studies. Conventionally, salient beliefs are identified to construct indirect items in a TPB questionnaire; however, the purpose of this study was to incorporate patients' beliefs into a theory-based self-management book. Therefore, thematic analysis enabled a more in-depth exploration of patients' beliefs which would prove more useful for the development of the booklet and, as mentioned above thematic analysis could also give consideration to the frequency of beliefs identified. It would appear that for this programme of research, thematic analysis would provide the more thorough analysis of the data and, therefore, was the chosen data analysis method for the qualitative investigations.

It was felt that cognitive interview methods were the most appropriate to test the usability of the booklet developed in this research programme. Cognitive interviews are based on cognitive models of information processing (Jobe, 2003) and are frequently used to develop and improve questionnaires. The main objectives of these methods is to gain an insight into the thought processes used by respondents to interpret a question, understand information, and then report an answer (Collins, 2003). These types of covert processes may be inaccessible by other interview methods. Researchers using these methods can identify sources of error due to wording of questions, format, and order of questions, and this can then drive the revision of questionnaire items. Others have used this approach to test the usability of online health information, patient communication systems, and interactive patient education systems (Sillence, Briggs, Harris, & Fishwick, 2007; Griffith, Sorenson, Jennings-Grant, & Fowler, 2005; Holzinger, 2002). Therefore, these cognitive interview methods could be useful in pre-testing written materials. The key methods of cognitive interview methods that are applicable to this thesis are discussed further below.

The two key techniques in cognitive interviewing are think aloud interviews, and probing questions. The think aloud method involves individuals verbalising all their thoughts while engaged in a task (Gilhooly & Green, 1996). Newell and Simon (1972) proposed that this method enabled an insight into the cognitive processes used by individuals, and accessed information held in people's short term memory. The researcher in this method has a passive role, they may prompt participants to keep talking but will not ask questions or provide direction to participants. The advantages of this method are that the process is respondent-led, free from interview-imposed bias, and open ended (Collins, 2003). However, this undirected format may prove difficult for participants and may result in participants talking about irrelevant topics. Participants may also feel burdened by this process, as identifying and justifying their thoughts requires intensive effort. Collins (2003) suggests that a limitation of this method is its reliance on verbal reports, therefore, disadvantaging individuals who are less articulate and who may find it difficult to verbalise their thoughts. Finally, it is suggested that not all cognitive processes are accessible to individuals, as some can happen so quickly that they leave no trace in working memory (Tourangeau, Rips, & Rasinski, 2000).

Probing questions are more retrospective and are designed to clarify a respondent's thoughts after they have completed a task (such as fill in a questionnaire). The interviewer asks specific questions to elicit how the respondent answered questions and understood the information presented. The researcher is engaged in a more active role as they deliver probes. Probes may be concurrent and retrospective. Concurrent probes are asked shortly after a participant has completed a subsection of a task, and retrospective probes are asked after completion of the full task. It is indicated that retrospective reports can elicit information about how respondents answered questions (Taylor, 2000). However, individuals may be unable to remember retrospectively exactly what they were thinking while completing the task (Taylor, 2000). The concurrent approach enables an individual to identify their cognitive processes more proximally, and thereby reduces the possibility of recall bias.

Probes may be scripted or created spontaneously in response to a participant (Willis, DeMaio, & Harris-Kojetin, 1999). Scripted probes are prepared in advance, which enables standardisation across interviews. Spontaneous probes are generated during the interview and can be in response to participant reactions during the task. Spontaneous probes are particularly useful as it is unlikely that all anticipated outcomes are identified before the commencement of testing education materials and questionnaires. The interviewer driven nature of probing questions can make the interview process easier for respondents, and prevent irrelevant discussions (Collins, 2003). A disadvantage is that there is a potential for bias, as probes may lead respondents to provide certain types of responses. This thesis used a combination of scripted and spontaneous probes, enabling the researcher to benefit from a standard format across interviews, and to respond to cues during the process.

Cognitive techniques have been used in the development and refinement of questionnaires for use in older adults and palliative samples (see Frank, Flynn, & Rothman, 2001; Jobe & Mingay, 1990; Murtagh, Addington-Hall, & Higginson, 2007). Murtagh and colleagues (2007) used think aloud, and probing questions, to identify inconsistencies and difficulties encountered by respondents with end-stage renal disease, in completing a questionnaire designed to measure symptoms and distress. This study found that respondents had difficulty understanding terms used in questionnaire items, such as nausea and problems with urination. The findings generated from this study were used to refine the measure. This study demonstrated that cognitive interview methods can be used in older and ill health patient populations.

It was decided for this thesis, that both the think aloud and probing questions would provide the most complete description of participants views of the booklet. In questionnaire design, the think aloud method can identify respondents understanding of words. It is suggested that in questionnaires, participant misunderstanding may be a result of questionnaire developers overestimating the level of understanding of the target group (Dillman, 2000). This type of understanding in the development of written patient information would be useful to ensure that information was comprehended by readers. Furthermore, this method would enable an understanding of individuals' understanding and decision making, in response to the interactive aspects of the booklet, such as the lifestyle contract, and diaries. This could help to determine whether these interactive elements are useful to the target population. It was felt that cognitive interviews lend themselves to pre-testing written materials and could identify individuals' perceptions of content and problems in reading, comprehension, and organisation.

5.2.2 *Quantitative Methods Used in the Research Programme*

There are a variety of experimental and quasi-experimental designs that can be used to determine the effectiveness of an intervention on patient outcomes. Both RCT trials (see McPherson, Higginson, & Hearn, 2001) and quasi-experimental designs (e.g. Dunn, Steginga, Rose, Scott, & Allison, 2004; Serxner, Miyaji, & Jeffords, 1998) have been used to evaluate patient education materials. The research design generally considered the 'gold standard' is the RCT (Cochrane, 1979). Quasi-experimental and RCT designs share similar characteristics, such as treatments / interventions and outcomes, however, the key distinguishing factor of the RCT is the random assignment of treatments / intervention. Random allocation ensures that different intervention groups are equivalent in the distribution of known and unknown factors that may have an influence on outcome, thereby reducing selection bias and establishing comparable groups (Jahad, 1998). The absence of random assignment in quasi-experimental designs threatens the internal validity of the study. The task confronting the researcher who uses quasi-experimental design is separating the effects of the intervention from those due to initial non-comparability between groups. The researcher has to identify the specific threats to valid causal inference that random assignment would rule out, and then in some way deal with these threats.

Quasi-experimental designs that could be appropriate for this research programme are controlled before and after studies (untreated control group design with pre-test and post-test design), and uncontrolled before and after studies (one-group pre-test and post-test design). The uncontrolled before and after study design collects data from the same study site before and after an intervention has been delivered. Any observed changes or differences in the data after the delivery of the intervention are attributed to the intervention. However, within this study design, the differences found cannot be confidently attributed to the intervention, as measures have not been taken to rule out other factors that may have influenced a change. Therefore, the effects of the intervention may be overestimated (Eccles et al., 2003). In a controlled before and after study, the researcher attempts to identify a control population that is comparable to the study population. It is hoped that a control group with similar characteristics to the study population may also experience the same trends and changes as the study group (Centre for Reviews and Dissemination, 1994). Any difference found between the data for the control and study populations is ascribed to the intervention. Therefore, the controlled before and after study makes it possible to rule out more threats to internal validity and has the stronger evaluative design. However, the main issue with this latter design is the difficulty in identifying a comparable control group (Centre for Reviews and Dissemination, 1994). Even when a comparable control group is identified, there are likely to be differences in baseline performance. The comparisons, therefore, rely on non-equivalent groups that differ in many ways from each other, in addition to the presence of a treatment being tested. Grimshaw, Campbell, Eccles, and Steen (2000) suggest that this imbalance between control and study groups may raise questions about whether both the control and study groups will experience similar trends or changes, and whether these two groups can be compared.

The question arises that if RCTs are the gold standard then why do researchers use quasi-experimental designs? Researchers may choose to adopt a quasi-experimental design due to insufficient sample size, practical issues (e.g. lack of resources), and ethical concerns (e.g. withholding a form of treatment from patients) or likelihood of contamination (see Dunn et al., 2004; Stephenson & Imrie, 1998; Black, 1996). Dunn et al (2004) decided that randomisation procedures were inappropriate in their study evaluating the effectiveness of radiation therapy video education, due to concerns about possible contamination. The site of patient recruitment would have made it impossible to prevent intervention participants from interacting with control participants. This increased the possibility of participants discussing the study with control participants, and control participants potentially requesting the patient education materials. Therefore, a longitudinal quasi-experimental design was utilised.

Considering the factors above, and the healthcare setting for this research programme, a RCT was considered possible and appropriate. This approach was chosen because the provision of patient lists identifying patients discharged from the Directorate of Elderly Care and Medicine at Southampton Hospitals Trust enabled recruitment of participants from outside the inpatient healthcare setting. This reduced the possibility of contamination that was more likely if recruitment occurred on patient wards. Other benefits to this study of a RCT included random assignment and blinding. The random assignment of participants enabled differences found in this study to be more confidently ascribed to the intervention, than differences between the groups. Blinding reduced the likelihood that participants' preconceived perceptions influenced their assessment of outcomes, and investigators perceptions of the groups influenced their management of participants (Jadad, 1998). A drawback to the RCT methodology is that a sufficiently large sample size was required to adequately power the trial. It was uncertain during the development of this trial whether a sufficient number of heart failure patients would participate. Therefore, to maximise data collection, control participants were randomised to receive either the NICE or control booklet after follow-up assessments. During analyses, this allowed a pre- and post-booklet analysis, which enabled a more direct comparison of the booklets in a larger sample. The provision of written information alone, via mailing, may not have been the most effective method of recruiting older adults onto the RCT. Research has suggested that older adults may perceive taking part in, or understanding, a research study too difficult (Harris, Smith, & Veale, 2005). A flexible approach is advocated in the literature for the recruitment of older adults, where information is presented in a variety of different ways to facilitate understanding (Harris et al., 2005). However, this was not feasible in the resources available.

Quantitative self-report outcome measures were used within the RCT to assess patient outcomes. Within these outcome measures, the TPB constructs were employed in their conventional method (Ajzen, 1991). It was, however, necessary to keep the questionnaires as short as possible to reduce the burden on heart failure participants, therefore only direct measures of the constructs were used. The utilisation of direct measures only is reported in the literature (Terry & O'Leary, 1995). The advantages of self-report outcome measures include: (1) generalisability possible; (2) researchers concepts used to measure constructs; (3) different question formats possible (e.g. closed, open, multiple choice); (4) quick to administer; (5) cost-effective and (6) enables large-scale research.

5.3 Summary

Both quantitative and qualitative research methods were appropriate and necessary for this research programme. Qualitative and quantitative methods were utilised sequentially to plan, develop, deliver, and evaluate a theory-based written intervention to promote heart failure self-management.

Chapter Six: Health Professionals' Views of the NICE Guidelines for Heart Failure Management: A Qualitative Study

6.1 Introduction

As discussed in Chapter 3, the Theory of Planned Behaviour has proved useful for identifying the attitudes, social influences, and perceived behavioural control that underlie health professionals' behavioural intention towards a clinical behaviour. The majority of studies have utilised the TPB primarily for establishing the utility of the model for predicting clinical or care behaviours. The TPB is also a model that proposes how to change behaviour, Fishbein & Ajzen (1975) propose that behaviour change occurs by influencing behavioural intentions. To influence intentions, it is necessary to identify the beliefs that form intentions, and either modify these beliefs or introduce new ones. The identification of these salient beliefs would form the first stage in planning a TPB intervention designed to implement guidelines. Previous research has established that salient beliefs differ between those individuals who intend or do not intend to perform a clinical behaviour (e.g. Walker, Grimshaw, & Armstrong, 2001), strongly suggesting that these beliefs underlie the intentions of health professionals. Research also indicates that interventions based on an assessment of potential barriers are more likely to be effective (Centre for Reviews and Dissemination, 1999; Grimshaw et al., 2001). The identification of salient beliefs and potential barriers will be used as a basis in this research programme for designing an intervention to promote implementation of the communication of the management plan guideline.

Studies that use the TPB to plan interventions require a different methodology and analysis from purely predictive studies. Survey questionnaire format is frequently employed when applying the TPB predicatively. This method involves presenting participants with a set of modal salient beliefs. These are normally selected from the most frequently cited beliefs obtained from conducting a small number of pilot interviews (Steadman, Rutter, & Field, 2002). However, this method may lead participants to rate or think about beliefs that are unimportant or irrelevant to them, and may restrict participants from presenting their own personal views and beliefs. Questions have arisen about whether the modal beliefs represented to participants are representative of participants' own beliefs.

The TPB has been utilised in an interview format (Marttila & Nupponen, 2000; Pinto, Colombo, & Gallani, 2006). The semi-structured interview approach is considered a 'more open and flexible channel than a survey questionnaire' allowing participants to express their own personal view (Marttila & Nupponen, 2000, p.959). Utilising this approach, Marttila and Nupponen (2000) found that the TPB was a useful and sensitive method for identifying the differences between patients' perceptions of outdoor aerobic exercise and everyday commuting activity. Pinto and colleagues (2006) employed the TRA in qualitative format to identify in-depth the salient beliefs of nurses towards using a pulmonary artery catheter. No previous research has employed the TPB in this way to explore the factors and beliefs related to the implementation of clinical guidelines.

The aim of this study was to identify the salient beliefs, social influences, and barriers that health professionals perceived when implementing the NICE guidelines for heart failure management. Due to no previous research utilising the TPB in an interview format to explore the implementation of guidelines or heart failure management, the interview schedule will also consist of questions that are not based on the TPB. This will enable an exploration of the factors and influences that are outside the boundaries of the TPB and its components. The analysis is divided into two parts; the first involves the identification of health professionals' salient beliefs regarding implementation of the NICE guidelines for heart failure management. The second part, involves the identification of health professionals' salient beliefs specifically related to the implementation of the communication of the management plan guideline.

6.2 Method

6.2.1 Subjects and Procedure

The Southampton and South West Hampshire Local Research Ethics Committee and the School of Psychology Ethics Committee, University of Southampton granted ethical approval for this study. The participants were health professionals, within primary and secondary care, who were involved in the clinical decision-making or care of heart failure patients. In primary care, an invitation letter was sent to 24 surgeries in the Eastleigh and Test Valley Primary Care Trust and 31 surgeries in the New Forest Primary Care Trust. A total of 66 health professionals were sent invitation letters, and information sheets (see appendix D), within the Elderly Care and Medicine Directorate and Cardiothoracic Directorate at Southampton University Hospitals NHS Trust. Participants wishing to take part in the study completed a consent form prior to the interview taking place.

The intention was to recruit similar numbers of participants from both secondary and primary care. However only a small number of GPs (n = 3) and practice nurses (n = 1) volunteered despite a large number of surgeries being contacted about the research. Likewise, it was intended to recruit participants from the Cardiothoracic Directorate; however, no health professionals within this directorate volunteered to take part in the study.

In total, 21 health professionals participated in the study; 8 consultants, 6 junior doctors (Specialist Registrars), 3 nurses, 3 GPs and 1 practice nurse. Due to the presence of only one practice nurse, the demographic information for this participant was combined with that of the nurses in secondary care. For a closer examination of their demographic and professional characteristics please refer to table 7.

Table 7. *Demographic and professional characteristics of health professionals*

Characteristics	Consultants (n = 8)	GPs (n = 3)	Junior doctors (n = 6)	Nurses (n = 4)
Demographic				
Mean age (years)	42	53	33.5	41.25
Age range (years)	36-55	45-61	30-37	30-54
Sex: Male	7	3	3	0
Female	1	0	3	4
Professional				
Time in present job (years)	8.2	20.6	1.75	6.25
Years since qualification (years)	18.6	28.6	10.6	14.5

At the beginning of the interviews, participants were asked a series of closed ended screening questions. These questions were used to ascertain whether health professionals had heard of the NICE guidelines for heart failure management, and whether they had read them, or were intending to read them. In circumstances where the health professional had not read the guidelines, they were presented with a summary of the key recommendations (see appendix A) prior to the interview, and were given time to read and reflect on these.

All participants took part in a semi-structured interview; these lasted between 20 to 90 minutes. The interview schedule (refer to appendix C) was designed with open-ended questions in order to elicit, in-depth, the factors that health professionals perceived as either inhibiting or promoting the implementation of the NICE guidelines for heart failure management in general, and the communication of the management plan.

The open ended questions based on the TPB included the views of health professionals (attitude), the views of significant others to the guidelines (subjective norm), the difficulties and factors that could assist in using these guidelines (perceived behavioural control), and whether health professionals intended to make any changes to their clinical behaviour (behavioural intention). The inclusion of additional questions not based on the TPB allowed health professionals to talk about factors influencing the implementation of the guidelines that were not captured by the TPB. Health professionals were also encouraged to mention any other factors that may have been important or relevant to the implementation of these guidelines.

6.2.2 Data Analysis

Thematic analysis, guided by the techniques proposed by Boyatzis (1998), was used to analyse the data. As no previous research had employed a semi-structured interview based on the TPB to explore the implementation of guidelines, an inductive approach was utilised to analyse the data, allowing the data to drive the analysis (Boyatzis, 1998). Due to insufficient numbers of health professionals in some groups, it was not possible to compare themes across the different health professional groups. All interviews were transcribed verbatim and each separate response by the interviewer and interviewee was numbered, along with the line of the text, in order to provide a clear referencing system. The analysis involved several steps. Firstly information was reduced by highlighting sections of the interviews that were relevant to the topics within the interview schedule. The researcher then became fully immersed in the raw data. Following Rubin and Rubin's (1995) thematic analytical model, the researcher read the data inquisitively, asking questions such as 'when, why, how and under what circumstances' (p. 265). The transcripts were reviewed repeatedly, moving backwards and forwards between transcripts, continually identifying and refining thematic labels. Categories were often combined or split and connections between interviews developed. Finally, the consistency of codes was determined by recoding an unmarked set of interviews. This enabled the identification of any inconsistencies among the themes. Any inconsistent codes identified were revised and re-tested for consistency and reliability. A coding document was produced to provide a clear description of the qualities of each theme (see appendix G & I for coding manuals). Diagrammatic representations were also produced to illustrate the central relationships and links between the core themes (see figures 3 & 4). The quotes presented in the results section are used to demonstrate 'normative' and 'minority' views. Prior to the presentation of quotes it is indicated whether the views are held by the majority, some, few, or one participant(s).

6.3 Results

6.3.1 Reading the NICE Guidelines

Just over half (57%, n = 12) of the health professionals had read the guidelines, one had only read the guidelines since hearing about the study, and five (24%) had only read the guidelines briefly. 10% (n = 2) of health professionals had read the summary recommendations, and 33% (n = 7) had not read the guidelines. The latter group consisted of all the nurses, two junior doctors and one consultant. Of these health professionals, more than half (n = 4) intended to read the guidelines, one health professional was unsure, and two had no intention. One health professional indicated that they had already read substantial research evidence and editorials based on the guidelines and, therefore, felt it unnecessary to re-read the same information in guideline format.

6.3.2 The NICE Guidelines for Heart Failure

The analysis generated six main categories of themes, (see appendix F for a summary of the analysis). These related to the views of health professionals towards the NICE and it's guidance, views of the NICE guidelines for heart failure, barriers to seeking and reading guidelines, factors that promoted or inhibited the implementation of guidelines, the outcomes achieved, and the other influences on clinical practice (see figure 3).

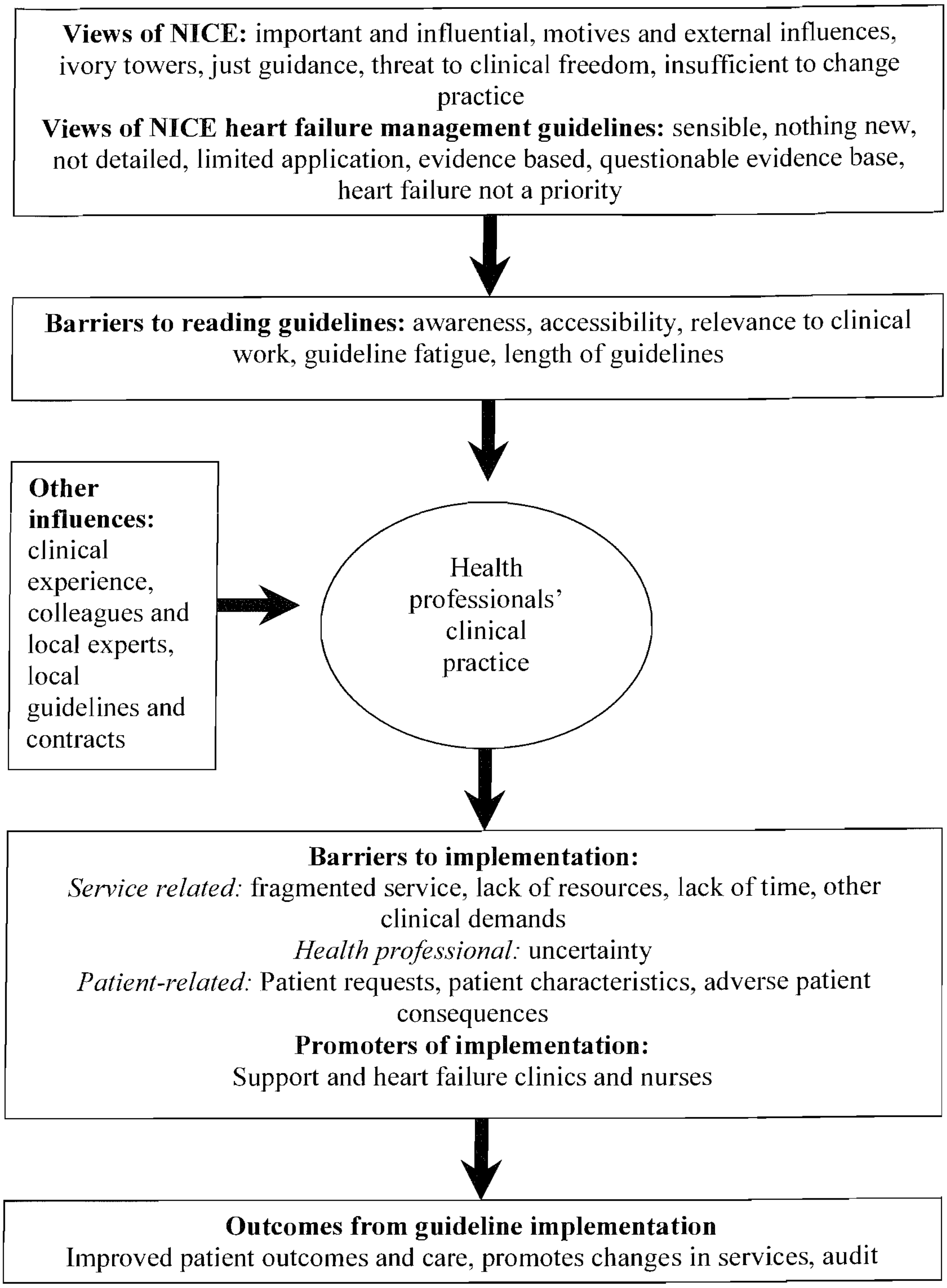

Figure 3. Themes related to the implementation of the guidelines for heart failure management

6.3.2.1 Views towards NICE and their guidelines.

A small number of health professionals' viewed NICE as a positive, important, and influential body in providing information about, and promoting evidence-based medicine. Several health professionals viewed NICE guidelines as providing support and guidance for managing illness. Some health professionals had used guidelines to guide their own clinical practice, or as a reference to ensure that practice was consistent with current evidence base. A few consultants and GPs reported that guidelines enabled uniformity of practice and provided a standard, to which they could compare their own clinical practice.

> *'It does help uniformity of decision-making, and no matter, whether they [patient] see a consultant or junior staff, at least the main cornerstones of treatment will be initiated' (Junior doctor, 17.38.4-6)*

A few health professionals expressed concern at the motives and external influences on NICE. These views were based on contentious decisions made by NICE in the past. As outlined by a consultant below, suspicions were aroused when a decision was made that was not supported by clinical evidence:

> *'You're always weighing up in your own mind, well you know, just what is the driver here, particularly when the evidence is a bit iffy' (Consultant, 7.38.9-10)*

Additionally, the relevance of NICE to the clinical environment was called into question. GPs perceived people employed by NICE as 'people in ivory towers' (GP, 9.68.2) who were removed from the clinical environment and, therefore, had no idea about the complexities of real clinical practice. Several doctors, consultants and GPs also suggested that guidelines were only relevant to an 'ideal world scenario rather than a real resource scenario' (Consultant, 13.53.2-3), and it was difficult to achieve the standards set by guidelines within the NHS service. The majority of health professionals were eager to emphasise that the guidelines were just guidance which were not intended to be applied rigidly in every situation, therefore, allowing clinical judgement. As reported by one Consultant:

> *'I mean like all guidelines... they are just guidelines and you've just got to be flexible and consider the patient. As long as people understand that you still have the freedom to exercise your own clinical judgement' (Consultant, 8.20.1-4)*

Some doctors and GPs considered guidelines as a threat to clinical freedom, that external forces increasingly drove medicine. Potential future developments were also discussed, such as the threat of legal proceedings if clinical practice departs from clinical recommendations. Finally, a few health professionals acknowledged that clinical guidelines were insufficient to change clinical practice.

> *'You don't get a sudden right angle turn in performance because a guideline is published' (GP, 15.83.4-5)*

6.3.2.2 Views towards the NICE guidelines for heart failure.

The majority of health professionals' perceived the guidelines as sensible and straightforward. For some health professionals the guidelines did not teach them anything new and their practice was already following what the guidelines outlined:

> *'I think on the whole they're very supportive and but it's like teaching your grandmother to suck eggs, really, I mean it's something that we're all already aware of...' (Consultant, 4.40.1-2)*

However, a few health professionals' viewed the guidelines as lacking detail, especially with regards to prescribing drugs and their titration, and palliation. These omitted areas were considered important in the management of heart failure. Some health professionals felt that the guidelines were limited in their application to clinical practice; they were only useful when dealing with patients who only had heart failure and applied more to younger patients. There were mixed views regarding the evidence base for the guidelines. A few health professionals viewed the guidelines as having a substantial evidence base, and used the guidelines to teach junior doctors about current best evidence-based practice. This was countered by views suggesting that guidelines were based on questionable evidence base. These health professionals suggested that only a small percentage of medical interventions were actually based on clinical evidence, with medical evidence generated by studies which included patients (e.g. younger and pure heart failure) not representative of the typical heart failure patient, and conducted in environments (e.g. abundant resources and manpower) not representative of the NHS. This was clearly described by a consultant:

> *'[The research studies] did warrant a fairly significant input of time and resources particularly in terms of beta blockers in heart failure... you don't see the input of resources that matches what was done for the patients in these studies' (Consultant, 5.26.3-7)*

A few senior doctors suggested that the evidence base for NICE was outdated and that new developments were emerging. Finally, a few health professionals observed that heart failure was not a priority within the NHS, and when patients had other co-morbidities these were sometimes considered more important.

> *'[Heart failure] I think is one of the conditions that is probably, we know it's there but it's not one that really takes priority... like cancer' (Nurse, 11.57.2-4)*

> *'We all sat round and we discussed each of the chronic care disease categories in turn, didn't discuss heart failure because there were other ones that took precedence' (GP, 20.40.6-8)*

6.3.2.3 Barriers to seeking and reading guidelines.

It was interesting to find that the majority of health professionals across both primary and secondary care lacked awareness about the guidelines for heart failure management. This was provided as a justification for not reading them and many advocated more active dissemination techniques.

> *'I didn't, (laughs) it's just when you showed them to me now that I even knew that they existed' (Nurse, 19.4.1-2)*

Participants experienced problems accessing guidelines, with a few health professionals being unaware of where to obtain guidelines or having insufficient computer experience to access guidelines online. The actual process of obtaining the guidelines was considered lengthy and time consuming. The relevance of guidelines to clinical practice was also discussed. One GP mentioned how the guidelines were not always relevant to primary care, as GPs did not always have a diagnosis to work with:

> *'If someone comes into your general practice and says 'I'm a bit short of breath on the stairs doctor', that's what you start with in general practice... people don't come in and say 'I've got heart failure' (GP, 15.75.5-7)*

Nurses' viewed guidelines as more applicable for the clinical work of doctors, and junior doctors' judged guidelines as more relevant for senior members of staff, as they were more responsible for decision-making.

> *'I suppose they (senior house officers) don't really need to read them (guidelines)... [because] it should be seniors that are making decisions about it (heart failure)' (Junior doctor, 16.32.7-9)*

The majority of health professionals mentioned guideline fatigue; there were numerous guidelines for each condition from a number of local or national sources. This made it difficult for health professionals to keep up to date with all available guidelines. The length of guidelines was also a barrier, guidelines were difficult and time consuming to read, and not user friendly if required for reference.

6.3.2.4 Barriers and factors that promote the implementation of guidelines. Barriers to implementation could be separated into those regarding the service, health professionals, or patients. Service related barriers referred to the fragmented service that was currently available for managing heart failure. This resulted in numerous services and health professionals being involved in the management of heart failure, as illustrated below:

> *'Heart failure is being managed by all sorts of people in primary care, secondary care, it's all a bit of a mess because there's a lot of it about, so everybody does a bit' (Consultant, 7.24.4-6)*

The interface between primary care and secondary care was not always effective, with health professionals in primary care being unaware of decisions and treatments proposed or implemented in secondary care. This hindered the successful management of patients in the community. The service structure was considered inadequate to ensure the successful follow-up and monitoring of patients with heart failure. This was further hindered by the lack of manpower and time in primary care. All health professionals emphasised time constraints and other clinical demands as barriers to implementing guidelines. Health professionals felt they had other more urgent clinical matters that required attention, and these were a priority over guidelines. Health professionals just did not have the time to read or plan the implementation of guidelines.

> *'[We] are spending lots of time either filling in bits of paper or reading, looking at bits of paper to find out what it is they're supposed to do. Meanwhile the patients lying in bed calling out for a bed pan or wanting their back rubbed or wanting to talk to a doctor and everyone's too busy dealing with their protocols or whatever' (Consultant, 7.78.26-30)*

> *'I think it would be something that I would [do] if I got a chance to but sometimes with some of the demands of my role it's just actually having the time to properly update yourself a bit more' (Nurse, 12.6.1-3)*

Another service barrier identified by all health professionals was lack of resources. The lack of echocardiograms increased waiting lists, making it difficult for doctors to access tests to confirm a diagnosis of heart failure. Additionally, there was a shortage of health care professionals, resulting in the delivery of services with sub-optimal staffing levels.

> *'There is no joke to say that on an acute medical ward, things like nursing staff are an endangered species' (Consultant 2.44.4-5)*

There was only one barrier identified by interviewees that was associated with the health professional, and this was uncertainty. Uncertainty was reported when there was a perceived clash between clinical experience, current opinion, and guideline recommendations. For example, consultants and GPs commented that previous medical teaching and evidence has suggested until fairly recently that beta blockers were not tolerated in patients with heart failure. However, recent evidence suggests that beta blockers are effective in patients with heart failure and can lead to improved patient outcomes (e.g. life expectancy). This led to uncertainty among doctors and could result in the variable prescription of beta blockers.

> *'And an example in the NICE guidelines might be the use of beta blockers... beta blockers have gone in and out of favour for yonks, at least the twenty years I've been in medicine and sometimes they are good [and] sometimes they're not' (GP, 20.14.1-4)*

> *'We probably under use beta blockers and we've always had this sort of excuse in our minds that old people tolerate beta blockers badly the evidence for that is not great so in fact we should be using beta blockers more' (Consultant, 7.22.3-5)*

The final set of barriers to the implementation of the guidelines related to patient factors. One GP emphasised how patients could block attempts to implement guidelines, particularly when these related to drug therapy:

> *'If you say to someone "I think you ought to go onto beta blockers", they'll say "oh, not another tablet doctor, I'm already on three, I don't want four". Is that a barrier to implementing the guidelines?' (GP, 15.48.2-5)*

This clearly demonstrates how patient requests can dissuade health professionals from implementing guidelines based on evidence-based practice. Consultants and junior doctors' decisions to implement guidelines were sometimes influenced by the physical status of a patient, such as frailty. Consultants and junior doctors did not want to inconvenience frail patients by scheduling further appointments, because of the difficulty they encountered travelling to attend them. This could lead to echocardiograms not being requested or less frequent monitoring of these patients.

> *'Sometimes you know particularly in elderly care...[it's] a conscious decision not to follow them up because they are very frail and you don't want to bring them to clinic, but that doesn't mean that they don't need follow-up' (Consultant, 8.64.2-5)*

Consultants, GPs and junior doctors were also aware that their clinical decisions could adversely affect the patient, and at times in the best interests of patients they had to deviate from guideline recommendations. The majority of doctors' concerns about adverse reactions related to older patients and in particular those who were frail. These concerns generally related to the prescription of beta blockers:

> *'Increasing evidence in the very elderly that there is a benefit if they can tolerate it but like a lot of things in the elderly, you've got lots of drugs that would be of benefit if tolerated and an awful lot of things aren't' (Consultant, 13.39.2-5)*

Two factors were mentioned that could promote the implementation of guidelines. Firstly, a few consultants and GPs mentioned support. This was required from colleagues, management, and audit teams, to ensure that implementation plans were created, discussed, implemented, and evaluated via audit. The majority of health professionals identified heart failure clinics and heart failure nurses as a necessary requirement to fully implement the NICE guidelines for managing heart failure. This would ensure a specialist service for heart failure, and enable continuity of care. Heart failure nurses could be utilised to educate and monitor patients within the community, therefore, providing the vital link between secondary care and primary care.

> *'There is a role for the specialist heart failure nurse, nurses in the communities for these patients, erm this might be the good thing that comes out of the guideline' (Junior doctor, 14.10.6-8)*

6.3.2.5 Outcomes resulting from guidelines.

The fifth category related to the outcomes that could be achieved by the implementation of guidelines. The main outcome anticipated from the delivery of evidence-based health care was improvements in patient care.

> *'[Following guidelines] will make the patient journey a lot better and be more efficient' (Consultant, 7.54.5-6)*

> *'It's there to improve the quality of patient care to make sure that we practice things which have a proper evidence base' (Consultant, 2.24.1-3)*

Furthermore, guidelines were seen as levers for improvement and could support changes required in the service to achieve implementation.

> *'In a sense these guidelines are really useful because they are levers to actually say to a primary care trust or to a secondary provider, "Oi, you know we have to find the money to actually provide this service because this is the gold standard, this is approved good practice and we're not meeting that' (Consultant, 2.18.8-13)*

Finally, a few senior doctors mentioned how guidelines served audit. Audit was seen as a mechanism through which health professionals could compare their own practice to a standard and could, on occasion, lead to changes in the procedures used within practice.

6.3.2.6 Other influences on the decision-making of health professionals. Participants' own clinical experience greatly influenced clinical decisions. For consultants, GPs, and junior doctors, this included the outcomes they had witnessed in patients from interventions or drug therapy they had prescribed.

> *'And we've all had bad experiences with individual drugs, you know, which perhaps influence what we do' (Consultant, 1.81.7-8)*

> *'I've actually got evidence of clinical improvement on ACE in the sense that the research tests it but when I put somebody on an ACE they come back saying they feel a lot better...now I know that some of them of course may have got better anyway but I [have] got some evidence in front of me that there is improvement' (GP, 20.52.9-13)*

Colleagues and senior members of staff influenced clinical practice. Junior staff members saw senior staff as sources of information, and observations of their clinical decisions and patient outcomes could inform their own clinical practice.

> *'[I] have to observe consultants doing it, seeing whether [their] patients do survive or even improve (laughs), and then that gives you confidence' (Junior doctor, 15.21.11-14)*

> *'[My clinical practice is based on work] within the various trusts with different consultants, but not actually based on what's in the NICE guideline' (Junior doctor, 14.40.3-4)*

More senior staff saw colleagues as sources of information. Interactions with colleagues included discussions about clinical practice, and the knowledge of respected local experts could influence practice.

> *'That (guideline recommendation) is not quite as effective as your colleagues saying, this is what I do' (GP, 20.40.14)*

Local guidelines, protocols and contracts also influenced clinical behaviour. The preference for local guidelines stemmed from the fact that they were locally owned and specifically related to local resources and services.

> *'For example, this general guideline produced from NICE, may not be applicable in every trust because of the different resources that [are] available, so guidelines should be locally produced and tailored to the needs of the local patients based on the resources available in a specific trust, otherwise it may not mean anything' (Junior doctor, 14.50.1-5)*

Local guidelines were also structured in a way that was more user friendly. Finally, one GP mentioned how trusting the sources that produced local guidelines made them more influential, and increased the likelihood that they would be incorporated into current practice.

6.3.3 Communicating the Management Plan to Patients

The analysis generated six main categories of themes (see appendix H for a summary of the findings), including health professionals' views of the guideline, barriers to implementing the guideline, patient related influences, outcomes of communication, patient self-management, and written information and management plans. For diagrammatic representations of the links between the core themes please see figure 4 below:

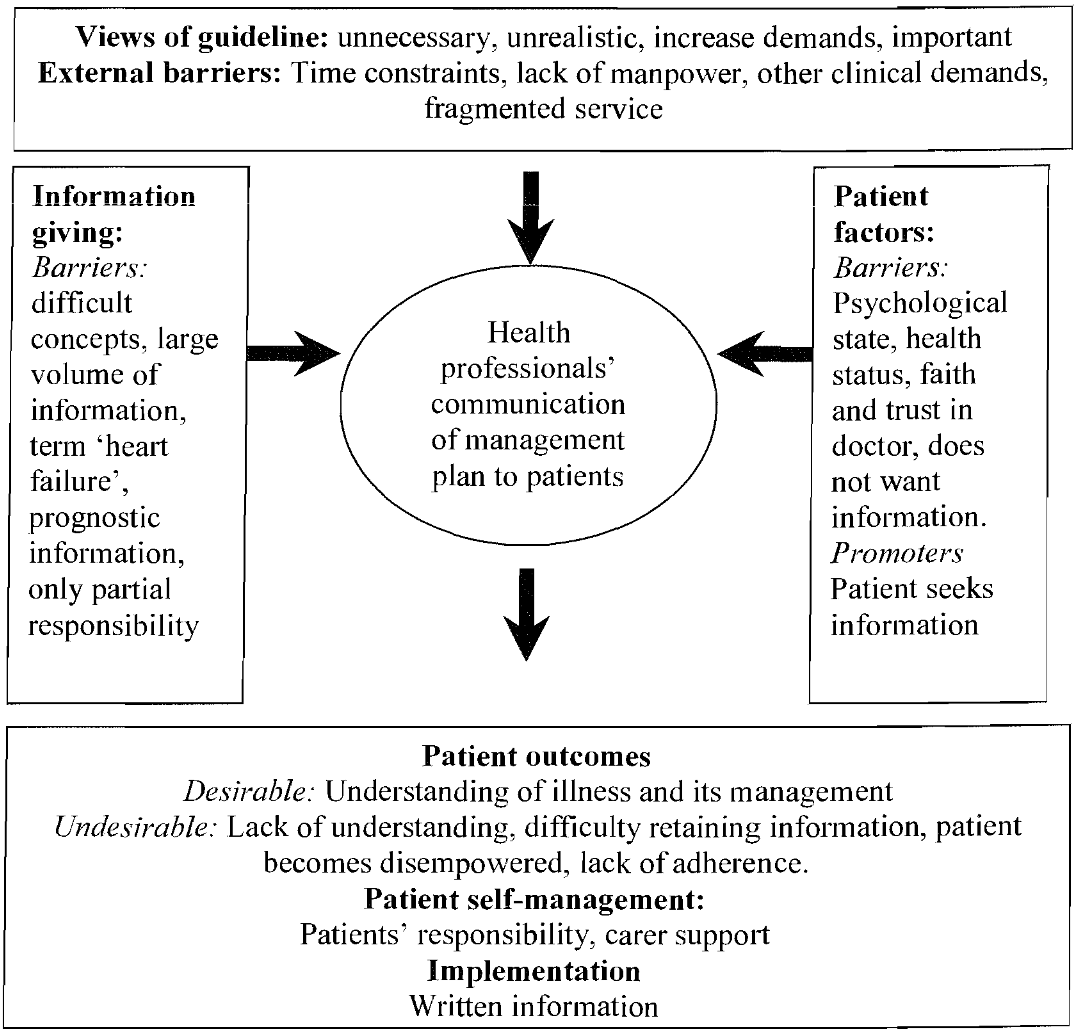

Figure 4. Themes related to the implementation of the communication of the management plan guideline

6.3.3.1 Views of the guideline 'communicating the management plan'.

Some health professionals felt that there was no need for a communication guideline; doctors felt they had adequate training in communication, and the suggestion that they did not involve patients in their management plan was patronising.

> *'I think as long as people are taught good communication skills then there should be no need for a formal guideline for it' (Consultant, 1.16.2-4)*

> *'[The] suggestion that we don't involve patients in their management plans is crazy really' (GP, 15.27.1)*

A few health professionals felt that the guideline was unrealistic once placed in context and was devised using the idea of the perfect patient. Furthermore, this communication guideline could increase the demands on health professionals.

> *'I don't think that they can underestimate the importance of good communication but it shouldn't be at the expense of other good clinical practice' (Consultant, 1.26.1-2)*

However, this was countered by views from a few health professionals who stressed the importance of communication in their work and regarded the guideline as a standard they could aspire to.

> *'But you know obviously you've got to put it into a guideline to mention it, because it is an important part, so it would have to go in definitely' (Nurse, 11.85.1-3)*

> *'Look at this guideline; this is what we're aiming for' (Junior doctor, 10.78.3-4)*

6.3.3.2 Barriers to implementing the guideline.

Two different types of barriers could be distinguished, external barriers and information giving barriers.

6.3.3.2.1 External service barriers.

External barriers included time constraints. All health professionals were constrained by time pressures and perceived inadequate time to provide patients with a full explanation about their illness, its management, complications, and prognosis.

> *'In fact you are just aware of the pressures of time, the whole time, you're trying to get through up to 10 new patients in a three hour clinic, plus two or three follow-ups, it's just really difficult' (Junior doctor, 6.118.4-6)*

> *'I think it's nothing to do with the fact that someone hasn't, it's just there doesn't seem to be enough time' (Nurse, 12.90.3-5)*

> *'It's just the time constraints that put a limit on what we can tell patients' (Junior doctor, 17.84.1-2)*

More than half of the health professionals felt that there was insufficient manpower to devote to communication. Within a health care setting, in theory, information giving could be delegated; however, insufficient staff numbers hindered this. Moreover, there were no specialist health professionals whose role was dedicated to providing information to heart failure patients. Health professionals had a range of other clinical demands to fulfil that competed for time, and admitted that, when their clinical workload increased, communication was normally the first thing to suffer.

> *'Unfortunately what tends to happen is that when you get busy you try and shorten that time (time for communication)' (Consultant, 1.32.3-4)*

> *Although it's probably the **last** thing (communication) that should go off, the first thing that goes is proper communication of what's happening (Junior doctor, 18.122.1-3)*

Finally, the process of information giving was further complicated by the fragmented service currently available for heart failure patients. Patients could encounter several health professionals during the course of their treatment that spanned both primary and secondary care, and none of these had explicit responsibility for communicating the management plan to patients. On occasions when communication between primary and secondary care was inadequate, information giving to patients suffered. GPs felt ill informed of their patient's management in secondary care, and subsequently were unable to provide up-to-date information to patients. Patients themselves lacked knowledge about changes to their treatment and, therefore, were also unable to share this information with their GP.

> *'As a GP I find myself try[ing] to generate that (management plan) but really it should have been educated to the patient from the start so that their patient can then share it with everybody that comes' (GP, 20.68.4-6).*

> *'GPs are a fundamental source of information for people in this respect but unless the GPs know the management plan they can't pass it on to the patients (laughs)' (GP, 15.44.3-5)*

6.3.3.2.2 Health professional information-giving barriers.

The second set of barriers related to information giving. Health professionals had to communicate difficult concepts to patients and acknowledged that they or colleagues may fail to explain medical information in a clear and simple manner.

> *'Did you understand what they just told you?" and they say "oh no, not really" and we have to sort of say it in layman terms because I have listened to doctors, not all of them, some of them are really really good, but they do use professional terms which mean absolutely nothing' (Nurse, 11.97.1-.5)*

Doctors felt that there was such a large volume of information to be given to patients about heart failure and its management that, on occasion, they felt they were bombarding patients with information. It was interesting to find that consultants and junior doctors felt uncomfortable using the term 'heart failure.'

> *'Although heart failure is the official term doctors are scared of using that to patients' (Junior doctor, 18.144.2)*

Doctors' perceived the term 'heart failure' as contentious and misleading; it did not correctly portray the illness. Patients incorrectly assumed that their heart had stopped working and that this could only mean death.

> *'You know, heart failure can only really mean one thing, which is death isn't it?' (Junior doctor, 18.146.1)*

> *'Pretty bad, "my heart has failed doctor", so we're cautious about it' (GP, 15.79.1)*

Information about diagnosis could evoke distress in patients, and this resulted in greater caution among doctors about using the term 'heart failure.'

> *'The word failure really scares them (patients), particularly with heart in front of it' (Junior doctor, 6.106.1)*

Some doctors felt uncomfortable providing prognostic information, particularly as the estimation of prognosis is difficult and uncertain for this medical condition. Some senior doctors mentioned that not all of their colleagues were aware of the short prognosis for heart failure, and this resulted in these issues not being discussed with patients.

> *'That's a key thing prognosis, that's another thing; we're very bad at telling patients' (Consultant, 8.136.5)*

> *'There's a lot of junior doctors and a few senior doctors who don't realise you know the prognosis is as bad as some of the common cancers' (Consultant, 8.148.3-4)*

Most health professionals expressed a sense of being only partially responsible for patients' understanding and processing of information. They felt that patients had to actively participate, to understand health information. Furthermore, if patients did not want to accept information then they were powerless to do anything about it.

> *'There's only so much you can do… I'm afraid we can't be responsible for everything' (Consultant, 4.1647.1-2)*

> *'We can provide them with all the information that they need and it always up to them to digest what is given to them' (Junior doctor, 14.72.20-22)*

6.3.3.3 Patient influences on communication.

Patient-related factors that influenced health professionals' communication included elements that hindered the transference of information between the health professional and the patient, and the factors that promoted the transference of information.

6.3.3.3.1 Factors that hinder communication and information giving.

Health professionals felt that the patient's psychological status and distress could thwart any intention to implement the guideline by providing information. Some health professionals reminisced about their previous experience with patients. These experiences included patients who were in denial and therefore, refused to accept information provided, and patients who were anxious and had difficulty retaining information. Health professionals were also aware that the information they provided could result in the patient becoming distressed. Negative patient outcomes were associated with the provision of information to patients by some health professionals.

> *'I think some patients don't want too much information actually because they find it quite frightening' (Consultant, 4.126.2-3)*

The patient's health status was also an influencing factor, the majority of health professionals were aware that some patients had numerous problems and, therefore, they had to manage a multitude of illnesses, and information associated with each of these. Health professionals in secondary care suggested that patients may be too unwell, and their priorities were on recovering and getting better, and not obtaining information.

Health professionals described how some patients did not want to play an 'active' part in decision-making and preferred to have 'faith and trust' in the decisions made by their doctors. This factor was most strongly associated with older patients.

> *'Older patients...sometimes they don't want to know, they just say "oh leave it to you doctor you know best, I'll treat you as best" and we do have to make decisions on their behalf' (Junior doctor, 10.68.9-12)*

> *'"what would you like me to do for you?" most people will look wide eyed and say "I don't know you're the doctor, you tell me", you know in its simplest there's that element' (GP, 15.94.7-10)*

6.3.3.3.2 Factors that promote communication and information giving.

There was only one factor that promoted the giving of information, and this was the patient who sought information and took responsibility to gain further knowledge. These patients would ask questions, seek information from other sources, or engage with health professionals to meet their informational needs.

> *'I get patients who've been on the net and they've had a look at what's current treatment for 'x' and 'y'' (Consultant, 7.92.10-11)*

> *'They've (patients) got loads of questions' (Consultant, 7.92.10-11)*

6.3.3.4 Outcomes from communication provided.

The fourth category of themes related to the outcomes from communication, which were divided into undesirable patient outcomes and desirable patient outcomes.

6.3.3.4.1 Undesirable patient outcomes.

In relation to undesirable outcomes, all the health professionals emphasised patients lack of understanding about their illness and its management. The majority of health professionals reported that patients did not adhere to their medication and linked this to patients' lack of understanding about the medications they were taking, and their benefits.

> *'I would imagine a lot of patients and relatives would say that they don't know enough about their condition and don't know enough about how it's been managed' (Nurse, 19.28.2-5)*

> *'I very rarely find a patient who understands their heart failure to the extent that they can actually monitor it by their own weight' (GP, 20.66.5-7)*

The majority of health professionals believed that heart failure patients experienced difficulty retaining information. Some of this difficulty was attributed to cognitive decline in some patients, and health professionals acknowledged the difficulty patients experienced in retaining all the verbal information provided in a consultation.

> *'That's what we find when they come back to outpatients anyway, they forgot a lot of what you told them' (Consultant, 5.81.4-6)*

A minority of health professionals felt that sometimes information did not actually empower patients but made them more confused and unable to participate in decision-making.

> *'Particularly with the generation (older) that I'm dealing with at the moment, it doesn't give them a choice, it just kind of causes bewilderment' (Consultant, 2.34.8-9)*

6.3.3.4.2 Desirable patient outcomes.

Health professionals proposed only one desirable outcome; patient understanding and awareness. Health professionals described these patients as more willing to take some responsibility for obtaining information about their illness.

> *'Puts responsibility on both sides as well, the more responsible patient has a better idea about their care' (Junior doctor, 17.53.8-10)*

6.3.3.5 Influences on patients' management of illness.

The promotion of self-management could result from the communication of the management plan to patients. The majority of doctors stressed the importance for patients to play an effective role in the management of their illness, and to take some responsibility. Effective patient self-management was considered part of the management plan. Two health professionals also specifically referred to the shared responsibility guideline which was a key recommendation in the NICE guidelines for heart failure management.

> *'You could argue that ultimately it is [a] patient's responsibility to take drugs and make lifestyle changes that are needed' (Junior doctor, 18.186.1-4)*

> *'Being able to manage some of their own chronic illness because that's part of your management plan' (Consultant, 2.150.9-12)*

> *'Heart failure should be seen as a shared responsibility in patient healthcare, yes I agree, and the patient needs to be very involved and empowered' (GP, 20.68.8-9)*

Finally, health professionals outlined the support that carers could give in all aspects of care, from understanding and retaining information through to assisting patients to manage their illness.

6.3.3.6 Written information and management plans.

It was clearly stated by some health professionals that, at present, a written management plan did not really exist.

> *'Well I mentioned already that the management plan doesn't exist in most cases' (GP, 20.98.1)*

> *'So I have if you like a management plan in my **own** mind and what I'm looking for' (GP, 20.112.4)*

> *'We don't always do as for say, written care plans, as regards to that, it's a sort of ongoing verbal communication really' (Nurse,11.63.4-6)*

The provision of written information varied greatly, from patients receiving no written information, to patients receiving a discharge home pack and/or being provided with copies of correspondence sent to their GP. Occasionally, some doctors would provide patients with simple handwritten information if they felt that a particular patient was struggling to understand or retain information.

> *'Occasionally I'll write things down, if someone looks a bit muddled on what drugs to take, I'll write that down but I won't do anything more than that' (Junior doctor, 6, 110, 1-3)*

The majority of health professionals perceived a lack of suitable written information. However, some health professionals suggested that patients may not want written information, as it may promote doubt and distress. A few health professionals were dubious about written information- that it may initiate questioning from patients about their decision-making. For example, asking why they had not been prescribed particular types of medication.

> *'And they (booklets/leaflets) can really scare the patient' (Junior doctors, 10.101.1)*

> *'When you hand out one of these leaflets the question is "why am I on that but not on this' (Consultant, 5.71.5-6)*

Some health professionals suggested that written information, especially in the form of a management plan, would be a good format through which to share information with patients, carers and other professionals. It was acknowledged that written information could assist in patients' retention and understanding of information, and supplement verbal information provided in consultations.

> *'I think it's very helpful for them if they have something they can read after they have seen you, so that they can refresh their memory about what you said' (Consultant, 5.77.5-7)*

6.4 Discussion

Some of the themes inductively identified using thematic analysis corresponded to the components of the TPB. Therefore, the relationship of the themes to the constructs of the TPB will be discussed, firstly in relation to the NICE guidelines for heart failure management, and then for the communication of the management plan guideline. For a closer examination of the relationship between the categories that emerged from the analysis and the components of the TPB, please refer to tables 8 and 9. Finally, a general discussion of the findings of this study is included and how they relate to existing research.

6.4.1. TPB and the Heart Failure Guidelines in General

6.4.1.1 Attitude.

Outcome beliefs underlie attitude and relate to the anticipated outcomes from performing a particular behaviour. Positive outcomes arising from the implementation of guidelines included improved patient outcomes. Guidelines were also viewed as a mechanism through which change could be achieved. For example, guidelines could influence the allocation of resources enabling evidence-based practice, or identify areas for improvement via audit which compares current practice with guideline recommendations. Some negative outcomes were also noted. For example, health professionals identified the possible adverse patient outcomes that could result from the prescription of beta blockers to patients. These negative outcome beliefs could result in an unfavourable attitude towards prescribing beta blockers and result in the variable uptake of this guideline.

6.4.1.2 Subjective norm.

With regard to normative beliefs, junior doctors and nurses perceived more senior staff members as sources of information, and would base their own practice on observations or discussions with these senior colleagues rather than on clinical guidelines. More senior members of staff perceived colleagues as sources of information, and a few suggested that these discussions influenced their clinical behaviour. This suggests that on occasion health professionals may be motivated to comply with the views of significant others. With regard to guidelines, local opinion leader interventions may have the potential to change health professional behaviour (Greer, 1988; Thomson O'Brien et al., 1999). Opinion leaders could be utilised to model appropriate behaviour and transmit information consistent with guideline recommendations, resulting in the implementation of these guidelines. Patients' views and actions also influenced the clinical decision-making of doctors. Doctors referred to examples of patients blocking attempts to prescribe or change medication.

6.4.1.3 Perceived behavioural control.

Themes for the barriers and potential facilitators for the implementation of guidelines relate to the construct of perceived behavioural control. Barriers to reading and seeking guidelines included difficulty accessing guidelines, guideline fatigue, and the length of guidelines. The perceived barriers identified included lack of time, other clinical demands, fragmented service, lack of resources, and patient characteristics (e.g. frailty). For example, the guidelines recommend that all patients with suspected heart failure should undergo an echocardiogram to confirm the diagnosis. However, lack of resources hindered the full implementation of this guideline. Support from colleagues, more heart failure nurses, and the development of heart failure clinics, were identified as factors that could promote the implementation of these guidelines. Health professionals also commented that their past experience influenced their present clinical practice. Ajzen (1991) suggests that past behaviour should be encapsulated within the concept of perceived behavioural control. Furthermore, research utilising the TPB to predict GPs' behavioural intention to prescribe antibiotics reported that past experiences significantly increased the variance explained in behavioural intention, suggesting that previous clinical experience could be important in predicting future intentions to prescribe medications (Walker et al., 2001).

Table 8 *Relation of the themes for the NICE guidelines for heart failure management to the components of the Theory of Planned Behaviour*

TPB component	Categories
Attitude	Improved patient outcomes
Positive outcomes	Promotes change within the service
	Audit
Attitude	Adverse patient consequences (e.g. side effects)
Negative outcomes	
Subjective norm	Colleagues and local experts
	Patient requests
Perceived behavioural control	Support
Help with implementation	Heart failure clinics and nurses
Perceived behavioural control	Lack of awareness
Barriers to implementation	Lack of accessibility
	Relevance to clinical practice
	Guideline fatigue
	Length of guidelines
	Fragmented service
	Lack of resources
	Lack of time and other clinical demands
	Patient characteristics
	Clinical experience

6.4.2 TPB and the Communicating the Management Plan Guideline

6.4.2.1 Attitude.

Negative outcomes associated with the implementation of the communication of the management plan guideline included increased demands on health professionals, and adverse patient outcomes such as psychological stress, difficulty retaining information, and disempowerment. Positive patient outcomes included patients' awareness of the nature and management of their illness. In communication with patients, health professionals were reluctant to use the term 'heart failure' partly because of expected negative patient outcomes (e.g. patient distress) from using the diagnosis. Health professionals also identified potential positive and negative outcomes from the provision of written information. Negative outcomes included increasing patient distress and/or confusion, and positive outcomes included better sharing of information with patients.

6.4.2.2 Subjective norm.

With regard to normative beliefs, health professionals perceived patient related factors to influence the amount and type of information given. Patients who did not want to know, or expressed faith and trust in the doctor, could lead to health professionals only providing a limited amount of information. Patients who actively sought information by asking questions and requesting information could influence health professionals to provide additional information. These findings suggest that on occasion health professionals may be motivated to comply with the views of significant others.

6.4.2.3 Perceived behavioural control.

Health professionals perceived several external barriers to the implementation of this guideline, including time constraints, lack of health professionals, other clinical demands, and fragmented service. A major barrier to implementation of this guideline was the lack of written management plans. The absence of a written management plan would make evaluation of the implementation of this recommendation very difficult. The uncertainty involved in establishing a prognosis could lead to health professionals deciding not to share this information with patients. Patient related barriers were identified by health professionals to giving information to patients, such as patients refusing information, or refusing to accept information, by expressing their faith and trust in the doctor. Furthermore, health professionals accepted only partial responsibility for providing information to patients.

The TPB does appear to be a useful framework for organising most of the themes identified within the analysis. More themes encompassed the construct of perceived behavioural control than either attitude or subjective norm. This suggests that perhaps perceived behavioural control is the most salient factor in the implementation of the communication of the management plan guideline. However, not all the themes identified by the analysis related to the TPB constructs, suggesting that the TPB may be unable to provide a full account of health professionals' behaviour in implementing guidelines. The themes not organised according to the TPB included those referring to the non-social influences on clinical practice (e.g. local guidelines) and the views of health professionals about guidelines, and NICE (e.g. motives and external influences on NICE, authors in ivory towers). Nonetheless, the TPB does appear to be a useful framework for understanding the implementation of clinical guidelines.

Table 9. *Relation of the themes for the communication of the management plan guideline to the components of the TPB.*

TPB COMPONENT	CATEGORIES
Attitude *Positive outcomes*	Patient has an understanding of their illness Good way to provide and share information
Attitude *Negative outcomes*	Increase demands Using term 'heart failure' Lack of patient understanding Patient difficulty in retaining information Patient becomes disempowered Lack of patient adherence Causes distress and promotes confusion
Subjective norm	Patient seeks information Faith and trust in doctor Patient does not want to know Carer support
Perceived behavioural control *Barriers to implementation*	Time constraints Lack of health professionals Other clinical demands Fragmented service Large volume of information Difficult concepts Giving prognosis Partial responsibility Patients psychological state and distress Health status of patient Written care plans not always available Written information not available
Perceived behavioural control *Help with implementation*	GP letters and discharge letters Hand written notes provided to patients

6.4.3 General Discussion: the NICE Guidelines for Heart Failure Management

Health professionals in this study reported a lack of awareness about the NICE guidelines for heart failure management, despite interviews being conducted one to two years following their dissemination. Research evidence suggests that passive dissemination techniques employed by NICE are ineffective (Bero et al., 1998; Davis, Thomson, Oxman, & Haynes, 1995; Oxman, Thomson, Davis, & Haynes, 1995) and, therefore, other more active dissemination techniques should be adopted by NICE to raise awareness of their recommendations. Research suggests that health professionals prefer guidelines that are concise, summarised and easily accessible (Langley, Faulkner, Watkins, Gray, & Harvey, 1998). However, the NICE guidelines for heart failure were reported to be too lengthy, difficult to access, conveying too much information, and were difficult to use as a reference.

Health professionals evaluated the relevance of guidelines to their clinical practice. The appraisal of guidelines and their perceived usefulness has been noted in previous research (Langley et al., 1998). Junior doctors regarded guidelines as more relevant to the work of senior colleagues, while nurses regarded guidelines as more applicable to the clinical practice of doctors. The implementation of guidelines within a health care setting can only be achieved by the co-operation of a variety of different health professionals. However, the findings of this study suggest that some groups of health professionals do not perceive guidelines as suitable to their clinical practice and decision-making.

Health professionals perceived the NICE guidelines for heart failure as sensible and not containing anything which was not already known about heart failure management. This finding suggests that educational interventions would be superfluous as health professionals already had the clinical knowledge needed for heart failure management. Therefore, in the event of sub-optimal practice, barriers other than knowledge are likely to exist. Some health professionals highlighted that the guidelines lacked details about prescribing medication and the palliative care of patients. The latter, in comparison to cancer care, is less developed for heart failure patients (Murray et al., 2002). A major theme to emerge from the interviews was the issue of lack of time. This finding is consistent with other research which has found that health professionals report inadequate time to retrieve and critically review information (Fairhurst & Huby, 1998), and report that they do not have enough time during consultations to access information (Langley et al., 1998). This study found that some health professionals felt they did not have time to even find guidelines, read guidelines, or consider the implementation of guidelines.

Only a few qualitative studies describe health professionals' accounts of their management of heart failure. A number of the themes emerging in this study were consistent with previous research. GPs in this study outlined how lack of communication between primary and secondary care resulted in their ignorance of changes to patients' treatment and, therefore, hindered patients' follow-up and monitoring in the community. These findings are consistent with Horne, Coombes, Davies, Hankins, and Vincent (1999), who reported that GPs were dissatisfied with the quality of information received from hospital colleagues. Barriers to the diagnosis of heart failure identified in this study centred on lack of access to echocardiograms, and this is reported elsewhere in the literature (Khunti, Hearnshaw, Baker, & Grimshaw, 2002; Fuat, Hungin, & Murphy, 2003). In accordance with existing literature, this study found that decisions about not requesting an echocardiogram did not solely centre on resource deficiencies, but also doctors' concerns about inconveniencing older adults (Fuat et al., 2003). In fact, this corresponds with the literature on patient views, where heart failure patients themselves report difficulty in getting to hospitals to attend appointments (Rogers et al., 2000).

In this study, health professionals reported that patients, at times, could resist changes to their medication. Freeman and Sweeney (2001) in their study found that doctors reported attempts by patients to block the implementation of evidence-based practice. As found by Marshall, Mead, Jones, Kaba, and Tovey (2002) health professionals in this study were also concerned about the adverse effects of new treatments on patients. In particular there were concerns about adverse patient outcomes resulting from decisions to prescribe beta blockers. Similar to the findings of Fuat and colleagues (2003), some doctors reported that during medical training they had been advised against prescribing beta blockers for heart failure, although current clinical recommendations were advocating their use. This resulted in uncertainty and the variable uptake of the prescription of beta blockers.

Previous research suggests that adverse patient reactions may have a negative effect on the doctor-patient relationship, resulting in GPs being reluctant to change medication, particularly if patients' symptoms are well controlled by their existing medication (Marshall, Mead, et al, 2002). Furthermore, Tomlin, Humphrey, and Rogers, (1999) suggest that the importance of the doctor-patient relationship may be more important to GPs than staying within the bounds of clinical effectiveness. In the event of conflicts between patient goals and clinical guidelines GPs may depart from evidence base practice to maintain a good relationship with the patient (Tomlin et al., 1999; Veldhuis, Wigersma, & Okkes, 1998). Previous research has identified that doctors may make a conscious decision not to follow best practice when they perceived patients to have other more pressing health problems, or when recommendations were not applicable due to old age or disease progression (Mottur-Pilson, Snow, & Bartlett, 2001). This was also found in this study, where the majority of concerns about adhering to guideline recommendations centred on concerns about adverse outcomes for older and frail heart failure patients. In summary, the implementation of clinical guidelines may be influenced by the relationships health professionals have formed with their patients. The decisions of health professionals may deviate from clinical guidelines, if they are not persuaded that evidence-based guidance is of benefit to the individual patient.

6.4.4 General Discussion: the Communicating the Management Plan Guideline.

Written information was proposed as the only method within current time constraints and lack of health personnel that could assist in the implementation of the communication of the management plan guideline. The findings of this study suggest that the provision of written information by health professionals was very poor. Health professionals' perceived a lack of suitable written material and were concerned about the potential adverse effects (e.g. disempowerment, confusion) of written information on patients. A major barrier to implementing this guideline emerged from the analysis; this was the acknowledgement by some health professionals that written management plans are not always available. Instead, as stated by a minority of health professionals, they consisted of an ongoing verbal communication between patient and health professional.

Therefore, any intervention developed in this research programme would have to take this barrier into consideration. Although this finding has implications for the design of the intervention, many of the management behaviours for heart failure are similar for all patients. For example, the majority of patients with heart failure are encouraged to monitor their weight, reduce their salt intake, take regular physical activity, and take their medication as prescribed. Therefore, a generic written information intervention might be appropriate.

Very little previous research has centred on doctor-patient communication in heart failure, particularly from the perspective of the health professional. This was the first study to investigate a range of health professionals' views towards communicating information about the management of heart failure to patients. A major barrier to communication was lack of time, these time constraints hindered the complete delivery of information to patients about their illness and its management. This barrier is also reported elsewhere in the literature with regards to communication of information to patients (Coulter, Entwistle, & Gilbert, 1999). A few health professionals admitted that when other important clinical and urgent demands competed for their time, then time spent communicating with patients usually suffered. Health professionals interviewed were aware that patients may encounter difficulty with retaining information. Health professionals acknowledged that they experienced difficulty explaining heart failure in simple terms and felt that they had to provide a vast amount of information. This mirrors reports by patients that doctors used complex terminology when providing information to them (Barnes et al., 2006).

Health professionals' decisions about providing information seemed to be partly based on their perceptions of the patient. The characteristics of the patient could either have a positive or negative influence on communication. Previous studies suggest that health professionals are likely to underestimate the information needs of patients (Horne & Payne, 2004). However, the concerns of health professionals about patients' resistance to information or involvement in decision-making are partly justified. Heart failure patients have reported that they have faith and trust in treatment decisions made by doctors (Rogers et al., 2000), and do not want information because it worries them (Barnes et al., 2006). Furthermore, as found in the cancer literature, there may be times during the illness trajectory when patients do not wish to actively seek information (see (Leydon et al., 2000).

Health professionals in this study reported that they encountered barriers to communicating information to heart failure patients about prognosis and diagnosis. Research with heart failure patients indicates that they obtain little information and report unanswered questions and confusion about their prognosis (Barnes et al., 2006; Murray et al., 2002; Rogers et al., 2000). The unpredictable course of heart failure and uncertainty about prognosis hindered health professionals' discussions with patients about prognosis; this is consistent with previous literature (Barnes et al., 2006). Health professionals were also uncomfortable providing patients with their diagnosis, due to the negative connotations associated with the term heart failure. This is consistent with literature which indicates that primary care patients perceived the term 'heart failure' to have more serious consequences, compared to a range of euphemisms used by doctors to explain the illness (Tayler & Ogden, 2005). However, the implications of not using the diagnostic term is highlighted in the literature on patient experiences, where patients discuss only becoming aware of having heart failure upon admission to hospital (Barnes et al., 2006). It appears from health professionals' reports that they wanted to avoid the potential risk of distressing patients by providing them with upsetting information. Perhaps as proposed in other studies, their actions were intended to maintain a good doctor-patient relationship (Tomlin et al., 1999; Veldhuis et al., 1998).

Health professionals reported that the current service for heart failure patients, which spanned both primary and secondary care and involved a variety of health professionals, hindered communication with patients. Particularly as no one service or health professional group was responsible for the provision of information to heart failure patients. This is consistent with previous research which has found that the numerous professionals involved in the care of heart failure patients disrupts the flow of communication (Barnes et al., 2006), and that GPs were dissatisfied with the quality of information received from hospital colleagues (Horne et al., 1999). The latter study also found that 83% of discharge information arrived after a patient with heart failure had been seen in primary care.

This study did find emerging themes not present in previous qualitative studies about doctor-patient communication or patients' management of heart failure. Health professionals' accounts emphasised the shared partnership required with patients in the management of heart failure. They felt that patients had to actively participate to gain knowledge about their illness, adhere to medication regimens, self monitor, and make lifestyle changes. This emphasised the important role of the patient in the management of their illness. Health professionals accounts in this study corresponded with another key recommendation in the NICE guidelines for heart failure. This states that 'management of heart failure should be seen as a shared responsibility between patient and healthcare professional' (NICE, 2003, p.3). Although this guideline was only directly referred to by a few health professionals, their accounts of the involvement of patients in the self-management of heart failure did not differ from those professionals who were not aware of this guideline. The successful implementation of this shared responsibility guideline is dependent on the knowledge and understanding of patients. Indeed, patients' ability to self-manage was seen as part of the management plan. NICE have produced an informational lay guideline booklet about heart failure management for patients, carers and the public to assist in the implementation of the shared responsibility guideline. Similarly, the achievement of implementation of the communication of the management pan guideline does not just arise from health professionals providing information to a patient, but more importantly involves the patient understanding his/her management plan in the context of overall heart failure self-management. Therefore, as identified by health professionals in this study, there is an interlocking relationship between knowledge of the management plan and actual self-management.

6.4.5 Limitations of the Study

There were a number of limitations to this study. As described in the method section, a total number of 66 participants in secondary care and 55 surgeries in primary were sent letters inviting them to take part in the study, and only 21 participants accepted. It is possible that these participants were not representative of all health professionals within the NHS, and may have had a special interest in clinical effectiveness or heart failure. It is possible that health professionals who did not want to be interviewed held different views from the health professionals who participated in this study. Secondly, due to social desirability factors, health professionals may have avoided providing accounts of occasions when they had deviated from clinical guideline recommendations, and may not have been comfortable criticising NICE, which is held in high prestige within the NHS. Thirdly, health professionals from within the Cardiothoracic Directorate did not wish to participate in this study. Health professionals in this directorate may have held different views about the implementation of the guidelines for heart failure management. Finally, although some differences between different groups of health professionals were identified, due to insufficient numbers of participants volunteering from Primary Care we were unable to systematically compare themes across groups of professionals within both primary and secondary care. Therefore, it is likely that differences exist between health professionals from different healthcare settings which were not identified in this study.

6.5 Implications of this Study for an Intervention to Implement Guidelines

Health professionals viewed providing information about heart failure, and its management, as being synonymous with the management plan. Health professionals' accounts of communication, were associated with discussions about how this information, were used by and responded to by patients. Indeed, information giving was seen as a tool to facilitate self-management among heart failure patients. Health professionals referred to the shared partnership required with patients to aid self-management. This corresponds with a key recommendation in the NICE guidelines, referring to the shared responsibility required between professionals and patients in the management of heart failure. The most common method identified by health professionals to aid information giving and self-management was the provision of written information. The findings of this study suggest that a booklet intervention may be the most appropriate intervention in current service provision to aid with the implementation of the communicating the management plan and shared responsibility guidelines.

6.6 Summary

This study demonstrated the usefulness of the TPB as a theory for understanding and explaining clinical behaviour. Health professionals perceived insufficient time to communicate with patients, and were sometimes unsure about what information patients wanted or could cope with. Although a health professional intervention was envisaged at the outset of this research programme, health professionals suggested written patient information materials as a method to implement the communication of the management plan guideline. A major barrier to the implementation of this guideline emerged from health professionals' accounts, and this was the absence of a written management plan in current service provision. This would make evaluation of this guideline very difficult. In addition, health professionals emphasised the importance of patients being actively involved in their health care. These comments corresponded to a 'shared responsibility' NICE guideline, which relates essentially to the implementation of the management plan. This guideline also appears very relevant to the successful management of heart failure. Therefore, as a result of these findings, this research programme will also be focusing on the implementation of this guideline. In the following study, the development of a written intervention is described to aid the implementation of the communication of the management plan and shared responsibility guidelines.

Chapter Seven: Development of a Theory-Based Booklet to Promote Heart Failure Self-Management

7.1 Introduction

This chapter will describe the development of a theory-based booklet, entitled 'Improving Heart Function' (IHF), to provide information about heart failure and its management to patients, thereby assisting in the implementation of the communication of the management plan and shared responsibility guidelines. This chapter introduces the background and rationale for the booklet intervention. This is followed by a discussion of the theory-based approaches incorporated in the booklet to promote heart failure self-management. Recommendations for producing quality written information that can inform the development of the IHF booklet will be outlined. A qualitative study was conducted which identified patients' salient beliefs about self-management behaviours, and their views about the booklet. The pilot of a knowledge scale will also be presented. Amendments to the booklet based on patients' feedback and patients' salient beliefs are then described. Finally, the IHF and NICE booklet are compared, and limitations of the IHF booklet are discussed.

7.2 Background and Rationale for Booklet Development

This section outlines the main findings from the first study in this research programme. These findings are then discussed in relation to the decision to develop a theory-based booklet to implement the communication of the management plan and shared responsibility guidelines.

The first study in this research programme identified potential barriers to the implementation of the 'communicating the management plan' guideline (see chapter 6). This study found that management plans were rarely written, and usually comprised informal verbal communication to educate patients about their treatment. The absence of a written management plan would make evaluation of the implementation of this recommendation very difficult. Health professionals' perceived several barriers to providing information to patients about their management plan; these included limited time, other competing clinical demands, and a lack of specialist staff (e.g. heart failure nurses). Health professionals were sometimes unsure about what information patients wanted or could cope with. Notably, most health professionals referred to the responsibility of patients in facilitating the management of heart failure, and a few health professionals directly referred to a 'shared responsibility' guideline. This guideline emphasises the co-operation between patient and health professional in the management of heart failure. As a result of these findings, the decision was taken that this research programme would also focus on the shared responsibility guideline, as the ability of patients to participate in their self-management was considered important for the management plan. Health professionals identified informational booklets as interventions which could assist in the communication of the management plan to patients. However, no suitable written materials were available for this purpose.

An intervention to promote health professional behaviour change was proposed at the outset of this thesis. However, a patient intervention was deemed more appropriate, as the partnership of patients in the management of heart failure was emphasised in the first study. The delivery of an intervention to health professionals could be complicated by barriers such as lack of time and health personnel, and the reimbursement of health professionals for their participation in research. The latter would be beyond the resources available for this study. Consequently, this research programme proposed to develop, deliver, and evaluate a written booklet intervention to communicate the management plan to patients and to promote shared responsibility for heart failure management. This intervention would bypass the barriers identified in the first study.

There are several other advantages to written patient interventions. Written interventions are easily deliverable and sustainable in current service provision and can supplement verbal information provided by health professionals. Written information is deliverable in patient's own homes, overcoming barriers identified by patients in travelling to external sites to attend interventions (Ekman et al., 1998). Previous interventions to improve health and clinical outcomes in heart failure patients have generally focused on multifaceted interventions, requiring a substantial amount of resources and changes to service delivery, which would be beyond the scope of this study. However, simpler interventions such as an hour long individual teaching session prior to discharge from hospital have demonstrated improvements in self-management (Koelling, Johnson, Cody, & Aaronson, 2005), and a centralised monitoring and support telephone intervention improved self-management and reduced readmissions (GESICA Investigators, 2005). Only one study evaluated a written intervention and found that heart failure patients receiving repeat mailings of generic patient information reported greater confidence, dietary and weight behaviour changes, less forgetfulness in taking medications, and fewer readmissions, compared to the usual care group (Serxner, Miyaji, & Jeffords, 1998). The broader literature indicates that written interventions can increase knowledge and has the potential to promote behaviour change (e.g. Coulter & Ellis, 2006; Raynor, 1998). These findings suggest that less resource-intensive interventions, such as patient information booklets, may influence patient outcomes and promote self-management in heart failure.

Educational materials (e.g. printed recommendations, electronic information) produce little or no effect in health professionals' clinical behaviour (see chapter 2). Health professionals in the first qualitative study mentioned that the NICE guidelines for heart failure had not provided any new evidence-based information about heart failure management. In these circumstances, an educational intervention would be superfluous, as it would only be reinforcing pre-existing knowledge. In contrast, research suggests that heart failure patients have significant deficits in their knowledge (e.g. De Geest et al., 2003; Artinian, Magnan, Christian, & Lange, 2002; Buetow & Coster, 2001; Cline, Bjorck-Linne, Israelsson, Willenheimer, & Erhardt, 1999). Therefore, a booklet intervention could prove useful in providing information, and may help patients to adhere to self-management if they lacked the knowledge to enable this (Raynor, 1998).

NICE have produced a generic informational booklet for patients, carers and the public to improve patient understanding of heart failure management (NICE, 2003b, see appendix J). NICE indicate that this booklet can assist in implementing the shared responsibility guideline (see appendix B). The information in this booklet could also facilitate the implementation of the management plan guideline. However, the NICE booklet has several weaknesses. The NICE booklet is atheoretical and only targets patient understanding/knowledge (see appendix B). Targeting knowledge alone may be insufficient to influence behaviour (Prohaska & Lorig, 2001; Raynor, 1998). Other amenable factors apart from knowledge, such as patients' beliefs about benefits and barriers, influence heart failure self-management (van der Wal et al., 2006; Evangelista, Berg, & Dracup, 2001; Bennett, Milgrom, Champion, & Huster, 1997). Models of behaviour change identify modifiable factors that influence behaviour. The booklet developed in this research programme was, therefore, theory-based and contained informational messages to target the amenable factors identified in models of behaviour change. Secondly, the NICE booklet provides only limited information about the non-pharmacological management of heart failure. However, the literature indicates that heart failure patients adhere less to non-pharmacological management behaviours (van der Wal, Jaarsma, & van Veldhuisen, 2005). Therefore, providing sufficient information and support to promote lifestyle changes and self-monitoring behaviours is necessary. Thirdly, information in the NICE booklet does not provide advice on how to perform self-management, and does not draw upon previous literature identifying the difficulties, concerns, and beliefs identified by patients in relation to heart failure self-management. The booklet developed in this research programme will draw upon previous literature and target the beliefs that underlie patients' self-management of heart failure.

The development of the booklet comprised three stages. In the first stage a pilot version of the booklet was developed in consultation with health professionals, and by considering previous literature in heart failure. The second stage involved piloting the booklet to obtain patients' views, and to identify their salient beliefs towards heart failure self-management. The final stage incorporated patient feedback, and targeted the salient beliefs identified by patients in a revised version of the booklet.

7.3 Aims and Theory Base of Booklet

This section discusses the aims of the booklet developed in this research programme and the theory-based approaches used to promote heart failure self-management. The primary aim of this booklet was to improve patients' knowledge about heart failure and its management. Knowledge about heart failure has been associated with patients' self-management (van der Wal, Jaarsma & van Veldhuisen., 2005; Ni et al., 1999). Research has shown that heart failure patients lack knowledge about their illness and its management (e.g. Agard, Hermeren, & Herlitz, 2004; Rogers et al., 2000). This suggests that heart failure patients may have inadequate information or hold misconceptions that prevent adherence to self-management. According to Raynor (1998) in these circumstances information can promote adherence. This suggests that the provision of information to heart failure patients may enable them to manage their illness more effectively. In addition, adequate knowledge is a necessary prerequisite to enable people to make informed decisions about elements of their care (Michie, Dormandy, & Marteau, 2002; Marteau, Dormandy, & Michie, 2001). Marteau and colleagues' (2001) model of informed choice also proposes that people's values and attitudes are important, and specifically whether behaviour reflects attitude. An informed decision to perform a behaviour would be based on adequate knowledge and a positive attitude towards the behaviour. The conceptualisation of attitude in this model is congruent with attitude in the TPB model.

Illness representations guided the content of information about heart failure in general. Illness representations are central to the self regulatory model (Leventhal, Meyer, & Nerenz, 1980) and encompass five broad dimensions: identity, cause, time-line, perceived consequences, and curability/controllability. These beliefs shape the way an individual understands their illness experience, and can influence an individual's ability to cope with their illness (Leventhal et al., 1980). Horowitz, Rein, & Leventhal (2004) found that heart failure patients' illness representations were reflective of an acute model of illness. Heart failure patients perceived themselves as having little control over their illness, and misinterpreted, and were unfamiliar with, the causes of worsening symptoms. This resulted in patients being inattentive to symptom changes indicative of worsening heart failure, and health care was only sought when the illness had deteriorated. This study clearly illustrates that patients did not perceive self-management behaviours to have an influence on their illness. Therefore, structuring information on these five dimensions should provide patients with information that represents a more accurate model of chronic heart failure and its management.

The TPB was the principal framework chosen for the booklet intervention because of the strengths of this model compared to alternatives (see chapter 4). The TPB has been previously utilised in written information interventions (see chapter 4, part II). Lorig (2001) suggests that patient education formed on an assessment of salient beliefs addresses the needs and perceptions of patients. Previous research has identified the influence of patients' beliefs about heart failure on self-management (van der Wal et al., 2006; Evangelista et al., 2001; Bennett et al., 1997). This finding is compatible with the

TPB, which proposes that changing the beliefs which underlie behaviour promotes behaviour change (Fishbein & Ajzen, 1975). Written information interventions based on the TPB should target the behavioural, normative, and control beliefs which underlie behaviour. The booklet in this research programme, therefore, targeted the behavioural and control beliefs which underlie taking medications as prescribed, physical activity, restricting salt intake, and regular weighing. Attitude and PBC are generally found to play a greater role in intention than subjective norm (Godin & Kok, 1996). Therefore, to limit the length of the booklet, normative beliefs were not targeted.

The identification of beliefs which distinguish between intenders and non-intenders is proposed in the development of interventions based on social cognition models (Sutton, 2002). This stage identifies beliefs most predictive of behaviour, and limits interventions to a few selective salient beliefs. However, these may not reflect the wider set of beliefs held by individuals. The booklet intervention in this research programme was intended to address all salient beliefs identified by heart failure patients in relation to self-management. This strategy would enable the booklet to address a wider range of beliefs, and increase the ability of the booklet to promote self-management in a larger proportion of heart failure patients. This approach has also been adopted in other TPB-based written information interventions (Chatzisarantis & Hagger, 2005; Hoogstraten, de Haan, & ter Horst, 1985).

The TPB is primarily a motivational theory. Influencing salient beliefs to increase PBC and make attitudes more favourable would encourage the formation of intention. However, intentions are not always sufficient for behaviour enactment (e.g. Godin & Kok, 1996; Orbell & Sheeran, 1998). Augmenting the TPB with volitional strategies may assist in translating these intentions into action (Ajzen & Manstead, 2007; Fishbein & Ajzen, 2005). The adoption of components from multiple theories to develop interventions is advocated in the literature (Hardeman et al., 2002; Kok & Schaalma, 2004; Lorig, 2001). The booklet in this research programme, therefore, also incorporated strategies from other leading theories of behaviour and behaviour change, and included implementation intentions, goal setting, self-monitoring, and modelling. The former two components have been adopted in previous TPB-based written information interventions (Hill, Abraham, & Wright, 2007; Murgraff, Abraham, & McDermott, 2007; Kelley & Abraham, 2004).

Implementation intentions comprise a basic plan of action; an individual specifies when, where, and how ('if situation Y is encountered, then I will perform behaviour X') a particular behavioural intention will be enacted (Gollwitzer, 1999; Gollwitzer, 1993). The literature has provided ample evidence that implementation intentions can be effective in facilitating behaviour (e.g. Sheeran & Orbell, 2000; Orbell, Hodgkins, & Sheeran, 1997; Orbell & Sheeran, 2002). For example, women who formed implementation intentions were twice as likely to perform breast self examination than women who did not form them (Orbell et al., 1997). Implementation intentions can be easily incorporated into written interventions and could assist in initiating self-management behaviours that patients had been intending to perform.

Goal setting is commonly used to promote behaviour change (Strecher et al., 1995) and enables individuals to plan a strategy towards the attainment of a desired behaviour. The most common goal structure is hierarchical; more immediate and proximal sub-goals lead to the attainment of a more distant higher goal (Austin & Vancouver, 1996). Abraham and Sheeran (2003) suggest that PBC may be partly determined by levels of planning (e.g. goal setting). A recent theory-based booklet intervention identified goal setting as the most crucial component in improving older adults' healthy eating and physical activity (Kelley & Abraham, 2004). The booklet intervention in this research programme will utilise goal setting to enable patients to develop a strategy to implement their behavioural intentions to perform self-management.

Theory and research on self-monitoring and modelling also guided the development of the booklet intervention. Self-monitoring enables individuals to evaluate their behaviour and provides feedback in relation to goal achievement (Bandura, 1986). This strategy improves behaviour in motivated individuals (Bandura, 1986) and increases self efficacy (Bandura, 1997). Self-monitoring in patient education interventions promotes awareness of behaviour (Prohaska & Lorig, 2001). In the booklet intervention, self-monitoring was, therefore, encouraged in order to enable patients to gain feedback about their self-management. Modelling is also a component of social cognitive theory and is a process whereby people learn from observing the actions of others, and the consequences resulting from those actions (Bandura, 1986). The booklet intervention included information describing the self-management of other people with heart failure. This information might influence future behaviour, particularly if patients believe that people similar to them can perform these behaviours and report favourable outcomes.

7.4 Recommendations for Developing Quality Written Information

Access to good quality information is an important component of health care. Evidence suggests that patient information is often poor in quality- containing inaccurate information, unexplained technical terms, irrelevant topics, and having high readability levels (Payne, Jarrett, Turner, & Large, 2000; Mumford, 1997; Coulter, Entwistle, & Gilbert, 1998; Petterson, 1994). Information that is difficult to understand will fail to impart knowledge, and can lead to increases in anxiety and depression (Mumford, 1997). The usefulness of written information can also be limited by poor design and writing. In recent years there has been a movement towards ensuring that written information is of the highest standard, clear, appropriate, and suitable for the intended target patient group. This has resulted in the development of recommendations for developing written information materials which focus on factors such as readability, legibility, and appropriateness of content (Ley, 1997; Coulter et al., 1998; Payne et al., 2000) (see table 10 below). The design characteristics of content, readability, legibility, language, and layout will be discussed further below. Most importantly, the involvement of users in the development and testing of patient information is emphasised in the literature (Raynor et al., 2007; Raynor, Savage, Knapp, & Henly, 2004). This process ensures that information is understandable and meets the information needs of the intended patient group.

Content: A review of health education materials found that many leaflets were too introductory in content, and so could not aid medical decision making (Coulter et al., 1998). Patient written information has been found to contain insufficient or unreliable information about treatment effectiveness (Coulter et al., 1998). A small number of materials were also regarded as containing unnecessary technical information (Coulter et al., 1998). There is a fine balance between providing too much and too little information to patients, and there is uncertainty in the literature about the type of information that patients desire during the course of their illness. The review by Coulter and colleagues (1998) found that patients at the initial stages of investigation and time of diagnosis wanted information about the illness, prognosis, and the tests that they may undergo. This review suggested that information about treatments was desired later in the illness trajectory. However, some participants wanted this information at a much earlier stage. The information required by patients is likely to differ according to illness, stage of illness, and the personal preferences of the individual for obtaining health related information.

The content of written education materials should not be solely driven by what health professionals deem as important. It is already established in the literature that health professionals' perceptions of what information patients need differs from that of the targeted patient group (Frattini, Lindsay, Kerr, & Park, 1998; Hagenhoff, Feutz, Conn, Sagehorn, & Moranville-Hunziker, 1994; Wehby & Brenner, 1999). Therefore, the involvement of the target group in the development of information materials is imperative to ensure that the information is oriented around topics that are of importance and relevance to them (Reid et al., 1995).

A clearly defined purpose for the written information is important, as readers who don't understand the intent behind the information may not attend to it as much (Doak, Doak, & Root, 1996). The content of materials should be up-to-date and evidence-based (Coulter et al., 1998). Only 19.5% of materials in the review by Coulter and colleagues (1998) were dated. The absence of a publication date prevents the reader from identifying whether the information presented is current (Coulter et al., 1998). Features in materials that promote the involvement of readers are appreciated by patients (Coulter et al., 1998). Strategies such as checklists, symptom diaries and spaces to write questions facilitate the process whereby the reader considers their current situation and the decision-making process (Coulter et al., 1998).

Readability: The readability level of written materials is fundamental to the materials' ability to deliver information that is understandable to the patient population. The literature has identified that the reading level of written information is higher than the reading ability of patients. For example, Mumford (1997) found that the majority of health related information leaflets were written at the level of university students. Estey, Musseau and Keehn (1991) found that a greater proportion (85.3%) of medical and surgical patients were able to comprehend material written at grade level 5 (reading age 10-11 years) compared to material written at the 9th grade level (44.1%, reading age 14-15 years). The literature suggests that reading materials should be targeted at a 5th to 6th grade level, which corresponds to the reading ability of 10 to 12 year olds (Doak et al., 1996; Estey et al., 1991). A survey in the UK found that 16% of the adult population had a reading age equivalent to or below an 11 year old (Department for Education and Skills, 2003). Therefore, materials should be written to enable people with lower readability levels to access health related information.

A number of readability formulas exist to determine the ease of reading written information (see Ley & Florio, 1996). Although these formulae could prove useful for the development of a booklet, shortcomings exist in their ability to determine readability. Firstly, these formulae rely on syllables within a word. However, there exist many monosyllabic words that are not common to every day vocabulary, and these words may be more difficult to read than regularly used polysyllabic words (Bailin & Grafstein, 2001). Sentence length also does not necessarily indicate actual readability. Written information with the lowest reading grades does not have the shortest sentences (Mumford, 1997). These formulae mainly use word lists to determine which words are easy to understand. Changes in vocabulary occur within society, therefore it cannot be assumed that people of different ages or from different socio-economic or socio-cultural groups all use and understand words in the same way (Bailin & Grafstein, 2001). Readability formulae can be useful in the development of written materials, however, the shortcomings associated with these formulae which are outlined above should be considered during their application.

Legibility: Legibility is the visual presentation of information. It refers to typeface, size and colour of text. An investigation into the attitudes of consumers to the design characteristics of written information found that patients preferred a font size of 10 to 11 (Bernardini, Ambrogi, Fardella, Perioli, & Grandolini, 2001). A minimum font size of 12 is recommended (Royal National Institute for the Blind, 2008; Coulter et al., 1998; Doak et al., 1996). Although for some target audience, such as older people who may have poorer eyesight, a larger font size may be more suitable (Glasper & Burge, 1992). An evaluation of 1087 leaflets available at hospices and palliative care units found that 47.3% of leaflets were written in a font size less than 12 (Payne et al., 2000). Petterson (1994) compared 70 hospital information leaflets according to the clear print guidelines of the Royal National Institute of the Blind (RNIB). This study found that 83% of materials were written using a font size smaller that the recommended minimum font size of 12. The authors suggest that this would make these materials more difficult for older people to read.

The RNIB (2008) recommend that a stylised typeface, blocks of capital letters, underlined and italicised text, should be avoided because they are all harder to read. The use of capital letters slows the reader (Albert & Chadwick, 1992), and it is recommended that underlining and italicising should be avoided for the purpose of emphasising text (RNIB, 2008). Written materials should maximise colour contrast (Doak et al., 1996). This involves having a good contrast in colour between the text and the background, the best contrast is black text on white background (RNIB, 2008).

Language: The words used in patient education materials should be selected carefully as these determine readability and comprehension. The language used in materials should be acceptable to the target group. It is indicated that simple materials are preferred and better understood by people regardless of their literacy levels (National Work Group on Literacy and Health, 1998; Estey et al., 1991). Short sentences are preferable in written materials (Maher, 1996; Hartley, 1994). Hartley (1994) suggests that long sentences are difficult to remember. He recommends that sentences of less than 20 words are acceptable, while those over 40 words should be re-written. Sentences should be simple, avoid complexity, contain one idea and few words; this makes it easier to understand and reduces the amount and number of words that need to be processed in short term memory (Doak et al., 1996). This is of particular importance with older people, who may experience some short term memory difficulties. The presentation of information in a 'how to' format is also recommended (Doak et al., 1996; Mayneaux, Murphy, & Arnold, 1996).

Payne and colleagues (2000), in their review of patient education materials for palliative care patients, found that the majority of leaflets (76.3%) contained no jargon. However, a minority (1.7%) of materials contained a moderate amount of jargon. Coulter and colleagues (1998) found that some written materials used technical terms or medical diagnoses sometimes without explanations of their meanings. Patients were found to prefer plain and simple terms, and disliked complicated and technical language (Coulter et al., 1998). It is recommended that jargon is avoided, and if medical terms are used then these should be explained (Bernier, 1993). Patients preferred a style of writing that was more facilitative than prescriptive (Coulter et al., 1998). An active and conversational style of writing is recommended (Doak et al., 1996; Albert & Chadwick, 1992). Personalisation is also preferable, the use of personal pronouns (I, we) in writing make the information more personal to the reader (Albert & Chadwick, 1992). This enables the written text to relate to the audience.

Layout: The organisation of material can also influence comprehension. The use of white space can help organise text as it separates paragraphs and subsections of text (Hartley, 1994). The spacing in written information (know as leading) is important. The RNIB (2008) suggest that there should be equal spacing between each word and 1.5 to 2 times space between sentences. Headings should stand out in the text, with a larger type size, bold text, together with plenty of space around them; this will help patients to navigate their way around the leaflet (Dixon & Park, 1990).

The repetition of key points is useful to emphasise important information (Reid et al., 1995; Webber, Higgins, & Baker, 2001). Bullet points are more useful in gaining the attention of the reader than solid blocks of text (Dickinson, Raynor, & Duman, 2001). A question and answer format can be effective. This allows an individual to find questions that may be relevant to them (Boyd, 1987). A clear and effective layout allows a reader to use written materials with more ease.

Table 10. *Recommendations for producing patient written information*
Department of Health, 2003; Coulter et al., 1998; Payne et al., 2000.

Appropriateness of content
• Use clear and simple language that is understandable to the reader. • Avoid technical words and acronyms. Provide explanations for medical terminology and avoid frightening language. • Use personal pronouns to personalise messages. • Use positive language and avoid negative, patronising or alarmist language. • Provide balanced evaluation of potential risks and benefits.
Content of booklet
• Ensure that common concerns and misconceptions are addressed. • Provide specific instructions. • Include quantitative information where appropriate. • Provide information about other available services or resources. • Leaflets should be dated. • Use short sentences to convey information (approximately 15-20 words). • Emphasise important information by highlighting or reinforcement. • Use present and active tenses when possible.
Legibility
• Use diagrams and pictures to illustrate text. • Use lower case letters with upper case letters where appropriate. This is easier to read than upper case alone. • Present information in small blocks of text. • Use question and answer, bulleted or numbered points to divide text. • Use clear headings. • Use an easy to read font size; point 12 or larger. Information for older adults should be 14 or greater. • Use white space which makes information easier to read.
Other
• Consider the information needs of minority groups. • Cater for differing patient requirements and information needs.

7.5 Development of the Improving Heart Function Booklet

This section describes the development of the IHF booklet. The use of previous research and theory-based approaches in the development of the booklet is outlined. It was important to ascertain the information that health professionals wanted to give to patients; this would ensure that the booklet was useful for clinical practice. It transpired that during 2002 health professionals in the Elderly Care and Medicine at Southampton General Hospital developed a pilot booklet for older heart failure patients which was never fully developed or disseminated due to funding constraints. This booklet, alongside a booklet developed by a local heart failure nurse, provided insight into the information health professionals wanted to share with patients to promote understanding. These booklets formed the foundation for the booklet intervention. The four management behaviours addressed by the booklet intervention were; taking medication as prescribed, regular physical activity, eating less salt, and regular monitoring of weight.

The title selected for the booklet was ‘Improving Heart Function’ (IHF). This title was chosen, instead of ‘Managing Heart Failure’, as health professionals in the first qualitative study referred to the negative associations linked to the term ‘heart failure’. The term Improving Heart Function suggests more controllability over the illness than the term ‘heart failure’, which suggests failure at the outset. The literature suggests that the term ‘heart failure’ impairs doctor-patient communication (Lehman, Doust, & Glasziou, 2005), and health professionals prefer to use a number of euphemisms instead (Barnes et al., 2006; Tayler & Ogden, 2005).

The pilot version of the booklet had 26 pages (see appendix K). The booklet advised patients to take their doctors’ advice or contact their doctor if they had any questions about their illness and its management. This also promoted an active role for the patient, and hence encouraged a shared responsibility.

7.5.1 Section 1: Understanding your Heart Function

The majority of the information in the section ‘understanding your heart function’, and at the beginning of the ‘improving your heart function’ section, was influenced by the illness representations central to the self-regulatory model (Leventhal et al., 1980). The booklet aimed to provide patients with information on the five broad dimensions of illness representations: identity, cause, time-line, perceived consequences, and curability/controllability. The *identity* dimension addressed what was wrong with the heart and the symptoms of heart failure (breathlessness, fluid retention, weight gain, tiredness, or general lack of energy). The *cause* dimension focused on a number of possible causes of heart failure. The *time-line* dimension was paid attention to by explaining that symptoms may develop gradually over time. The time-line for prognosis was not discussed, as the course of heart failure is unpredictable, and making an estimation of prognosis for heart failure is very difficult (Cowie, 2003). The perceived *consequences* of heart failure were addressed in the symptoms section, which acknowledged that it may be difficult for patients to carry out normal everyday tasks. The *curability* and *controllability* dimension was incorporated by providing information that heart function could be improved by making lifestyle changes and getting treatment from the doctor. It was also mentioned that the damage to the heart could not be cured, but that it was possible to exert control over the illness.

7.5.2 Section 2: Improving Heart Function

To improve knowledge about self-management, informational messages specifically targeted deficits in knowledge and misunderstandings. To encourage shared responsibility, informational messages encouraged patients to share information, ask questions, and address concerns with health professionals. Different types of informational messages targeted different antecedents to behaviour. To produce a change in attitude, informational messages emphasised the positive consequences of performing self-management, and the negative consequences of not performing self-management. To influence PBC, informational messages provided guidance, instruction, and encouragement to increase patients' sense of control over their self-management. Direct instructions for a specific action encouraged formation of an intention. Implementation intentions and goal setting facilitated the translation of intention into behaviour.

Take your medications as prescribed: Factors shown to influence medication taking include patients' beliefs about the necessity of medication and concerns about adverse consequences from taking medications specifically prescribed for them (Horne &

Weinman, 1999; Horne, Weinman, & Hankins, 1999). Therefore, to influence attitude, informational messages on the benefits of medication taking for symptom control and heart function were included. Negative consequences, such as side effects, are associated with medication taking in people with chronic illnesses (Barber, Parsons, Clifford, Darracott, & Horne, 2004). Therefore, to encourage a positive attitude, the belief strength for this negative belief was decreased by informing readers that most patients take their medications without any problems. However, instructions for contacting their doctor if they experienced side effects were included, which promoted an active role in self-management.

Heart failure patients have a complex medical regimen (Martinez-Selles et al., 2004) and experience forgetfulness in managing their tablets (Cline et al., 1999; Stromberg, Brostrom, Dahlstrom, & Fridlund, 1999). The latter may decrease PBC. Patients have identified lists as a method for managing medications (Riegel & Carlson, 2002). A medication chart was, therefore, included in the booklet to increase PBC. This enabled patients to list their medications, and could assist in reducing forgetfulness. This medication chart also instructed patients to include when and where they would take their medications, enabling them to form an implementation intention for each of the medications in a chart format.

Heart failure patients are often unaware that medication treatment is life long (Agard et al., 2004), and some stop or take their medications intermittently (Michalsen, Konig, & Thimme, 1998). The booklet informed patients that they should continue to take their tablets until advised otherwise by their doctor. One study found that only 10% of patients collected enough prescriptions to take digoxin as prescribed over a year long period (Monane, Bohn, Gurwitz, Glynn, & Avorn, 1994). Repeat prescriptions are the responsibility of the patient, therefore, patients were advised to ensure that they did not run out of tablets. Patients were referred to explanations of commonly prescribed medications for heart failure in the back of the booklet, so that they could become familiar with the actions of their medications.

Weighing regularly: Heart failure patients regard daily weighing as an unimportant part of their self-management (Ni et al., 1999; Carlson & Riegel., 2001). To change attitude, informational messages explained the benefits of regular weighing to monitor fluid retention. To increase PBC, instructions were provided for regular weighing and directed patients to a weight chart. This weight chart included an implementation intention specifying when they should weigh everyday to promote this self-management behaviour. The implementation intention was based on pre-existing instructions in heart failure management for regular weighing to detect early fluid retention. The implementation intention used in this booklet only specified when patients should perform daily weighing, and not where. Research has found that implementation intention plans which specify only when a behaviour will happen have increased attendance to cervical screening (Sheeran et al., 2000). Patients were also instructed to immediately record their weight in the chart, thus enabling self-monitoring, and immediate self-evaluation, which positively influences behaviour (Bandura, 1986).

Physical activity: Decreasing physical activity is a common coping strategy adopted by heart failure patients in response to symptoms (Bennett, Cordes, Westmoreland, Castro, & Donnelly, 2000). To influence attitude, the negative consequences of not engaging in physical activity were explained, while emphasising the positive benefits of physical activity for their illness. Heart failure patients have questions about the type and amount of physical activity they should engage in (Bennett et al., 2000). Uncertainty about exercising safely may reduce PBC, therefore, the booklet provided suggestions on safe types of physical activity and instructed patients on avoiding over-exerting themselves. Physical limitations are likely to influence physical activity, and patients with such limitations may have a decreased sense of PBC. To increase PBC, instructions for light exercising whilst sitting were also included. To influence attitudes in patients with limited mobility, informational messages outlining the positive benefits of light physical activity were included.

Eat less salt: To influence attitude, the negative consequences of fluid retention from high salt intake were explained. The literature indicates that patients lack understanding about how to reduce salt intake, and that they also encounter difficulties in interpreting the salt content on food labels (Neily et al., 2002). These factors may decrease PBC. Therefore, instructions were provided about reducing salt, such as not adding salt to their food, and using other seasonings for taste. Advice on how to read food labels was included, and foods high and low in salt were identified.

Other self-management behaviours: Information on monitoring symptoms, eating a healthy diet, stopping smoking, reducing or stopping alcohol, and immunisation against influenza, was also included. Patients were provided with a section to write down notes, useful numbers, and a space to list questions they wanted to ask health professionals. The latter would assist in helping patients who may forget to ask health professionals questions in the consultation.

Social support: Gallant's (2003) review on social support and chronic illness self-management concluded that greater levels of social support are related to better self-management behaviours. The heart failure literature has produced mixed findings for the influence of social support on self-management. Qualitative studies report that heart failure patients comment on the support of others in assisting them to self-manage (e.g. Riegel & Carlson, 2002; Simpson, Farris, Johnson, & Tsuyuki, 2000; Stromberg et al., 1999). Therefore, the booklet encouraged patients to seek support from others, and provided details of support groups.

The lifestyle contract: Patients were encouraged to complete a 'contract'. This involved patients identifying a lifestyle change to improve their heart function. Patients were instructed to make a specific goal plan which gradually increased in difficulty and complexity. This type of contract and goal planning has been incorporated in other self-management booklets (see Yardley & Kirby, 2006) and can be used to promote behaviour change. Such contracts allow patients to develop goals that are relevant to their lifestyle, and enables patients to make a commitment. The contract was consistent with the four step goal setting approach used in nutrition counselling, namely, patients (1) identifying a need for change; (2) establishing a goal; (3) adopting a goal directed activity and self-monitoring, and (4) identifying a self reward (Cullen, Baranowski, & Smith, 2001). The contract also encouraged patients to identify someone who would support him or her to make the changes, as a mechanism through which to gain social support (Prohaska & Lorig, 2001).

7.6 *Pilot Evaluation of a Knowledge Questionnaire and Pilot Evaluation of IHF booklet and Elicitation of Patients' Salient Beliefs.*

This section presents a pilot of a knowledge questionnaire and a qualitative study which identified patients' salient beliefs about self-management and patients' views about the pilot IHF booklet. The piloting of written information on intended users is essential to ensure that information is understandable, acceptable and meets patients' informational needs. This qualitative study aimed to identify the views of heart failure patients about the IHF booklet and to ascertain whether the information and theoretical strategies, used in the booklet, were acceptable and useful to patients. The TPB proposes that changing the beliefs which underlie behaviour promotes behaviour change, therefore, patients' beliefs about heart failure self-management were elicited. These beliefs would then be targeted in the booklet intervention.

7.6.1 *Participants and Procedures*

The participants were patients with a confirmed diagnosis of heart failure. All patients, who were deemed able to provide informed consent by health professionals, were approached about the study. Two consultants from the Directorate of Elderly Care and Medicine introduced the study to patients who attended their outpatient clinics for a 6 week period. Those patients who expressed an interest were introduced to the researcher, who then provided potential participants with an information sheet and consent form (see appendix L & M). Patients were informed that they should contact the researcher or return the consent form, if they were interested in participating, and a convenient time and location for the interview would be arranged.

Fourteen participants were informed by the Consultants about the study and received information about the study. All 14 participants subsequently agreed to take part. Upon consent, all participants completed a demographic questionnaire. Of the 14 heart failure patients that participated, 8 were male and 6 were female. The sample had a mean age of 72.3 years (SD=11.3) and this ranged from 42 to 85 years. All participants apart from one were White British. The remaining participant stated that his/her nationality was not stated in the options available. Half of the participants had engaged in further or higher education.

Participants first completed a pilot knowledge questionnaire and took part in a semi-structured interview, which consisted of two parts. Firstly, participants were asked a series of open-ended questions to elicit their salient beliefs about taking medication as prescribed, regular physical activity, healthy eating and restricting salt intake, and regular weighing (see appendix N). Questions about the advantages and disadvantages of performing these self-management behaviours elicited behavioural beliefs, while questions about problems encountered and help required in performing these self-management behaviours elicited control beliefs. To access participants' views about the booklet the think aloud method and probing questions were used. In the second part of the interview, participants were encouraged to provide their views of the booklet by using the 'think aloud' method. The 'think aloud' method involves participants verbalising their thoughts about the booklet and its content, as they read the booklet. The researcher prompted participants to keep talking through the whole process. Probing questions were also used and these were concurrent, retrospective, scripted, and spontaneous. Scripted concurrent probes were delivered upon completion of a subsection of the booklet. Retrospective probes were used after the participant had read the complete booklet. Spontaneous probes enabled the researcher to respond to any hesitations or reactions (e.g. uncertainty) to the information in the booklet. The 'think aloud' method enabled collection of participants initial thoughts and reactions, while probes enabled further clarification of their responses. These methods gathered information about participants' comprehension, interpretation, and their views on the usefulness, format, and content of the information they had just read. Heart failure patients were also encouraged to mention any other factors that may have been important or relevant to the self-management of heart failure, or regarding their informational needs.

7.6.2 Pilot Knowledge Scale

This scale was piloted in this sample as questions from it may subsequently be used as part of an outcome measure for the evaluation of the booklet intervention. The questions in this pilot knowledge scale were developed by considering the existing research literature on heart failure patients' knowledge of their illness, including their misconceptions and doubts (see section 3.2). Feedback on the scale was obtained from two consultants from the Directorate of Elderly Care and Medicine. The pilot knowledge scale (see appendix R) consisted of 20 questions addressing all aspects of heart failure, and a total score of 28 was possible. Participants had to identify the actions of three medications commonly used to treat heart failure and these included ACE inhibitors, beta blockers, and diuretics. The scale had 10 multiple choice items; 6 items required participants to tick only one response per question, whereas 4 items expected participants to tick two or more responses. When participants were expected to tick more than one response, their correct responses were summed and their incorrect responses deducted. 10 of the items required participants to rate statements as true or false.

7.6.3 Data Analysis

Descriptive statistics were used to analyse the data from the pilot knowledge scale. Thematic analysis, guided by the principles proposed by Boyatzis (1998) was used to analyse the qualitative data. A deductive approach was utilised to analyse the data collected about patients' salient beliefs, allowing the theory of TPB to drive the identification of themes relevant to the constructs within the theory. An inductive approach was used to analyse the data collected on participants' views of the booklet, allowing the data to drive the analysis (Boyatzis, 1998). All interviews were transcribed verbatim and each separate response by the interviewer and interviewee was numbered, along with the line of the text, in order to provide a clear referencing system. The quotes presented in the results section are used to demonstrate a range of views. Just how many of the participants held views were indicated prior to the presentation of quotes.

7.6.4 Results: Pilot Evaluation of a Knowledge Scale

Participants gained a mean knowledge score of 19 (SD = 2.79), with scores ranging from 15 to 24. All participants correctly identified that their heart was having problems pumping blood around their body, that they were responsible for ensuring that their tablets did not run out, that water retention put an extra strain on their heart, and that exercise was not bad for their heart. The majority of participants correctly identified that they needed a flu jab every year (93%, n = 13), that they couldn't stop taking their drugs if they experienced side effects (86%, n = 12), that lifestyle changes could improve the function of the heart (93%, n = 13) and that they have responsibility for the management of their heart failure (86%, n = 12). The majority of participants (93%) correctly reported that they could do regular light exercise. However, participants did have some misconceptions. 29% (n = 4) of participants thought that their heart condition could be cured, and nearly half of participants (43%, n = 6) thought that it was safe to take additional medicines over the counter.

Of the 12 participants that responded to the question about when patients should weigh themselves to monitor their fluid retention, only a third of participants correctly identified that they should weigh themselves before breakfast and after going to the toilet, while another third thought that they should weigh themselves after breakfast, after going to the toilet- a quarter of participants would weigh themselves before breakfast, and before going to the toilet. About two-thirds of participants (64.3%, n = 9) correctly reported that salt promoted fluid retention and increased weight. Only half of participants knew that five or more portions of fruit and vegetables were recommended daily for a healthy diet. Furthermore, 21.4% (n = 3) of participants, when experiencing worsening of symptoms, would wait a few days to see if their symptoms improved before contacting their doctor.

Participants were asked to identify common symptoms of heart failure from a list of 8. Participants on average were able to identify two to three symptoms of heart failure out of the four heart failure symptoms listed (shortness of breath, swelling of ankles, tiredness, and retaining fluid). 93% of participants were able to correctly identify that shortness of breath and swelling of ankles were common symptoms of heart failure. However, there appeared to be more confusion among this sample about tiredness and retaining fluid as common symptoms of heart failure. 5 participants did not identify tiredness or retaining fluid as symptoms associated with heart failure. A minority of participants identified symptoms that are not association with heart failure, such as skin rash (n = 2), difficulty swallowing (n = 1), and high temperature (n = 1).

Participants' knowledge about their medications was poor. A total score of 8 was possible for the medication questions, and participants on average correctly identified 3 actions of their medications. Only 28.6% (n = 4) were aware that ACE inhibitors reduced swelling and breathlessness, and none identified that this medication could also remove water and salt out of the body. Less than half of participants (43%, n = 6) identified that beta blockers slowed the rate at which the heart pumped. Just over half the participants (57%, n = 8) were aware that diuretics helped to take salt and water out of the body, and just less than half (43%, n = 6) were aware that they also reduced swelling and breathlessness.

7.6.5 Results: Identification of Salient Beliefs

7.6.5.1 Taking medications as prescribed by the doctor.

Behavioural beliefs: Most patients reported both favourable and unfavourable outcomes from taking their medications as prescribed by the doctor. Unfavourable outcomes related to unpleasant side effects, which normally resulted in patients feeling more unwell.

> *'I think sometimes there's certain tablets that just don't agree [with you] and make you feel ill' (2.277)*

Favourable outcomes included the ability of medications to keep their heart working, make them feel better, and help them live longer.

> *'Well this new medication I'm on now, I feel better than I have for 10 to 12 years' (5.333-334)*

> *'If it helps you live a little longer you've got to do these things [take medications]' (11.24)*

Control beliefs: Patients perceived difficulty with managing medications, and sometimes were unable to take medication as instructed. A few participants stated that at times they forgot to take their medication.

> *'Even this morning, I think I'm a tablet missing but I don't know' (13.126-127)*

The difficulty of managing medications was related to two reasons. Firstly, some patients experienced difficulty in managing the large number of tablets prescribed, particularly when they had to be taken at different times.

'You've just got to remember which ones [tablets] to take and which ones not to take' (2.298-299)

'Eleven different types of pills, some in the morning, some in the evening. That takes a bit of controlling' (3.298-299)

Secondly, some patients found it difficult to keep up to date with the frequent changes to their medications.

'Well I've got to keep up with what he [doctor] says, that's the problem. I mean I put it [list of medications] on the computer and run a sheet off to give to doctors or anybody [health professionals]. But then when I go to see him, he may alter something, and then I've got to alter everything and make a new one [list of medications]' (12.23-26)

Very few patients made suggestions about strategies that could assist in taking medications as prescribed. Methods proposed included making a list of their medications or using pill boxes/dispensers to organise their tablets.

'Well I write it down, make note' (7.291-292)

'We've got a stacking system, they're very good' (7.232)

'If I didn't do the tablets in the thing (pill box), I wouldn't take them because I would think have I took them or have I not' (13.72).

7.6.5.2 Participating in regular physical activity.

Behavioural beliefs: The majority of patients suggested keeping mobile as an advantage of regular physical activity.

'Keep me moving; keeps my joints moving as much as I can' (6.168)

> *'Well it keeps me mobile' (12.44)*

Only a few patients mentioned the benefits of physical activity for their heart, or their symptoms, and it appeared that the majority of patients felt that regular exercise was for general fitness only.

> *'Exercise gets your body moving and your heart moving and everything's going round' (2.245-246)*

> *'Do it [exercise] to help my breathing' (12.44)*

Disadvantages of regular physical activity included a worsening of symptoms, such as breathlessness and tiredness, and some patients reported feeling more unwell. There was no mention of the benefits of doing a little exercise despite a small increase in symptoms.

> *'When I get back here [home], god I'm just so grateful, I just want to lie here and just sleep for the rest of the day' (11.82-83)*

> *'If I walk 100 yards now, I'm out of breath, I'm absolutely finished' (4.86)*

> *'I can't really do much, if I make my bed in the morning, that's me finished' (13.21-22)*

Control beliefs: Both breathlessness and tiredness were frequently mentioned as factors that could hinder engagement in physical activity.

> *'Only the breathing, that's the main thing, that's the main thing for not doing any exercise' (12.62-63)*

The existence of other physical health problems prevented some patients from engaging in physical activity.

> *'When exercise is concerned I can't do very much because I've got arthritis in my shoulders, see I've got a job to walk so I can't do much walking' (6.60-2)*

> *'I don't do very much at all. You see the other problem is my back; my back is in pain all the time it doesn't go away' (13.97-98)*

Some patients expressed a lack of awareness about their physical limitations, and did not know how to engage in physical activity safely. The latter could result in patients over-exerting themselves physically. Some patients suggested that knowing their own limitations could help them to take part in physical activity and reassure them that they are not stressing their heart.

> *'That's when I was moving and I thought I shouldn't be doing this it's heavy [lifting heavy boxes], sometimes I do it without thinking' (7.83).*

> *'You've got to know your limitations because for the simple reason that that heart of yours can go at any time, if you're not careful' (2.259)*

7.6.5.3 Regular monitoring of weight.

There was great difficulty in identifying behavioural and control beliefs for this management behaviour, as patients did not appear to have the relevant knowledge about the association between weight increases and fluid retention. In fact, one heart failure patient seemed unaware that regular weighing was a management behaviour for heart failure.

> *'I didn't know I had to weigh myself everyday to be honest with you' (10.34-35)*

More than half of the patients thought that an advantage of regular weighing was to monitor their body fat.

> *'I don't know, I suppose it would tell me whether I'm eating too much' (11.36)*

One patient was unsure whether weight changes were an indication of water retention or increased body fat.

> *'I'm not sure whether it's [weight gain] water or whether it's my diet' (10.22)*

A patient described how they only monitored their weight when they noticed swelling. In these circumstances, weighing was used to confirm the existence of fluid retention, but not as a self-management behaviour which could identify early signs of fluid retention and initiate appropriate self-management (e.g. increase diuretic drug therapy).

> *'I must admit I don't weigh every morning. If I see a change in my legs [swelling], I jump on the scales to see if I've altered a bit. If I'm going to the hospital or go to see my doctor, I weigh myself to see what I can tell him. But I don't do it everyday, I must admit' (1.89-92)*

Behavioural beliefs: The few patients who were aware of the association between weight increases and fluid retention commented on the advantages of monitoring weight as a method of controlling fluid retention, and one patient reported that he adjusted his diuretics to self-manage his water retention.

> *'I do it as a matter of course now [regular weighing], just to make sure I'm not retaining fluid as it's one of the things that they [doctors] told me I should keep an eye on' (8.205-207)*

> *'I don't do a daily record I must admit but I do weigh myself to keep an eye on things. To make sure it's not going too mad and adjust the water tablets up and down depending on how things are going' (1.112-114)*

Control beliefs: Participants' perceived having a stable weight as a factor that would discourage regular weighing. However, it is worth noting that only patients with inadequate knowledge about weight monitoring held these control beliefs.

'But then you get on there [scales] every morning and you're the same weight, you get fed up with it' (13.123-124)

'My weight stays the same everyday so I would find it boring if I stood on the scales everyday and it said the same everyday' (14.29-31)

7.6.5.4 Healthy eating and the reduction of salt.

As with the regular monitoring of weight, it was very difficult to obtain behavioural beliefs for eating a healthy diet. Patients lacked knowledge about the relationship between salt intake and fluid retention. Interestingly, a few patients had reduced their salt intake but were unsure how this influenced their symptoms or heart condition.

'Participant: Main thing is keeping away from salt; I don't have very much salt'
Interviewer: 'What's the advantage?'
Participant: 'I don't know not very good for you' (12.72-74)

'I just do what they tell me, cut down on your salt, so I don't have any salt' (2.259)

Behavioural beliefs: A few patients identified food tasting bland as a disadvantage of eating a healthy and a low salt diet.

'I used to be one of those people that like to taste my food and not have it tasting bland' (11.90)

*Control beliefs: So*me patients commented that they were unsure how to identify the salt content in food, and faced uncertainty when trying to select foods low in salt.

'The thing around here is that you can't always get the things that they tell you to eat' (10.99-100)

'Knowing what to eat and what not to eat and how to find out if it [food] has too much salt' (6.186)

7.6.6 Patients' Views of the Booklet

Comments made by participants about the information contained in the booklet focused principally on seven sections of the booklet. These will be discussed below, along with participants' overall evaluation of the booklet. For the remaining sections of the booklet, patients seemed quite satisfied with the information and did not propose any changes that could make the booklet more helpful.

7.6.6.1 Overall evaluation of the booklet.

All the patients made very favourable remarks about the booklet as a whole. They perceived the booklet as providing new information, which was easy to understand and relevant.

> *'It covers everything that has happened and opened my eyes a little bit' (1.254)*

> *'I can't say that I've read anything like that with all the different things in it, that have really applied to me' (1.263-264)*

> *'A lot of it is related to my sort of situation so for me personally it would have been very helpful to walk out with this [after a clinic appointment]' (8.369-370)*

Some participants used the booklet as a 'yard stick' against which they could compare their own health and self-management behaviours.

> *'Most of them I do, like this book suggests you know I'm not far off the mark' (11.162-163)*

A few participants used the information in the booklet to reinforce their understanding about the illness and it's management. The information in the booklet seemed to reaffirm what patients thought they knew about their condition and its management.

> *'Yes to understand more things, I'm beginning to realise what they [doctors] are saying. You can guess at what they are saying but when you read it again, you see you are right, but you like to make sure'. (11.122-124)*

7.6.6.2 Understanding your heart function section.

The majority of patients commented that the information in this section explained the workings of the heart very simply, using language that was easy to understand. One participant mentioned that the layman terminology used in the booklet was similar to that used by health professionals.

> *'I mean the language you're using here is actually some of the language that the doctor I saw initially was using to keep things fairly sort of in layman's terms' (9.71-73).*

7.6.6.3 Description of symptoms.

The majority of patients viewed the symptoms discussed in this section as similar to the ones they experienced regularly.

> *'I have experienced what it says here' (1.13)*

The information also assisted in helping some patients to understand why they experienced certain symptoms.

> *'That's what it is, because of the ankles swelling, this [information in booklet] tells you why, it's swelling, because it's not pumping all the fluid in your body back to your heart. That is interesting, now I know why; I kept on wondering why my legs swell'. (11.114-117)*

7.6.6.4 Taking your medication.

The majority of patients found the information in this section useful. One patient found the advice about writing down their medications particularly helpful. This demonstrates how the booklet might be useful in assisting patients to use strategies that could help them to manage their heart condition more successfully.

> *'This is what I should do, is write it down what I'm taking and when because its [medication] beginning to change. If I am not careful I might forget one day. Its*

> *getting to the point where I'm saying to myself 'be careful, mind you don't forget which ones to take when' (14.19-26)*

Responses to the medication chart varied, one patient thought that the chart was not useful, while some patients thought the chart could be potentially very helpful. A few patients commented that they had already established a successful strategy for managing their medications. One patient commented that the medication chart in the booklet was more useful than the system she had devised for monitoring and managing her medication.

> *'That would be helpful [medication chart], like when you go to another hospital or something they ask you [about medications] and I can't remember. I just know that I'm taking my tablets but I forget the name and things. Good idea that' (11.159-161)*

> *'This is what I wanted to know, what I can do. If I get very busy there are times when I leave it a bit late. I don't forget it altogether, but I leave it a bit late' (14.14-16)*

> *'It would help [medication chart] because the list I've got is terrible' (13.122)*

7.6.6.5 Regular weighing.

The information in this section prompted the majority of participants to comment that they did not weigh themselves regularly.

> *'Weigh yourself, I don't weigh myself everyday, only when I think about it' (14.27)*

The patients who did not weigh themselves regularly did not understand the relevance of the weight recording chart. However, the patients who did engage in self-monitoring their weight viewed the chart as useful for noticing a change in their weight.

> *'I don't record it [weight] though I suppose by recording it you would see a trend' (9.219-220)*

7.6.6.6 Additional self-management information.

All of the patients mentioned that the sections on smoking and alcohol were not relevant as they did not smoke and the majority did not drink alcohol, or only consumed alcohol within the limitations recommended by their doctor. In addition, patients suggested that information about a medication called spironolactone should be included in the medication section, as it was one commonly prescribed to them. Patients also requested information on blood tests and their purpose, in relation to prescribed medication.

7.6.6.7 Contract to change behaviour.

Some patients found the idea of setting small goals very useful.

> *'Give yourself a small goal and aim for it and then a little bit more and a little bit more, that really works' (3.291-292)*

> *'Yes I do think this would be useful for the simple reason that a lot of people if they're given something official, they read it and think it says that here I'll do that' (9.183-185)*

However, the majority of patients found it difficult to fill in the contract and sought guidance from the interviewer. Patients found it particularly difficult to identify the health related goals that could improve their self-management, and the setting of sub-goals that would aid the achievement of their final goal.

> *'What do you want me to put there, it says here, what's your final target'? (3.369)*

Patients who were satisfied with their management of heart failure did not perceive the contract as relevant or useful.

'I'm quite happy with what I do now, I've done that all my life so I can't really relate that to any of these questions' (5.313).

7.7 Amendments to the IHF Booklet

This section describes how patients' feedback and identified salient beliefs were incorporated to improve the IHF booklet (see appendix P for an overview of the theory-base, patient literature, and patient feedback, which informed the development of the IHF booklet). The patient interviews indicated that patients had misunderstandings and lacked knowledge to successfully self-manage. The dimension of control in illness representations was, therefore, strengthened by including additional informational messages which described how patients could manage their heart function by taking their medications, monitoring and controlling their symptoms, and making changes in their lifestyle. In particular, it was emphasised that they were the most important person in managing their heart condition. Horowitz and colleagues (2004) found that heart failure patients did not connect exacerbations in their symptoms to their lack of self-management. This may have been likely in this sample of heart failure patients, as they lacked knowledge about regular weighing and reducing salt. Therefore, in the section for the common symptoms of heart failure, information was included which stated that heart failure symptoms were due to their illness, not taking medications properly, or not eating properly (e.g. too much salt).

Medication taking: To change attitude, favourable outcomes identified by patients, such as feeling better and living longer, were added. Modelling was also incorporated by stating that other people with their heart condition felt better when taking their medications properly. Patients encountered difficulties in managing changes to their medication and so, to increase PBC, patients were advised to use the medication chart to monitor changes in their medications. Patients identified pill dispensers and boxes as methods that could assist the management of tablets therefore this advice was included in the booklet. Modelling was incorporated by informing patients that other people with their heart condition found medication lists helpful. This informational message also indicated that this strategy could be easily adopted by people similar to them, thus increasing PBC. To initiate action, specific instructions were included which told readers to write down their medications in the chart and to put it somewhere they will see it everyday.

Physical activity: Patients generally did not identify positive outcomes for their illness, and its symptoms, from regular physical activity. Further information was included to promote a more positive attitude towards physical activity. Patients' control beliefs identified concerns about exercising safely. Therefore, to increase PBC, instructions were provided on exercising safely. The unfavourable outcomes of not exercising, such as an increase in symptoms, were included. To promote the formation of an intention and to initiate this behaviour, patients were instructed to set goals. As patients experienced difficulty with identifying health related goals and the setting of sub-goals in the lifestyle contract, during the pilot evaluation of the IHF booklet, guidance and examples were provided on the setting of goals and how to increase them.

Monitoring fluid retention, regular weighing and reducing salt: Participants had deficits in knowledge related to regular weighing and fluid retention. The booklet, therefore, concentrated on providing more information on these aspects of management. To influence attitude, the negative consequences of fluid retention were emphasised, including adding to the workload of the heart, and worsening symptoms. Informational messages also included the positive outcome of preventing further worsening of symptoms by dealing with fluid retention early. To increase PBC, patients were provided with encouragement, by outlining that a few simple changes could help to monitor and reduce fluid retention, thus indicating that they have the ability to control their fluid retention. To increase PBC, specific instructions were provided about when to weigh everyday, and the amount of weight gain that indicates fluid retention. Encouragement was provided by stating that other patients easily adopted this behaviour. Modelling was used by informing patients that other people with their heart condition monitored their weight by keeping a daily record. To increase PBC for reducing salt intake, further instructions were provided about reducing salt intake, and recommendations for daily salt intake were included.

Other amendments: The lifestyle contract was omitted, as patients experienced difficulty in completing the contract and, in particular, identifying and setting goals.

The difficulty encountered by patients would reduce the usefulness of the contract. The sections on smoking, alcohol consumption, and healthy eating were reduced as patients indicated that they were already aware of this information. Finally, the content of the final version of the booklet was matched to the recommendations suggested in the literature for producing patient information (see table 10). A question and answer format was utilised with patients' modal salient beliefs and informational needs used to formulate questions in the booklet. This ensured that the booklet's content focused on the areas most important to patients.

7.8 Discussion

7.8.1 Pilot Knowledge Scale

The literature has identified that heart failure patients have misconceptions and lack knowledge about their heart condition (e.g. Horowitz et al., 2004; Rogers et al, 2000). This was also found from heart failure patients responses to questions in the pilot knowledge questionnaire. There were some items in the pilot scale that had ceiling effects and, therefore, these items may not be able to distinguish between patients with different levels of knowledge. The preliminary findings, from the pilot knowledge scale, suggest that some heart failure patients did not understand the actions of their medications, were unable to identify the common symptoms associated with heart failure, and appeared not to understand how to monitor their fluid retention, or the actions of a high salt intake on fluid retention. If participants are managing their heart failure with this level of knowledge, then it is likely that participants are not fully aware of the symptoms that indicate an exacerbation of their illness, and are thus unable to adequately monitor their symptoms.

7.8.2 Comparison of Booklets

The booklets were of similar length, with the NICE booklet comprising 21 pages and the 'IHF' booklet comprising 25 pages. The Flesch Reading Ease formula was applied to the two texts, using the grammar and spelling function in Microsoft Word. The output of the formula is given on a 0 to 100 scale, where a higher number indicates easier reading. The IHF booklet had a higher Flesch Reading Ease Score than the NICE booklet, indicating that the IHF booklet was easier to read (see table 11). 24% of the sentences were passive in the NICE booklet compared to 9% in the IHF booklet.

Table 11. *Flesch reading ease scores for the NICE and IHF booklets*

Booklets	Sentences per paragraph	Mean words per sentence	Passive sentences	Flesch Reading Ease Score	Klesch-Kincaid Grade Level	UK school yr and age (to nearest integer value)
NICE booklet	3.4	19.8	24%	52.1	10.9	15-16 years Year 11
IHF booklet	1.6	15.2	9%	68.9	7.3	12-13 years Year 8

Differences in the presentation of leaflets alone can have differing effects on outcomes such as attitude and intention, despite containing the same information (Michie, di Lorenzo, Lane, Armstrong, & Sanderson, 2004). Every effort was, therefore, made to ensure that the booklets were as similar as possible in presentation, so that any differences in outcome could be more confidently attributed to their content. Pictures were, therefore, not used in the IHF booklet, despite this being a recommendation for patient written information (see table 10). The IHF booklet included more bullet points, clearer headings, and boxes with key points to improve the style of the information provided. However, the main physical style of presentation was similar to the NICE booklet. A comparison of adherence to recommendations for producing written information in the two booklets (see appendix Q), suggested that the IHF booklet conformed more closely to these recommendations. The contents of the booklets do differ the NICE booklet includes information not covered in the IHF booklet – namely, techniques for the diagnosis of heart failure, explanation of other treatments including pacemaker, defibrillator and surgery, information on coping with heart failure, prognosis, and depression and anxiety. This information was not included in the IHF booklet, because its focus was on helping patients to manage their symptoms (the 'shared responsibility' guideline). The IHF booklet provided information that both health professionals and patients identified as important in managing heart failure, and suggested strategies that could improve adherence to self-management behaviours. The IHF booklet also targeted patients' misconceptions or informational needs, as identified during qualitative interviews.

7.8.3 Limitations

This IHF booklet may be limited in scope. Firstly, the difficulty that patients encountered with the lifestyle contract highlighted the importance of personal support during the self-management of heart failure, which should ideally be provided by a specialist in a one-to-one situation. The involvement of a specialist would support patients to set self-management goals that were appropriate to their lifestyle, and provide encouragement and information. However, the resources required for a booklet-based education programme with a healthcare specialist are beyond those available for this study. Likewise, the lack of resources for specialist support prevented the use of strategies such as development and rehearsal of skills for self-management, which could potentially have been very useful to patients (Prohaska & Lorig, 2001). In addition, the strategies (e.g. goal setting, modelling, social support) that were adopted in this booklet were applied in a very minimalist way. A more full scale use of these strategies would have required face-to-face/group sessions, or delivery of information in a different format (e.g. video or computer): for example, this booklet utilised modelling in written form. However, applying modelling more intensively would have required providing patients with the opportunity to observe others perform self-management, either via a group situation, pictures in booklets, or video footage (Prohaska & Lorig, 2001). Again, the resources were not available to deliver such interventions. The booklet did not include information on all aspects of heart failure, such as the diagnosis of heart failure and treatments such as pacemakers, defibrillators, or surgery. This information may have proved useful to patients, however, incorporating this information would have increased the length of the IHF booklet considerably. Tailored print communications are better read, remembered, and are more effective at influencing behaviour, than generic information (Skinner, Campbell, Rimer, Curry, & Prochaska, 1999). However, the lack of a written or computerised management plan, in current service provision, impeded the delivery of information that was tailored to an individual's specific circumstances.

7.9 Summary and Conclusions

This study highlighted the importance of incorporating a theoretical framework for the development of booklet interventions. Theories of behaviour change identify amenable factors that can be targeted by written information, and strategies from a number of theory-based approaches can be utilised in written patient information, to influence behaviour. The piloting of booklet interventions is recommended in the literature (Hoffman & Worrall, 2004), and provides an indication of the potential effectiveness of booklets, before proposals for wider dissemination. In the following study, the effectiveness of the NICE and IHF booklets on improving patient outcomes is evaluated. This study will help to determine whether the IHF booklet should be more widely disseminated. In addition, the final study in this research programme will address the question 'Are theory-based written booklet interventions more effective in improving patient outcomes?'

Chapter Eight: RCT evaluating a Theory-Based and Atheoretical Booklet for Heart Failure Patients

8.1 Introduction

To communicate current best evidence to patients, NICE have produced a lay booklet version of the NICE guidelines for heart failure management (NICE, 2003b). According to NICE, this booklet could assist in improving patients' knowledge, thereby implementing the shared responsibility guideline. However, merely providing written information, and targeting knowledge, is unlikely to influence behaviour (Raynor, 1998). Other amenable factors apart from knowledge, such as patients' beliefs about benefits and barriers, influence heart failure self-management (van der Wal et al., 2006; Evangelista, Berg, & Dracup, 2001). This suggests that although knowledge is a necessary prerequisite for heart failure self-management, it is insufficient alone to influence behaviour (van der Wal et al., 2006). Interventions attempting to influence heart failure patients' self-management behaviour, should draw upon psychological theories of behaviour change, and target amenable factors identified by these models that predict behaviour.

This research programme developed a booklet Improving Heart Function (IHF), which draws upon principles of behaviour change theory, recommendations for producing patient information materials, and the heart failure self-management literature (see Chapter 7). This booklet intended to improve patient knowledge, but also specifically targeted the amenable factors of attitude and PBC proposed by the TPB to influence intention and behaviour. The evaluation of patient information booklets is advocated in the literature (Hoffman & Worrall, 2004; Coulter, Entwistle, & Gilbert, 1998; Mayberry & Mayberry, 1996). It was imperative, therefore, to evaluate the IHF booklet prior to any proposals for wider dissemination. This chapter reports a pilot Randomised Controlled Trial (RCT), which investigated the effectiveness of this booklet in improving knowledge, and influencing self-management behaviour. The aim of this study was to explore whether a theory-based booklet would produce greater improvements in knowledge, and exert a greater influence on the cognitive determinants of self-management behaviour, compared to a no-booklet group and the atheoretical NICE booklet.

The primary outcome measure in this RCT was knowledge, since patient understanding has been proposed by NICE as an audit criterion for the shared responsibility guideline. This outcome was considered important in this study because previous research has repeatedly reported that heart failure patients lack knowledge and understanding about their illness (e.g. Stromberg, 2005; Buetow & Coster, 2001). Patients may, therefore, have inadequate information or hold misconceptions that prevent adherence to self-management (Raynor, 1998).

The evaluations of other interventions to improve heart failure patients' knowledge and self-management, have lacked a theoretical basis, resulting in very little understanding of the reasons why an intervention has been successful or unsuccessful (see chapter 3). This RCT assessed the mediators of behaviour identified by psychological models of behaviour, in order to provide an insight into the mechanisms underlying the effectiveness, or ineffectiveness, of the booklet interventions in influencing self-management behaviour. The evaluation of the booklets, therefore, also included measurement of key theoretical constructs from the TPB (Chapter 4). According to this theory, attitudes, subjective norm, and PBC predict behavioural intention, while intention and PBC are the proximal determinants of behaviour. This RCT evaluated both attitude and PBC. The IHF booklet was not designed to influence subjective norm, therefore, it was not deemed necessary to evaluate this construct. According to the TPB, the following associations should exist between the variables in the model:

(1) As attitude towards the self-management behaviour becomes more positive the intention to perform the self-management behaviour should increase
(2) As PBC increases the intention to perform the self-management behaviour should increase
(3) As PBC increases the likelihood of the behaviour being performed should increase provided that PBC reflects actual control
(4) As intention increases the likelihood of the behaviour being performed should increase

Enablement was also assessed in this RCT. Enablement measures a distinct form of satisfaction, and has been used to assess the subjective benefit that patients perceive as a result of primary care consultations (Howie, Heaney, Maxwell, & Walker, 1998).

Enablement can be defined as a measure of an individual's perception of their ability to cope with, and understand, their illness - and their confidence in maintaining their health as a result of healthcare (Howie et al., 1998). This concept of enablement could be utilised to evaluate interventions other than healthcare consultations and, within this study, could provide an assessment of the benefit patients perceive from receiving the booklet interventions.

The Patient's Charter proposes that patients' decisions about their healthcare should be informed (Department of Health, 1991). The literature characterises an informed choice as one that is based on good knowledge, and reflects the attitudes and values of the individual (Marteau, Dormandy, & Michie, 2001). If heart failure patients lack adequate knowledge, then decisions by heart failure patients regarding self-management may be uninformed. Therefore, as an exploratory analysis, this study also classified whether choices made by patients at baseline are informed or uninformed, according to their knowledge and attitudes.

This study investigated whether a theory-based booklet was more successful in increasing knowledge and influencing heart failure self-management behaviours than an atheoretical booklet. This pilot trial would enable the methodology proposed to evaluate the booklets to be tested and along with the findings from this trial, could be used to inform the design of a larger definitive trial, should this be appropriate. This trial was only adequately powered to evaluate the main outcome of knowledge (see sample size calculation), therefore, it provided a definitive test of the primary hypothesis, but tests of the other hypotheses were secondary and exploratory.
The primary hypothesis predicted that:

- The IHF booklet would improve knowledge more than the control condition

The secondary (exploratory) hypotheses predicted:

- The IHF booklet would improve knowledge more than the NICE booklet
- The IHF booklet would improve enablement more than the NICE booklet and the control condition
- The IHF booklet would produce greater improvements in attitude, PBC, intention, and behaviour, for the self-management behaviours, as compared to the NICE booklet and control condition

8.2 Method

8.2.1 Design

This was a RCT in which participants were randomised to either receive the IHF booklet, NICE booklet, or to the waiting list control (see figure 6). Knowledge, enablement, and the TPB constructs (attitude, PBC, intention, and behaviour) were assessed at baseline and at two week follow-up for all the groups. Once the two week follow-up questionnaire was received from the control participants, they were randomised to either receive the IHF booklet or NICE booklet. Therefore, control participants also completed assessments at a second follow-up, two weeks after receiving the booklets.

8.2.2 Measures

8.2.2.1 Knowledge.

There were no suitable measures to assess heart failure knowledge at the planning stages of this study. Therefore, a knowledge questionnaire was developed and piloted among a small group of patients (see appendix R and section 7.6.3). Just prior to the commencement of the trial, a knowledge scale (Dutch Heart Failure Knowledge Scale) with established validity and reliability was published (van der Wal, Jaarsma, Moser, & van Veldhuisen, 2005, see appendix S). This scale was found to have considerable overlap with the scale developed for this trial and, therefore, 12 of the 15 items[3] from the Dutch scale that were deemed appropriate for this study were used for the study questionnaire[4] (see appendix S). The excluded items from the Dutch Heart Failure Knowledge Scale related to the causes of heart failure and fluid restriction. The former was excluded as there were many reasons for developing heart failure, and the latter because this was not a self-management behaviour of interest to this study. The Dutch Heart Failure Knowledge Scale had some shortcomings; primarily the scale focused on the non-pharmacological management of heart failure, did not examine patients' identification of heart failure symptoms, and only included one general question about medication taking. Therefore, it was deemed appropriate to include 15 (8 multiple choice and 7 true and false) questions from the pilot knowledge scale, developed for this

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[3] Approval obtained from author of the Scale, Martje van der Wal, via email correspondence on 14th December 2005

[4] Approved by Dr Syed Zaman, Consultant in the Directorate of Medicine and Elderly Care, Southampton General Hospitals NHS Trust.

study, which had already been amended as a result of patient feedback and input from Dr Syed Zaman, Consultant in Medicine and Elderly Care. Some of the items from the Dutch Heart Failure Knowledge Scale were simplified to increase participant understanding of the multiple choice options[5], and additional responses were added to two items from this scale upon consideration of responses to our pilot questionnaire.

The knowledge scale consisted of 27 items and a total score of 35 was possible. The scale had 20 multiple choice items; 16 items required participants to tick only one option per question, whereas 4 items expected participants to tick two or more responses. When participants were expected to tick more than one response, their correct responses were summed, and their incorrect responses deducted. Seven of the items required participants to rate statements as true or false.

8.2.2.2 Enablement.

The Patient Enablement Instrument (PEI: Howie et al., 1998) was used to measure enablement. The instrument comprises six items which assess an individual's perceptions of their understanding of their illness, ability to cope with the illness, and confidence in managing their health. This instrument was originally designed to be administered following a healthcare consultation, and participants are asked 'As a result of your visit to the doctor today do you feel you are…?'. These items are usually scored using a 3-point scale with the response options of, much better/more, better/more, and same or less (Howie et al., 1998). This study incorporated all the items from the scale but altered some aspects of this instrument for the purpose of measuring change in enablement as a result of the booklet interventions. To assess participants' enablement at baseline we could not ask participants if they felt better about elements of their care, as they had not received any form of intervention. Therefore, participants rated how much they agreed with each item (e.g. How much do you agree that you are…?) on a five-point Likert scale with response options of strongly agree, agree, uncertain, disagree or strongly disagree. This Likert scale was used to maintain consistency with responses to the TPB items (for simplicity of responding). Participants received the lowest score

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[5] Approval obtained from author of the Scale, Martje van der Wal, via email correspondence on 15th December 2005

of 1 for strongly disagree, and the highest score of 5 for strongly agree. Summed scores for all six items ranged from 6 to 30.

8.2.2.3 TPB variables.

Items to measure attitude, PBC, intention and behaviour were developed specifically for this study, as originally proposed for the TRA (Ajzen & Fishbein, 1980; Fishbein & Ajzen, 1975). Attitude was assessed using two items and PBC, whilst intention and behaviour were assessed using single items. All were assessed using a 5-point semantic differential scale. The components of the TPB are normally assessed using a 7-point scale, however, the adoption of a 5-point or 3-point scale is advocated in the literature if this is more suitable for the study population (Godin & Kok, 1996). In this study, it was envisaged that for older and unwell participants a TPB questionnaire using a 5-point scale would be easier to complete.

Attitudes are an individual's overall evaluation of whether a behaviour is favourable or unfavourable (Ajzen & Fishbein, 1980). Literature regarding individuals' beliefs about medication was drawn upon to select the adjectives that would be used to assess participants' attitudes to self-management behaviours. Research into beliefs about medications suggests that there are two key factors; necessity and concerns (Horne, Weinman, & Hankins, 1999). Although these two factors relate directly to taking medication, they could be useful concepts to utilise, for evaluating the attitude of participants to lifestyle and self-monitoring self-management behaviours for heart failure. Therefore, to assess attitude, participants were asked to rate how important/unimportant (necessity factor), or harmful/beneficial (concerns) they perceived each self-management behaviour to be. The two attitude items were summed to provide an overall score for this construct.

PBC refers to an individual's confidence that they can perform the behaviour. PBC was measured by asking participants to rate how easy or difficult they found each self-management behaviour. To limit the length of the questionnaire, only one item relating to PBC was used. The decision to measure perceived difficulty rather than perceived control stemmed from findings which suggest that perceived difficulty is a better predictor of behavioural intention (Trafimow, Sheeran, Conner, & Finlay, 2002).

Intention was assessed using a single item. Participants rated how strongly they agreed or disagreed that they intended to perform each self-management behaviour, over the course of the next week, on a five-point Likert scale, with the options, strongly agree, agree, neither, strongly disagree, disagree. Behaviour was also assessed using a single item. Participants rated how frequently they had performed the behaviour in the past week on a five-point Likert scale with the options every day, almost every day, sometimes, rarely, not at all.

8.2.2.4 Informed choice.

Participants were classified according to whether they had made an informed or uninformed decision, based upon their knowledge, attitudes, and behaviour. The sample size in this study was not considered adequate to allow a comparison of the proportions of people making informed or uninformed decisions in the groups in the RCT. Instead an assessment of informed choice was conducted on the whole sample at baseline. An informed choice occurred when individuals' self-management behaviour reflected their knowledge and attitudes. In the context of heart failure self-management, an informed decision to *perform* self-management was present when an individual had a positive attitude towards the behaviour, had relevant knowledge, and performed the behaviour. An informed choice to *not perform* a self-management behaviour occurred when an individual had a negative attitude towards the behaviour, had relevant knowledge, and did not perform the behaviour. Uninformed choices arose when individuals' self-management behaviours did not reflect their knowledge and/or attitude. Uninformed choices can be further sub-divided into two groups, completely uninformed and partly uninformed. Completely uninformed choices are present when an individual's behaviour was inconsistent with their attitude and they lacked relevant knowledge. Partly uninformed choices resulted when an individual's behaviour was either based on poor knowledge but was consistent with their attitude, or was based on relevant knowledge but inconsistent with their attitude.

To classify participants' responses as informed or uninformed, a cut off point for both attitude and knowledge had to be established from which knowledge could be classified as either good or poor - and attitude classified as positive or negative. As there are no external criteria for what constitutes good or poor knowledge, or positive or negative attitude, the scale defined the cut off point rather than the sample (e.g. median). Utilising the median as a cut-off point would simply split the sample into two halves. Therefore, the mid-point score of 17 was taken to classify knowledge as good or poor, with scores above 17 (18-35) indicating good knowledge, and scores 17 and below indicating poorer knowledge. Ideally, the use of separate knowledge scores for the different self-management behaviour would have been preferable, as patients' knowledge may vary for different management behaviours. However, the knowledge scale utilised in this study was inadequate to provide such a measurement, as the items measuring knowledge for some self-management behaviours were limited. Therefore, an assessment of overall knowledge was used in this study to assess informed choice. The mid-point of 5 was taken to classify attitude, with scores above 5 (6-10) indicating a positive attitude, and scores 5 or below indicating a negative attitude. This criterion for classifying patients has been utilised in previous research using this model of informed choice (see Michie, Dormandy, & Marteau, 2003; Marteau et al., 2001).

In addition, participants had to be classified according to whether they had performed a self-management behaviour. It was necessary to establish a cut-off point for categorising self-management behaviour which was most consistent with the advice provided by health professionals and patient information. Apart from medication taking, the other self-management behaviours did not have to be performed every day. Therefore, for medication taking, participants were classified as performing the behaviour if they responded every day, and as not performing the behaviour if they responded nearly every day, sometimes, rarely or never. Reducing salt intake was necessary regularly to prevent exacerbations. Therefore, for reducing salt intake, participants were classified as performing the behaviour if they responded every day, or nearly every day, and not performing the behaviour if they responded sometimes, rarely, or never. The recommended levels for physical activity are two to three times a week and, therefore, participants were classified as performing the behaviour if they responded every day, nearly every day, or sometimes, but not performing the behaviour if they responded rarely or never. The advice for regular weighing is dependent on the severity of heart failure, generally this behaviour is not recommended daily for people with mild heart failure. Therefore, participants were classified as performing the behaviour if they responded every day, nearly every day, or sometimes, but not performing the behaviour if they responded rarely or never.

8.2.2.5 Questionnaires.

The baseline questionnaire pack (see appendix W) consisted of the knowledge scale, TPB variables, enablement scale, demographic (e.g. level of education), healthcare (e.g. contact with GP, hospital doctor), and previous information provision items (e.g. information obtained from other sources about their illness). This pack also included an introductory letter from a consultant in the Directorate of Elderly Care and Medicine (see appendix T), information sheet (see appendix U), and consent form (see appendix V). The follow-up questionnaire (see appendix X) consisted of the knowledge scale, TPB variables, and enablement scale. Every effort was made in the development of the questionnaires to keep the number of scales and questions to a minimum, to reduce the burden on heart failure patients.

8.2.3 Participants

All participants had a confirmed diagnosis of heart failure and had received care under the Medicine and Elderly Care clinical team. Participants either had a recent inpatient admission, or had appointments at weekly outpatient clinics run by two Elderly Care and Medicine Consultants.

Potential participants were identified using two methods:

1. Inpatient discharges - Patient lists of discharged heart failure patients were compiled by an information analyst. These reports excluded patients with a known cognitive impairment, as these patients may have experienced difficulty giving informed consent. Patients with clinical codes indicating Alzheimer's disease, dementia, and other cognitive illnesses were excluded[6]. The initial list generated was for the period August 2005 to January 2006, and then monthly patient lists were generated between February 2006 and September 2006. 573 patients with heart failure were identified during this 13 month period, and all

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[6] Advice and guidance was provided by Dr Syed Zaman, Consultant in Medicine and Elderly Care

were mailed a study pack comprising an information sheet, consent form, and baseline questionnaire.

2. Outpatient attendance - Patients with a diagnosis of heart failure were identified from medical notes at weekly Medicine and Elderly Care outpatient clinics[7], between March 2006 to June 2006. The clinic nurse approached suitable patients and, if they agreed to hear about the research project, they were introduced to the researcher. The researcher briefly introduced the study and provided a study pack to interested participants. 39 suitable patients were identified, 31 of whom were provided with information about the study. Please see figure 5 for the reasons why 5 patients were not approached and 3 patients were not provided with information about the study.

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[7] Approval was obtained from two Consultants who each had an outpatient clinic

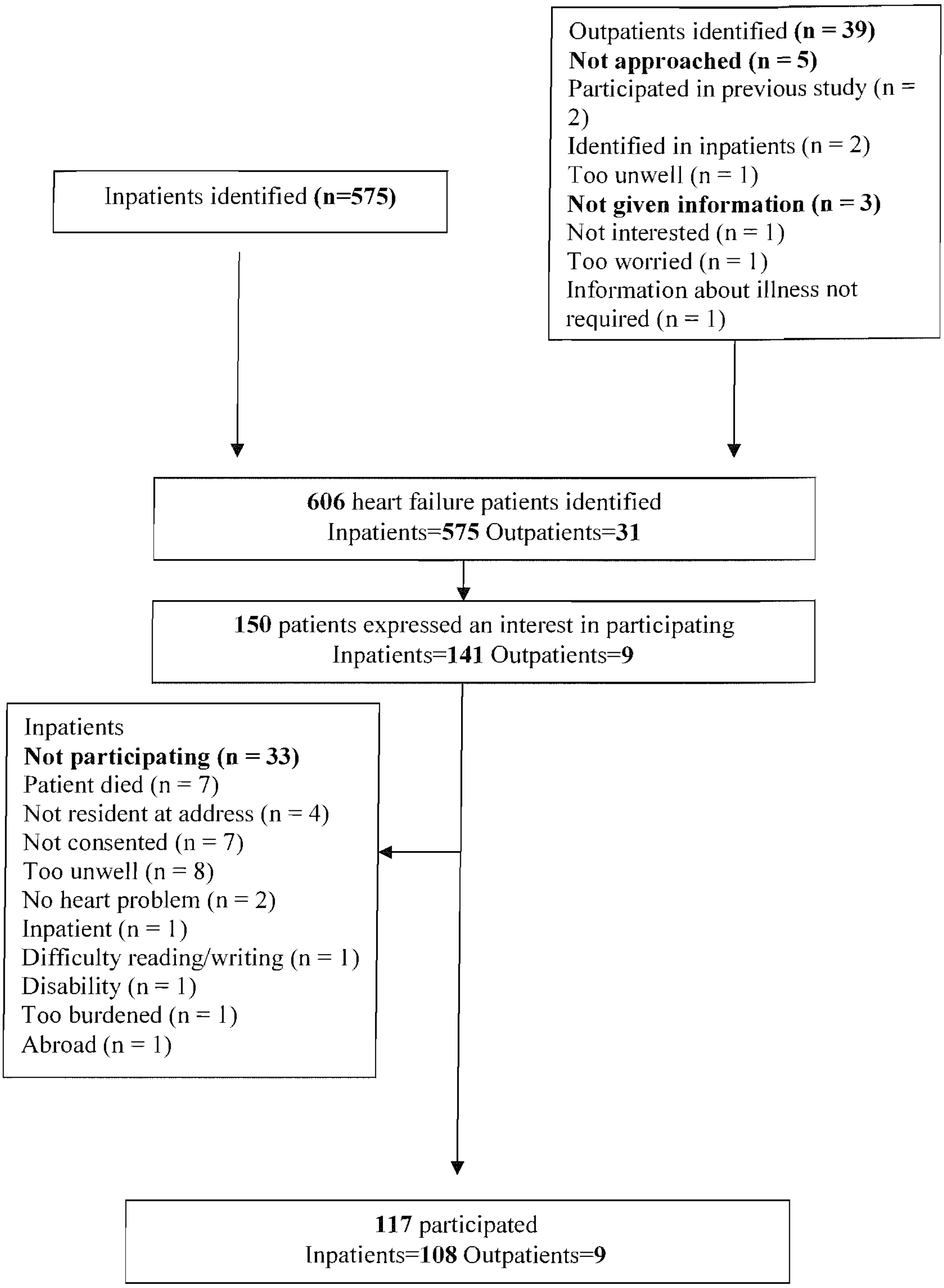

Figure 5. Flow of participants to recruitment onto the trial

8.2.4 Procedure

The Southampton and South West Hampshire Local Research Ethics Committee and the School of Psychology Ethics Committee, University of Southampton granted ethical approval. No ethical concerns were envisaged. Both booklets advised their readers to seek advice from their doctor or nurse if they had any questions about any aspect of their illness and its self-management. In the event of a participant becoming distressed after receiving information about the study, or receiving the booklet(s), they would be advised to meet their GP as soon as possible. If the participant felt unable to do this, then the Chief Investigator would offer to contact the GP on their behalf. Upon ethical approval, consent was sought from all the Consultants, within the Directorate of Medicine and Elderly Care, to contact discharged heart failure patients under their care about the study. Consent was obtained from all 34 Consultants and 23 of whom opted to provide their patients with introductory signed letters by them (see appendix T). The patients of the remaining Consultants were provided letters signed by the Clinical Service Manager.

Figure 6 details the procedure for the study. Upon receipt of the consent form and baseline questionnaire, participants were randomised using permuted block randomisation into one of three conditions:

1. Theory-based booklet – participants were sent the IHF booklet
2. Atheoretical booklet – participants were sent the booklet prescribed by NICE
3. Waiting list control – participants were randomised into one of the above two groups (theory-based/atheoretical booklet), only after completing and returning their two week follow-up questionnaire.

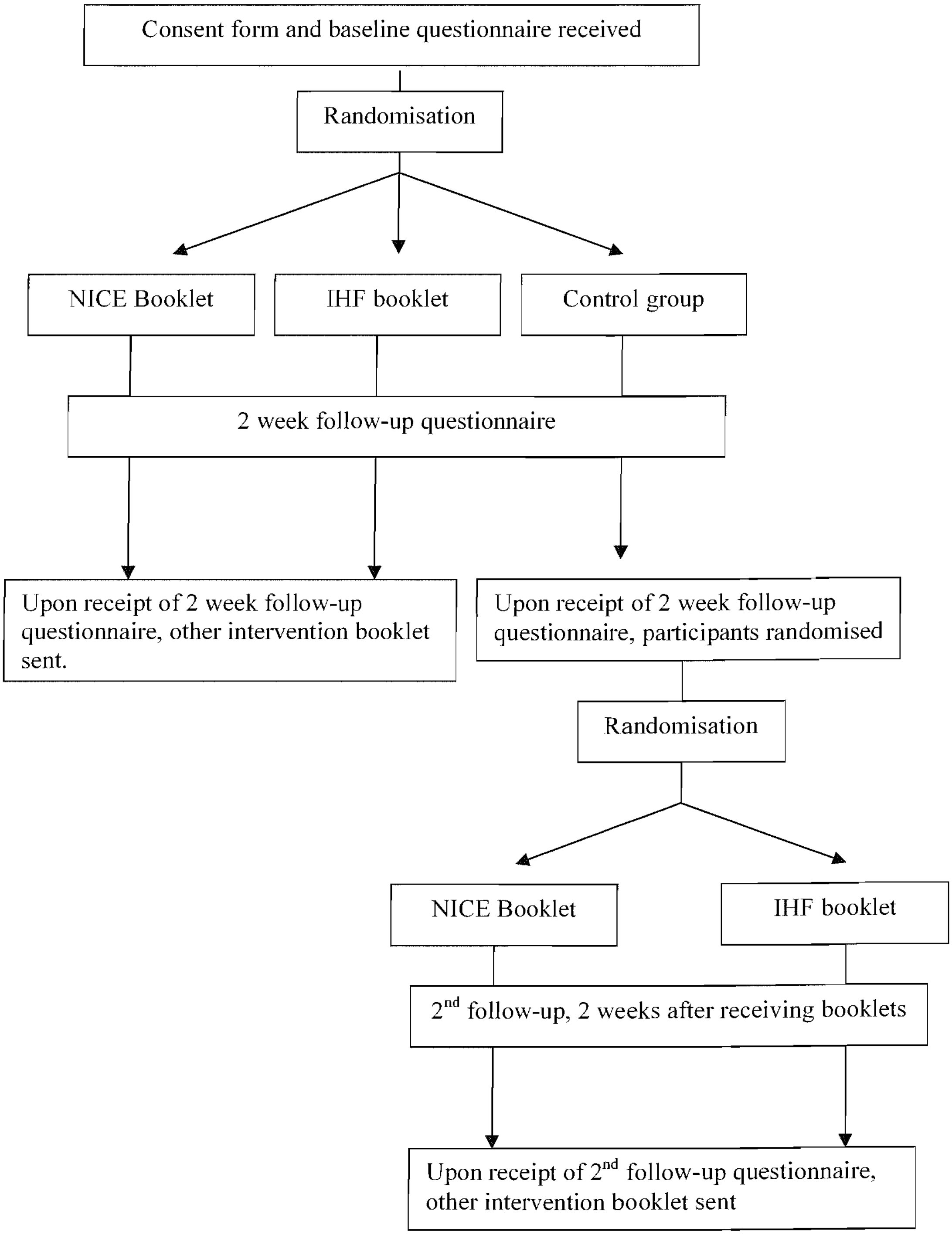

Figure 6. A Flow chart of the process in the trial

The Chief Investigator was not blind to whether participants were allocated to a booklet or control group, as resources were not available to employ a researcher to complete all the administrative duties associated with the RCT. However, an independent researcher randomised participants, and the Chief Investigator was only informed of whether the participant was a control or booklet intervention participant. This was to ensure that control participants were identified for randomisation upon receipt of their two week follow-up questionnaire. The Chief Investigator was not aware of which booklet a participant had received during the trial.

Participants were allocated to a group in the RCT by tables of random numbers, to which the Chief Investigator did not have access. Simple randomisation can lead to different numbers of participants between groups; this can be overcome by block randomisation. Following baseline assessments, participants were allocated in blocks of three to the IHF booklet (A), NICE booklet (B), and the control group (C) using the following number criteria (see Pocock, 1983):

- ABC for digit 1
- ACB for digit 2
- BAC for digit 3
- BCA for digit 4
- CAB for digit 5
- CBA for digit 6
- Ignore numbers 0, 7-9

Following receipt of the second follow-up from control participants, they were allocated in groups of two to receive either the IHF booklet (A) or NICE booklet (B), using the following number criteria (see Pocock, 1983):

- AB for digits 0-4
- BA for digits 5-9

For all follow-up questionnaires, telephone follow-up calls were conducted if questionnaires had not been received within a two week period. This ensured that as much data as possible was collected from participants during the trial. Once participants had completed their duration in the study, they were sent a copy of the booklet they had not received as part of the RCT.

8.2.5 Study Power

A calculation of required sample size (statistical method for determining trial size: Pocock, 1983) found that 144 patients in total (48 per group) would be required for this study to achieve 80% power with a significance level of 0.05, two-tailed. The effect size was calculated on the basis of an effect size of d = 0.48 for the outcome of knowledge found in a study that compared a written intervention with a no-booklet control (Barlow & Wright, 1998)[8]. No comparable effect sizes could be identified in the literature for a booklet comparison and, therefore, the trial could not be adequately powered for this.

8.2.6 Data Treatment

The range, minimum, and maximum scores were checked on all variables. When two answers were given for the same question, they were treated as missing. Substitutions for missing data were made for the PEI with a participant's personal average, if more than half of the items for the scale had been completed (Ware, Kosinski, & Dewey, 2000). No substitutions were made for single item scale data.

The distributions for all variables were examined and several items were not normally distributed. For attitude to medication taking, physical activity, and salt intake, a large mode occurred at 10 indicating a very positive attitude. Therefore, all these variables were recoded as a dichotomous variable, with participants classified as having a positive attitude if they responded strongly agree to both attitude items, or as a less positive attitude if they did not. The distributions for PBC, intention and behaviour were all skewed for medication taking, with a mode occurring for the response extremely easy for PBC, strongly agree for intention, and every day for behaviour. Therefore, these items were also dichotomised. PBC was recoded as easy if participants responded with extremely easy, and less easy for all other responses. Intention was recoded as strong intention for responses strongly agree and lower intention for all other responses.

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[8] Barlow and Wright (1998) evaluated knowledge as an outcome in a RCT which evaluated a written booklet with a no-booklet control in a sample of rheumatoid arthritis patients. No similar studies were identified from the heart failure literature; therefore this study was used to estimate sample size.

Behaviour was recoded as every day if participants responded every day, and not every day for all other responses.

All scales were checked for reliability and all had good internal reliability, with alpha coefficients greater than 0.7 (Loewenthal, 2001). Cronbach's alphas for attitude were 0.7 for medication taking, 0.8 for physical activity, 0.9 for restricting salt intake, 0.8 for regular weighing and 0.9 for enablement.

Control participants were randomised to a booklet intervention following receipt of their two week follow-up questionnaire, and then completed another follow-up questionnaire post-booklet (see figure 6). Analysis conducted on data for baseline and two week follow-up assessments would not include control participants' scores for their post booklet follow-up. Therefore, two new variables were created for every outcome in the study, and these represented pre-booklet and post-booklet scores. This would allow control participants' pre- and post-booklet responses to be included in analyses where comparisons were made directly between the two booklets. The pre-booklet variables comprised participants' responses to the study questionnaire just prior to receiving the booklet; these were baseline scores for intervention participants, and two week follow-up assessments for control participants. The post-booklet variables comprised participants' responses to study questionnaires completed following the booklet: these were two week follow-up assessments for intervention participants, and the second follow-up assessments for control participants.

For the remainder of this chapter, the terms 'pre-booklet' and 'post-booklet' will be used when analyses have used these newly created variables. 'Baseline' will refer to participants' scores on the first questionnaire completed in the study prior to randomisation. 'Two week follow-up' will refer to participants' scores on the second questionnaire completed in the trial; this would be following the booklets for the intervention participants, and the second follow-up questionnaire completed by control participants.

8.2.7 Statistical Analysis

All statistical analyses were performed using the Statistical Package for Social Sciences (SPSS) (Version 14). The following statistical analyses were conducted to test whether the IHF booklet was more effective at improving outcomes, compared to the NICE booklet and control groups. To test the primary hypothesis, participants' knowledge scores at baseline, and at two week follow-up, were used to calculate a change score. The change score was calculated by subtracting a participant's score at baseline from their score at two week follow-up. A between subjects ANOVA was then conducted to determine whether there were significant differences in the change scores between the groups in the trial. This was followed by Bonferroni ad-hoc tests to compare the groups in the trial with each other. This helped to ascertain which groups in the trial differed significantly from other groups in the trial. The same statistical analysis was conducted to compare differences between the groups on enablement and the TPB variables. For the dichotomised TPB variables (see data treatment) the NcNemar test was used to determine if differences existed between baseline and the two week follow-up scores. The analyses were conducted separately for each group in the RCT. It was decided not to perform these analyses on the medication taking behaviour variable as it was very positively skewed, resulting in only three participants in the 'not every day' group.

For the pre and post booklet variables, the hypotheses in this study were investigated by using a mixed (2*2) ANOVA. These were computed for knowledge, enablement, attitude, PBC, intention, and behaviour. These ANOVA's were followed by paired t-tests to show which group had showed greater change. These analyses would allow a comparison between the two booklets using a larger sample. To explore associations between the dependent variables in the trial, correlation matrixes were created for knowledge, enablement, attitude, PBC, intention, and behaviour for each self-management behaviour, for both baseline and post-booklet scores. For the skewed TPB variables correlations using Spearman rank were performed. For all other variables Pearson's product moment correlation was calculated. Finally, an ad-hoc sample size calculation was conducted to assess if the trial had adequate power.

8.3 Results

150 patients responded to the mailed information about the study (see figure 5). 33 of these responses were from families or patients stating that they were either unable or unwilling to take part in the study. Please see figure 5 for the reasons that patients could not participate in the study. 117 patients consented to participate in this study. Of these, 71 were male (60.7%) and 46 were female (39.3%). The sample had a mean age of 75.8 years (SD=11.3) and this ranged from 34 to 95. 108 patients were recruited from the inpatient medical setting (92.3%) and 9 from outpatient clinics (9%). 36 had a diagnosis of congestive heart failure (30.8%), 69 left ventricular failure (59%) and 12 unspecified heart failure (10.3%). Of this sample, 19 dropped out before completing all the measures, and 4 withdrew from the study (see Figure 7). This left a sample size of 94 participants.

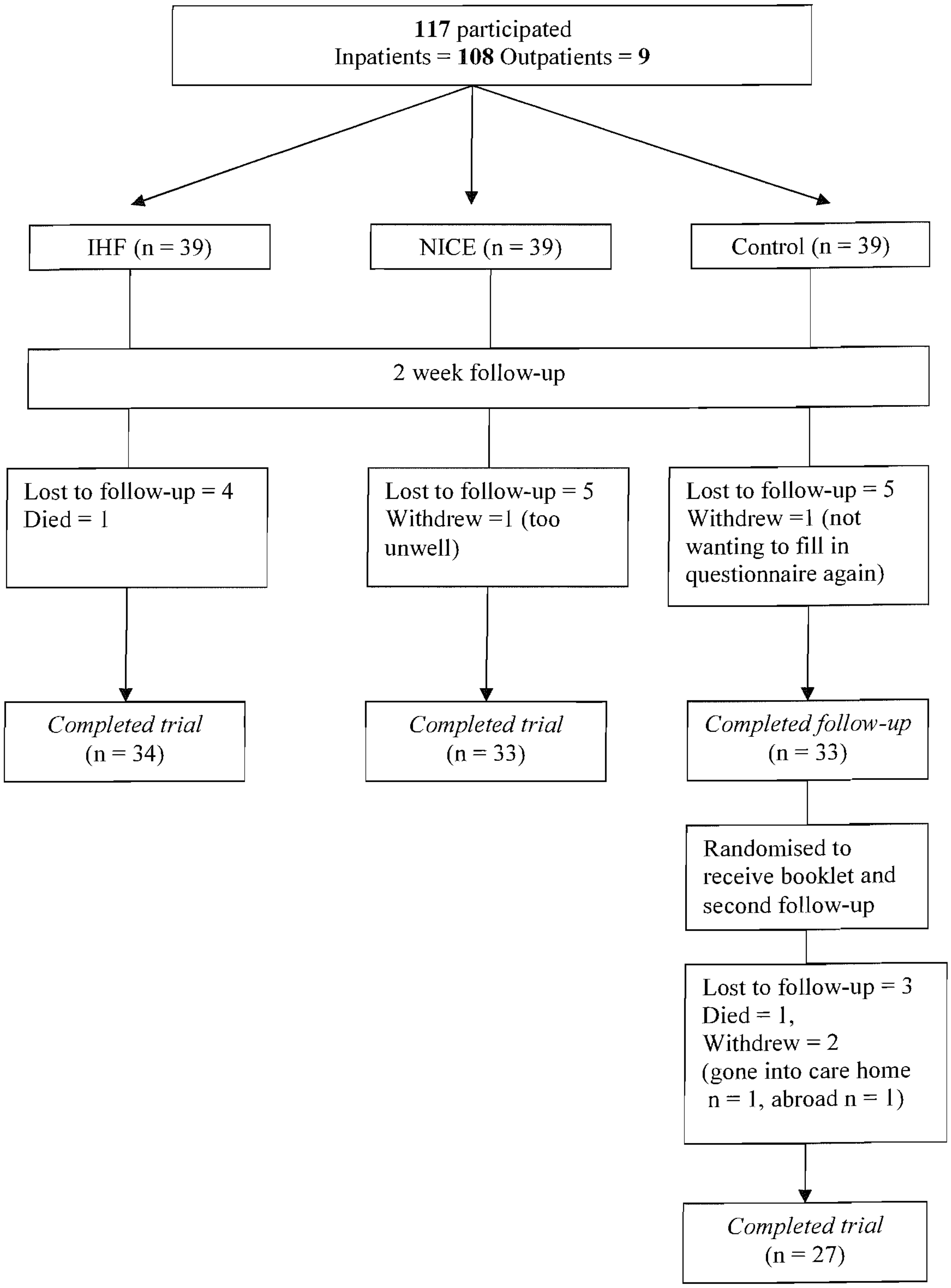

Figure 7. Flow of participants through the trial

As seen in table 12, the majority of participants reported seeing their GP every month (26.1%, n = 30) or every two to three months (40%, n = 46). However, 18.3% (n = 21) of participants reported that they only saw their GP when they felt unwell or perceived it as necessary. Just over half of participants (54%, n = 60) reported that their last appointment with their hospital doctor had been within the last month. The majority of participants had spent a night in hospital in the previous three months (60.7%, n = 71). Only 7.8% (n = 9) of participants reported having a specialist nurse for their heart condition, and contact occurred every month (n = 3), twice a year (n = 1), once a year (n = 4), and one participant reported that the healthcare provided by the nurse had now stopped.

As seen in Table 13, most participants (62.6%, n = 72) reported receiving information about their heart condition, and the majority (70.8%, n = 51) acquired this information more than three months prior. The majority of participants received verbal information (70.8%, n = 51), and this was received from their hospital doctors (63.9%, n = 46). Only 15% (n = 9) of participants received written information from their hospital doctor or GP.

At baseline, the majority of participants rated their understanding of their heart condition as either good (47%, n = 55) or poor (24.8%, n = 29). Very few participants, (8.5%, n = 10) rated their understanding as very good. Likewise, the majority of participants rated their understanding of heart failure self-management as good (45.3%, n = 53) or poor (25.6%, n = 30). Only 10.3% reported their understanding of heart failure self-management as very good. The majority of participants either agreed (44.3%, n = 51) or strongly agreed (39.1%, n = 45) that they needed more information about their heart condition.

Baseline reports indicated that 113 (97.4%) participants reported taking their medications as prescribed every day, 78 (67.8%) participants reported engaging in physical activity either every day, almost every day or sometimes, 82 (71.9%) participants reported restricting their salt intake every day or almost every day, and 64 participants (56.1%) reported weighing themselves either every day, almost every day or sometimes.

Table 12. *Patients' contact with health professionals and healthcare services*

Contact characteristics	Frequency % (n)
Contact with GP	
Every 2 weeks	3.5% (4)
Every month	26.1% (30)
Every 2-3 months	40.0% (46)
Twice a year	8.7% (10)
Once a year	3.5% (4)
Other e.g. when necessary/unwell	18.3% (21)
Last appointment with doctor at hospital	
Past week	27.0% (30)
2-3 weeks ago	8.1% (9)
1 month ago	18.9% (21)
2-3 months ago	24.3% (27)
More than 3 months ago	21.6% (24)
Last time spent a night in hospital	
Past week	5.1% (6)
2-3 weeks	4.3% (5)
1 month ago	21.4% (25)
2-3 months ago	29.9% (35)
4-6 months ago	17.1% (20)
Over 6 months ago	22.2% (26)
Do you have a specialist nurse and if so, how often do you see him/her	
Yes	7.8% (9)
Every month	3.0 (2.6%)
Twice a year	1.0 (0.9%)
Once a year	4.0 (3.4%)
Other: has now ceased	1.0 (0.9%)
No	92.2% (107)

Table 13. *Provision and sources of information received by patients*

Information characteristics	Frequency %(n)
Have you received information about your heart condition	
Yes	62.6% (72)
No	37.4% (43)
If answered yes:	
How long ago did you receive this information	
Less than 2 weeks	4.2% (3)
1 month ago	12.5% (9)
2-3 months ago	12.5% (9)
More than 3 months	70.8% (51)
The source that provided the information	
Hospital doctor	63.9% (46)
GP	18.1% (13)
Nurse	8.3% (6)
Family member/friend	5.6% (4)
Organisation	2.8% (2)
Other: cardiac rehabilitation	1.4% (1)
How was the information given to you	
Verbal information	70.8% (51)
Published book	4.2% (3)
Booklet/leaflet	25.0% (18)

8.3.1 Knowledge

Participants at baseline had a mean knowledge score just above the mid-point at 20.3 (SD = 3.97), with scores ranging from 9 to 29. Only a minority of participants (8.2%) did not correctly identify that the problem with their heart was its inability to pump enough blood around the body. All participants correctly identified that it was important to take their medications for heart failure regularly, and 97.4% were aware that they required a flu jab every year. The majority of participants (80.5%) knew that swelling in the legs was due to fluid retention, and that weighing regularly was to check for fluid retention (80%). However, 38.6% of participants thought that they should weigh themselves now and then, and less than half (48.1%) were aware that they should weigh themselves before breakfast, after going to the toilet. Very few participants (7.3%) knew that an increase in weight of a few pounds was an early indicator of fluid retention, and only half of participants identified rapid weight gain as an indication that their heart failure was getting worse (55.6%). A third of participants (33%) reported that their heart condition could be cured, and 22.9% indicated that they had no responsibility for the management of their heart condition. In addition, 26.3% of participants experiencing an increase in breathlessness or swelling reported that they would wait a few days to see if they got better.

The primary hypothesis in this study was to test the effects of the IHF booklet on knowledge, compared with the control condition. The secondary knowledge hypothesis was to test the effects of the IHF booklet on knowledge, compared with the NICE booklet. Table 14 shows that both booklets improved knowledge - however, the IHF booklet appeared to improve knowledge more than both the NICE booklet and control group.

Table 14. *Mean knowledge scores and change scores for each group in the RCT at baseline and 2 week follow-up*

Group	Mean and standard deviation (SD)		Change scores (baseline and 2 week follow-up)	Sample size
	Baseline	Time 2		
IHF	20.6 (4.2)	23.3 (5.0)	2.9 (3.5)	39
NICE	20.5 (3.7)	21.6 (4.2)	1.1 (2.9)	32
CONTROL	20.7 (3.8)	20.9 (3.6)	0.2 (3.1)	33

Between baseline and follow-up, knowledge scores improved most in the IHF group, a little in the NICE group, and virtually unchanged in the control group. A between-subjects ANOVA reported a significant effect of group (F (2, 97) = 7.54, p = 0.001, $\eta_p^2 = 0.14$). Bonferroni post-hoc tests revealed that the results were in the direction predicted by the primary hypothesis and the secondary knowledge hypothesis. The IHF booklet group was significantly different from the control (p = 0.001) and NICE booklet group (p = 0.004). However, no significant differences were found between the control and NICE booklet groups (p = 0.46).

To explore the differences between the booklets using the whole sample, analyses were undertaken using the pre- and post-booklet knowledge scores. Again, the mean scores for knowledge showed a greater increase after receiving the IHF booklet, than after receiving the NICE booklet. Participants in the IHF booklet group had a pre-booklet mean knowledge score of 20.7 (SD = 4.0), and a post-booklet mean knowledge score of 24.0 (SD = 4.8). Participants in the NICE booklet group had a pre-booklet mean knowledge score of 20.6 (SD = 3.6), and a post-booklet mean knowledge score of 21.3 (SD = 4.7). A repeated measures ANOVA revealed a significant interaction between time and booklet type (F (1, 92) = 13.83, p < 0.001, $\eta_p^2 = 0.13$). Paired t-tests supported the prediction in the secondary knowledge hypothesis, demonstrating that the IHF booklet (t = 6.42, df = 46, p < 0.001) had produced greater improvements in knowledge, compared to the NICE booklet (t = 1.80, df = 46, p = 0.08).

8.3.2 Enablement

Secondary hypotheses included exploring the effects of the booklets on enablement. Table 15 shows that both booklets slightly increased enablement from baseline, and a slight reduction in enablement was observed in the control group.

Table 15. *Mean enablement scores and change scores for each group in the RCT at baseline and 2 week follow-up.*

Group	Mean and standard deviation (SD)		Change scores (baseline and 2 week follow-up)	Sample size
	Baseline	Time 2		
IHF	21.3 (3.4)	22.3 (2.7)	1.0 (2.1)	35
NICE	21.6 (3.8)	21.8 (4.6)	0.3 (4.7)	31
CONTROL	21.5 (4.5)	21.2 (4.9)	-0.3 (3.8)	33

Although the means for enablement were in the direction predicted by the secondary hypothesis, analyses did not indicate that there was a significant difference between the groups from baseline to two week follow-up. This was confirmed by a between-subjects ANOVA (F (2, 96) = 1.03, p = 0.36, $\eta_p^2 = 0.02$), showing no interaction between time and group. To explore the differences between the booklets in a larger sample, analyses were undertaken using the pre- and post-booklet enablement scores. Participants in the IHF group had a pre-booklet enablement mean score of 21.1 (SD = 3.2), and a post-booklet enablement mean score of 22.6 (SD = 2.8). Participants in the NICE booklet group had a pre-booklet enablement mean score of 21.8 (SD = 3.8), and a post-booklet enablement mean score of 22.2 (SD = 4.4). There was a significant main effect of time (F (1, 90) = 6.317, p = 0.01, $\eta_p^2 = 0.07$) indicating that, over time, patients' enablement scores improved, however, there was no interaction (F (1, 90) = 2.74, p = 0.08, $\eta_p^2 =$ 0.03).

8.3.3 TPB Variables

The findings for the self-management behaviours will be presented below. These analyses were conducted to test the effects of the IHF booklet on the TPB constructs, compared with the NICE booklet and control group.

8.3.3.1 Taking medications as prescribed.

All variables for this self-management behaviour were dichotomised. McNemar tests (2x2) compared scores at baseline with two week assessments for attitude (positive vs. less positive), PBC (easy vs. less easy), and intention (strong vs. less strong). No significant difference was reported for attitude between baseline and two week follow-up for any of the groups (IHF, McNemar[9] p = 0.5; NICE, McNemar p = 1.0; Control, McNemar p = 1.0). Likewise, no significant differences were reported for PBC (IHF, McNemar p = 1.0; NICE, McNemar p = 0.25; Control, McNemar p = 0.63) and intention (IHF, McNemar p = 0.73; NICE, McNemar p = 0.63; Control, McNemar p = 1.0)

McNemar tests (2x2) were performed on pre- and post- booklet scores, as described above, for baseline and two week assessments. No significant difference in attitude (IHF, McNemar P = 0.25; NICE, McNemar P = 1.0), PBC (IHF, McNemar P = 0.18; NICE, McNemar P = 0.25) and intention (IHF, McNemar P = 0.34; NICE, McNemar P = 1.0) was reported between the pre- and post-booklet scores. The findings suggest that neither booklet significantly influenced attitude, PBC, or intention, for taking medications as prescribed. However, it is worth noting that responses to all these variables were very positively skewed at baseline, limiting the potential for improvement.

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[9] SPSS does not give the value of the McNemar chi-square, just its p-value

8.3.3.2 Engaging in regular physical activity.

Attitude was dichotomised for regular physical activity. A 2x2 McNemar test compared attitude (positive vs. less positive) at baseline with two week assessments. The frequencies for attitude are presented in table 16.

Table 16. *Frequencies for attitude scores regarding regular physical activity at baseline and time 2 assessments*

	IHF		NICE		Control	
Baseline	Time 2- attitude					
	Less positive	Positive	Less positive	Positive	Less positive	Positive
Less positive	10 (45.5%)	12 (54.5%)	10 (71.4%)	4 (28.6%)	8 (53.3%)	7 (46.9%)
Positive	1 (7.7%)	12 (92.3%)	1 (6.3%)	15 (93.8%)	4 (23.5%)	13 (10.6%)

Table 16 shows that in the IHF group, 12 (54.5%) of the participants who had a less positive attitude at baseline changed to a more positive attitude at the two week follow-up. This change was greater than the one observed for the NICE booklet and control groups. The McNemar tests indicated that this change in attitude was significant for the IHF booklet group (McNemar P = 0.003) but not for the NICE booklet group (McNemar P = 0.38) or control group (McNemar P = 0.55).

For the remaining TPB variables, the means (see table 19) and change scores (see table 17) indicated that PBC slightly increased in the IHF booklet and the control group, but decreased a little in the NICE booklet. Intention and behaviour increased in both the IHF booklet and the NICE booklet, but decreased in the control group. The IHF booklet did influence the TPB variables somewhat in the directions predicted.

Table 17: *TPB change scores for physical activity for each group in the RCT.*

TPB variables	IHF booklet		NICE booklet		Control group	
	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N
PBC	0.43 (1.50)	30	-0.12 (0.97)	25	0.03 (1.30)	30
Intention	0.12 (0.88)	34	0.06 (1.06)	31	-0.16 (0.88)	32
Behaviour	0.15 (1.28)	34	0.12 (1.41)	31	-0.45 (1.12)	33

Between- subject ANOVAs found no effect of group for PBC (F (2, 82) = 1.38, p = 0.26, $\eta_p^2 = 0.03$), intention (F (2, 94) = 0.77, p = 0.46, $\eta_p^2 = 0.16$), and behaviour (F (2, 95) = 2.38, p = 0.10, $\eta_p^2 = 0.05$).

For the pre- and post-booklet analyses, the mean scores (see table 24) showed that while PBC increased in the IHF booklet, it remained unchanged in the NICE booklet. Intention increased in the IHF booklet but decreased in the NICE booklet, while behaviour increased for both the booklets. Repeated measures ANOVA analyses indicated that there were no significant interactions between time and group for intention (F (1, 77) = 0.62, p = 0.43, $\eta_p^2 = 0.008$), and behaviour (F (1, 77) = 0.43, p = 0.51, $\eta_p^2 = 0.006$), but there was a significant interaction between time and group for PBC (F (1, 77) = 4.2, p = 0.04, $\eta_p^2 = 0.052$). The IHF booklet increased participants' sense of PBC. This was confirmed by paired t-tests, which showed that PBC (t = 2.45, df = 39, p = 0.019) significantly improved pre and post the IHF booklet. However, this was not found for the NICE booklet group (t = 0.56, df = 39, p = 0.58).

Attitude scores for the pre- and post-booklet scores were dichotomised. The frequencies for attitude are presented in table 18. A similar pattern to the one observed at baseline and two week assessments was reported, i.e. a greater number of participants in the IHF booklet had a more positive attitude post-booklet compared to pre-booklet. A 2x2 McNemar test reported that this change in attitude was significant for the IHF booklet (McNemar P = 0.002), but not for the NICE booklet (McNemar P = 0.55).

Table 18. *Frequencies for attitude scores regarding regular physical activity pre and post the booklets*

	IHF		NICE	
Pre booklet	Post booklet- attitude			
	Less positive	Positive	Less positive	Positive
Less positive	10 (40.0%)	15 (60%)	15 (68.2%)	7 (31.8%)
Positive	2 (9.1%)	20 (90.0%)	4 (17.4%)	19 (82.6%)

The findings overall for regular physical activity suggest that the IHF booklet influenced attitudes by making them more positive, and increased participants' sense of PBC.

Table 19. *Descriptive statistics for the TPB variables for physical activity at baseline and 2 week follow-up for each group of the RCT*

	IHF booklet		***NICE booklet***		***Control group***	
TPB variables (range of scores)	Baseline Mean (SD) (N)	Time 2 Mean (SD) (N)	Baseline Mean (SD) (N)	Time 2 Mean (SD) (N)	Baseline Mean (SD) (N)	Time 2 Mean (SD) (N)
			Doing planned physical activity			
PBC (1-5)	2.60 (1.61) (N = 36)	3.09 (1.42) (N = 33)	2.73 (1.60) (N = 30)	2.64 (1.45) (N = 28)	2.57 (1.52) (N = 37)	2.58 (1.43) (N = 31)
Intention (1-5)	3.69 (0.95) (N = 39)	3.79 (0.81) (N = 34)	3.78 (1.08) (N = 37)	3.94 (0.95) (N = 32)	3.42 (1.15) (N = 38)	3.45 (1.09) (N = 33)
Behaviour (1-5)	3.10 (1.21) (N = 39)	3.26 (1.17) (N = 35)	3.49 (1.28) (N = 37)	3.56 (1.24) (N = 32)	2.82 (1.37) (N = 39)	2.61 (1.20) (N = 33)

8.3.3.3 Restricting salt intake.

Attitude was dichotomised for restricting salt intake. Therefore, a 2x2 McNemar test was performed on attitude (positive vs. less positive), comparing baseline with the two week assessments. McNemar tests indicated that there was no significant change in attitude for any of the groups (IHF, McNemar P = 0.45; NICE, McNemar P = 1.0; Control McNemar, P = 1.0). Attitude was very positively skewed at baseline, limiting the potential for improvement.

The means (see table 21) and change scores (see table 20) indicated that PBC increased somewhat for the IHF booklet, decreased for the NICE booklet, and remained unchanged for the control group. Intention and behaviour increased for the IHF, but decreased for the NICE and control groups. Thus, as predicted by the hypothesis, the IHF booklet did influence the TPB variables somewhat in the directions predicted.

Table 20: *TPB change scores for restricting salt intake for each group in the RCT*

TPB variables	IHF booklet		NICE booklet		Control group	
	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N
PBC	0.35 (1.74)	29	-0.04 (1.14)	25	0.00 (0.67)	28
Intention	0.32 (0.98)	34	-0.13 (0.82)	30	-0.25 (0.76)	32
Behaviour	0.47 (1.08)	34	-0.17 (1.12)	30	-0.30 (1.05)	33

A between-subject ANOVA reported a non-significant effect of group for PBC (F (2, 79) = 0.02, p = 0.98, $\eta_p^2 = 0.001$). However, a significant effect of group was found for intention (F (2, 93) = 4.10, p = 0.02, $\eta_p^2 = 0.081$) and behaviour (F (2, 94) = 4.88, p = 0.01, $\eta_p^2 = 0.09$). Bonferroni post-hoc tests found no significant differences for intention between the NICE and IHF booklet (p = 0.11), or between the NICE booklet and control group (p = 1.0). However, the IHF booklet group was significantly different from the control group (p = 0.02) in intention. Similar results were found for behaviour, with significant differences between the IHF booklet group and the control group (p = 0.01). Non-significant differences were found between the booklets (p = 0.06) and between the NICE booklet and control group (p = 1.0) for salt restricting behaviour.

The means for the pre- and post- booklet analyses showed that the IHF booklet influenced the TPB variables in the direction predicted by the TPB hypothesis, with PBC, intention, and behaviour increasing. The NICE booklet produced improvements only in behaviour and declines in PBC and intention were observed (see table 24). A repeated measures ANOVA found no significant interaction between time and group for PBC ($F (1, 76) = 0.62, p = 0.43, \eta_p^2 = 0.008$), intention ($F (2, 76) = 0.88, p = 0.35, \eta_p^2 = 0.01$) or behaviour ($F (1, 76) =1.83, p = 0.18, \eta_p^2 = 0.02$).

Attitude scores for the pre- and post- booklet scores were dichotomised. A 2x2 McNemar test indicated that attitude did not improve over time for either booklet (IHF booklet, McNemar $P = 0.11$; NICE booklet, McNemar $P = 1.0$). Again, as with baseline, attitude was very positively skewed, this left very little scope for improvement.

The overall findings indicated that, between baseline and two week follow-up, there was a significant difference between the IHF booklet group and control group, for intention and behaviour. However, there were no significant differences in the TPB variables between the two booklets.

Table 21. *Descriptive statistics for the TPB variables for limited salt intake at baseline and 2 week follow-up for each group of the RCT*

	IHF booklet		*NICE booklet*		*Control group*	
TPB variables (range of scores)	Baseline Mean (SD) (N)	Time 2 Mean (SD) (N)	Baseline Mean (SD) (N)	Time 2 Mean (SD) (N)	Baseline Mean (SD) (N)	Time 2 Mean (SD) (N)
			Limited salt intake			
PBC (1-5)	3.74 (1.44) (N = 34)	4.12 (1.41) (N = 33)	3.34 (1.63) (N = 29)	3.64 (1.47) (N = 28)	3.97 (1.31) (N = 32)	4.23 (1.18) (N = 31)
Intention (1-5)	4.36 (0.78) (N = 39)	4.66 (0.54) (N = 35)	4.38 (0.76) (N = 37)	4.39 (0.76) (N = 31)	4.18 (0.87) (N = 38)	4.03 (1.10) (N = 33)
Behaviour (1-5)	4.18 (1.21) (N = 39)	4.63 (0.69) (N = 35)	4.14 (1.25) (N = 37)	4.19 (1.28) (N = 31)	3.79 (1.19) (N = 38)	3.61 (1.41) (N = 33)

8.3.3.4 Weighing regularly.

The means and change scores (see tables 22 and 23) indicated that attitude and behaviour in all groups showed an increase. However, for PBC there was an increase for both the booklet groups, but a decrease for the control group: and for intention, there was an increase for the IHF booklet, but the NICE booklet group and control group remained almost unchanged.

Table 22: *TPB change scores for weighing regularly for each group in the RCT*

TPB variables	IHF booklet		NICE booklet		Control group	
	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N
Attitude	1.70 (1.79)	30	1.07 (2.46)	30	0.29 (2.02)	31
PBC	0.42 (1.24)	26	0.20 (1.32)	25	-0.28 (0.84)	29
Intention	0.65 (0.98)	34	0.10 (0.88)	30	0.13 (1.07)	32
Behaviour	0.65 (1.20)	34	0.48 (1.12)	31	0.18 (0.95)	33

Between-groups ANOVAs found no effect of group for PBC ($F(2, 77) = 2.72$, $p = 0.07$, $\eta_p^2 = 0.06$) and behaviour ($F(2, 95) = 1.54$, $p = 0.22$, $\eta_p^2 = 0.03$). However, a significant effect of group was found for attitude ($F(2, 88) = 3.27$, $p = 0.04$, $\eta_p^2 = 0.07$) and intention ($F(2, 93) = 3.24$, $p = 0.04$, $\eta_p^2 = 0.07$). Bonferroni post-hoc tests showed that there was a significant difference between the IHF booklet and control group conditions for attitude ($p = 0.04$). Non-significant differences were found between the two booklet groups ($p = 0.82$) and between the NICE booklet and control group ($p = 0.46$) for attitude to regular weighing. The Bonferroni post-hoc tests for intention did not identify any significant differences between the groups.

The pre- and post- booklet means for attitude, PBC, intention, and behaviour showed improvements for both booklets (see table 24). ANOVA results were consistent with the findings from the baseline and the two week follow-up analyses. There was no significant interaction for PBC ($F(1, 70) = 0.22$, $p = 0.64$, $\eta_p^2 = 0.003$) and behaviour ($F(1, 70) = 0.94$, $p = 0.3$, $\eta_p^2 = 0.013$), although significant main effects for time were identified for PBC ($F(1, 70) = 5.790$, $p = 0.02$, $\eta_p^2 = 0.08$) and behaviour ($F(1, 70) = 16.76$, $p < 0.01$, $\eta_p^2 = 0.19$). A significant interaction between time and booklet group was found for both attitude (F (1, 70) = 7.34, $p = 0.008$, $\eta_p^2 = 0.095$) and intention (F (1, 70) = 6.99, $p = 0.01$, $\eta_p^2 = 0.091$). Paired t-tests revealed similar findings to those between baseline and two week follow-up. Improvements in attitude were significant for both the IHF ($t = 5.1$, $df = 40$, $p < 0.001$) and NICE ($t = 2.05$, $df = 44$, $p = 0.05$) booklets, whereas intention was only significant for the IHF booklet ($t = 4.31$, $df = 44$, $p < 0.001$) but not for the NICE booklet ($t = 0.00$, $df = 44$, $p = 1$). It is worth noting that although attitude significantly improved in both booklets, the effects was greater for the IHF booklet. The findings suggest that the IHF booklet influenced attitudes by making them more positive and increasing participants' intention to perform daily weighing.

Table 23. *Descriptive statistics for the TPB variables for regular weighing at baseline and 2 week follow-up for each group of the RCT*

	IHF booklet		***NICE booklet***		***Control group***	
TPB variables (range of scores)	Baseline Mean (SD) (N)	Time 2 Mean (SD) (N)	Baseline Mean (SD) (N)	Time 2 Mean (SD) (N)	Baseline Mean (SD) (N)	Time 2 Mean (SD) (N)
			Regular weighing			
Attitude (1-10)	7.37 (1.91) (N = 35)	8.79 (1.79) (N = 34)	7.31 (2.55) (N = 36)	8.16 (2.22) (N = 31)	8.00 (2.01) (N = 37)	8.53 (1.65) (N = 32)
PBC (1-5)	3.81 (1.47) (N = 32)	4.19 (1.26) (N = 32)	3.80 (1.49) (N = 30)	4.14 (1.22) (N = 29)	4.13 (1.26) (N = 31)	3.87 (1.38) (N = 31)
Intention (1-5)	3.41 (0.93) (N = 39)	4.06 (0.84) (N = 35)	3.38 (1.11) (N = 37)	3.52 (1.29) (N = 31)	3.13 (1.14) (N = 38)	3.36 (1.32) (N = 33)
Behaviour (1-5)	2.82 (1.32) (N = 39)	3.60 (1.22) (N = 35)	2.73 (1.35) (N = 37)	3.09 (1.49) (N = 32)	2.55 (1.52) (N = 38)	2.85 (1.46) (N = 33)

Table 24. *Descriptive statistics for the TPB constructs pre and post the booklets*

TPB variables	*IHF booklet* Pre-intervention Mean (SD)	*IHF booklet* Post-intervention Mean (SD)	*NICE booklet* Pre-intervention Mean (SD)	*NICE booklet* Post-intervention Mean (SD)
Doing planned physical activity				
	N=40		N=39	
PBC	2.68 (1.58)	3.25 (1.35)	2.82 (1.54)	2.82 (1.52)
Intention	3.73 (0.93)	3.83 (0.93)	3.72 (1.05)	3.64 (1.04)
Behaviour	3.0 (1.18)	3.3 (1.07)	3.40 (1.33)	3.46 (1.23)
Limiting salt intake				
	N=39		N=39	
PBC	3.95 (1.26)	4.15 (1.31)	3.82 (1.48)	3.77 (1.42)
Intention	4.46 (0.64)	4.62 (0.54)	4.36 (0.81)	4.33 (0.93)
Behaviour	4.28 (0.94)	4.64 (0.54)	4.15 (1.33)	4.21 (1.2)
Regular weighing				
	N=35		N=37	
Attitude	7.49 (1.91)	9.06 (1.57)	7.86 (2.15)	8.35 (1.81)
PBC	3.97 (1.36)	4.37 (1.09)	3.78 (1.46)	4.05 (1.25)
Intention	3.4 (0.95)	4.03 (0.92)	3.43 (1.19)	3.46 (1.22)
Behaviour	2.91 (1.36)	3.57 (1.31)	2.7 (1.31)	3.11 (1.47)

8.3.3.5 Summary of the effects of the booklets on the TPB variables.

In summary, for taking medications as prescribed, there were no significant differences between time and group for any of the TPB variables, and this was replicated in the pre- and post- booklet analyses. Between baseline and the two week follow-up, an increase in restricting salt behaviour and intention was observed for the IHF group, compared to the control group. However, this difference did not prove significant between the two booklets. Between baseline and the two week follow-up, a significant improvement in attitude for physical activity was found for the IHF booklet group only. This finding was replicated in the pre- and post- analyses. The pre- and post- analyses also found that there was a significant improvement in PBC in the IHF booklet, compared to the NICE booklet. With regards to regular weighing, between baseline and the two week follow-up, there was a significant improvement in attitude for regular weighing for the IHF booklet group, compared to the control group. In the pre- and post- analyses the IHF booklet group, was found to improve attitude significantly, compared to the NICE booklet group. The pre- and post- analyses for regular weighing also found that intention improved significantly for the IHF booklet group, compared to the NICE booklet group. Results supporting the hypotheses were found for both physical activity and weight monitoring. The IHF booklet showed greater improvements in attitude and PBC for physical activity, and in attitude and intention for regular weighing.

As this was an exploratory analysis, it is also interesting to look at the differences and the direction of change in the means between baseline and the two week follow-up, even if these did not reach significance. For the IHF booklet, differences in the means were in the direction predicted by the hypotheses for all the self-management behaviours. For the NICE booklet, there were some instances, where the change in the mean showed a decline, for example decreasing PBC for physical activity and restricting salt intake.

8.3.4 Correlations among the Variables Evaluated in the RCT

8.3.4.1 Correlations at baseline.

There was a strong correlation between the items from the pre-existing knowledge scale (van der Wal, Jaarsma, Moser & van Veldhuisen, 2005), and the knowledge scale developed for this study ($r = 0.77$, $n = 117$, $p < 0.01$). Knowledge was positively correlated with attitude for all the self-management behaviours. Apart from a significant correlation between knowledge and attitude for restricting salt intake (0.28), the correlations were very small (0.03 to 0.12). The correlations between PBC and knowledge did not appear to have a trend. These correlations were small but negative for taking medications and physical activity, and positive for restricting salt intake and regular weighing. The latter correlation reached significance. The correlations between knowledge and intention ranged from 0.16 to 0.25, reaching significance for physical activity and restricting salt intake. Positive but small non-significant correlations (0.03 to 0.18) existed between knowledge and behaviour.

The TPB variables were correlated in the directions proposed by the TPB for all the self-management behaviours (see tables 25 to 28). For each self-management behaviour there was a significant medium positive correlation between attitude and intention (0.30 to 0.59). PBC was positively correlated with intention and behaviour for each self-management behaviour (0.17 to 0.45 and 0.19 to 0.37 respectively), as was intention and behaviour (0.10 to 0.74). The correlation between PBC and intention reached significance for regular physical activity and weighing regularly. The correlations between PBC and behaviour, and between intention and behaviour, reached significance for all the self-management behaviours apart from taking medication as prescribed. The correlations for physical activity and regular weighing were all significant for the TPB variables. A similar pattern emerged for restricting salt intake apart from a small non-significant positive correlation between PBC and intention. In contrast, only the correlation between attitude and intention was significant for medication taking.

Table 25. *Spearman's correlations for knowledge, enablement, and TPB variables at baseline for taking medications as prescribed.*

Scale	1	2	3	4	5	6
1. Knowledge	--	.06 (116)	.12 (115)	-.001 (95)	.18 (115)	.08 (116)
2. Enablement		--	.14 (115)	.66 (95)	.23* (115)	.02 (116)
3. Attitude			--	.28* (95)	.32** (114)	.18 (115)
4. PBC				--	.20 (94)	.19 (95)
5. Intention					--	.10 (115)
6. Behaviour						--

*p<.05 **p<.01

Table 26. *Bivariate correlations for knowledge, enablement, and TPB variables at baseline for planned physical activity.*

	1	2	3	4	5	6
1. Knowledge	--	.06 (116)	.11 (110)[1]	-.02 (104)	.25** (114)	.18 (115)
2. Enablement		--	.35** (110)[1]	.36** (104)	.36** (114)	.33** (115)
3. Attitude			--	.44** (98)[1]	.45** (108)[1]	.29** (109)[1]
4. PBC				--	.45** (103)	.37** (103)
5. Intention					--	.74** (114)
6. Behaviour						--

*p<.05 **p<.01

[1] Spearman's rank order correlations

Table 27. *Bivariate correlations for knowledge, enablement, and TPB variables at baseline for restricting salt intake*

	1	2	3	4	5	6
1. Knowledge	--	.06 (116)	.28** (115)[1]	.12 (95)	.20* (114)	.03 (114)
2. Enablement		--	.29** (115)[1]	.02 (95)	.30** (114)	.24** (114)
3. Attitude			--	.25* (94)[1]	.45** (113)[1]	.32** (114)[1]
4. PBC				--	.17 (94)	.23* (94)
5. Intention					--	.67**(113)
6. Behaviour						--

*p<.05 **p<.01

[1] Spearman's rank order correlations

Table 28. *Bivariate correlations for knowledge, enablement, and TPB variables at baseline for regular weighing*

	1	2	3	4	5	6
1. Knowledge	--	.06 (116)	.09 (108)	.23* (93)	.16 (114)	.17 (114)
2. Enablement		--	.23* (108)	.16 (93)	.28** (114)	.30** (93)
3. Attitude			--	.46** (89)	.59** (106)	.43**(106)
4. PBC				--	.45** (92)	.30** (93)
5. Intention					--	.66** (113)
6. Behaviour						--

*p<.05 **p<.01

8.3.4.2 Correlations among variables post-booklet.

To compare the associations between the variables following the booklet intervention, correlations were conducted separately for each of the booklet groups on post-booklet values (see tables 29 to 32 for the IHF booklet and tables 33 to 36 for the NICE booklet). Positive correlations existed between attitude and knowledge for both booklet groups. The correlations were significant for all the management behaviours in the IHF group (0.30 to 0.36) apart from medication taking (0.18), but were not significant for any of the management behaviours following the NICE booklet (018 to 0.28). The IHF group had small, but positive, correlations between knowledge and PBC (0.04 for medication taking and 0.21 to 0.25 for the other management behaviours). In contrast, the NICE booklet group had small, but negative, correlations between knowledge and PBC for all the self-management behaviours (-0.06 to -0.15), apart from a positive association for regular weighing (0.17). Both groups had small correlations between knowledge and intention. These were positive for all the self-management behaviours for the IHF booklet group (0.02 to 0.22), but negative for medication taking and physical activity in the NICE booklet group. Both groups also had small non-significant positive correlations between knowledge and behaviour, apart from a small negative correlation for physical activity following the NICE booklet.

All correlations between attitude, PBC, intention and behaviour were in the direction proposed by the TPB for both booklets. These correlations were all significant for regular weighing and physical activity following both booklets, apart from a non-significant positive correlation between PBC and intention for physical activity, following the IHF booklet. For restricting salt intake, only the relationship between intention and behaviour reached significance following the IHF booklet, and attitude and intention following the NICE booklet. All the correlations between attitude, PBC, intention, and behaviour were significant for taking medications as prescribed for the NICE booklet group, but these correlations were small and non-significant in the IHF booklet.

8.3.4.3 Summary of baseline and post-booklet correlations.

Positive correlations existed between knowledge and attitude at baseline, and following both booklets. However, the correlations between attitude and knowledge were greater following the booklets, compared to baseline (baseline 0.09 to 0.12 for all management behaviours apart from restricting salt intake 0.28, post-IHF booklet 0.18 to 0.36, post-NICE booklet 0.18 to 0.28). The IHF booklet group had larger correlations between attitude and knowledge, compared to the NICE booklet group. At baseline no trends were identified in the correlations between knowledge and PBC. However, following the IHF booklet, correlations between knowledge and PBC were small but positive. In contrast, the correlations between knowledge and PBC were small, and negative for all the self-management behaviours apart from regular weighing following the NICE booklet. Relationships among the TPB variables remained somewhat similar for regular weighing and physical activity, following both booklets, compared to baseline. However, the correlations among the TPB variables reduced in strength for restricting salt intake following both booklets, compared to baseline. Also the correlations between the TPB variables for medication taking became more positive following the NICE booklet. However, this effect was not observed for the IHF booklet.

Table 29. *Spearman's correlations post-IHF booklet for knowledge, enablement, and TPB variables for taking medications as prescribed.*

	1	2	3	4	5	6
1. Knowledge	--	.13 (46)	.18 (46)	.02 (44)	.09 (46)	.01 (46)
2. Enablement		--	.14 (45)	.12 (43)	.18 (46)	.12 (46)
3. Attitude			--	.26 (43)	.11 (45)	.29 (45)
4. PBC				--	.10 (43)	.05 (43)
5. Intention					--	.28 (46)
6. Behaviour						--

*p<.05 **p<.01

Table 30. *Bivariate correlations post-IHF booklet for baseline knowledge, enablement, and TPB variables for planned physical activity.*

	1	2	3	4	5	6
1. Knowledge	--	.13 (46)	.36* (47)[1]	.25 (44)	.05 (45)	.17 (46)
2. Enablement		--	.29 (46)[1]	.53**(43)	.31* (45)	.43** (46)
3. Attitude			--	.37* (44)[1]	.47* (45)[1]	.43** (46)[1]
4. PBC				--	.08 (42)	.33* (43)
5. Intention					--	.71** (45)
6. Behaviour						--

*p<.05 **p<.01

[1] Spearman's rank order correlations

Table 31. *Bivariate correlations post-IHF booklet for knowledge, enablement, and TPB variables for restricting salt intake*

	1	2	3	4	5	6
1. Knowledge	--	.13 (46)	.31**(46)[1]	.21 (43)	.02 (46)	.13 (46)
2. Enablement		--	.34* (46)[1]	.25 (43)	-.04 (46)	.04 (46)
3. Attitude			--	.51** (43)[1]	.19 (46)[1]	.27 (46)[1]
4. PBC				--	.16 (43)	.23 (43)
5. Intention					--	.48** (46)
6. Behaviour						--

*p<.05 **p<.01

[1] Spearman's rank order correlations

Table 32. *Bivariate correlations post-IHF booklet for knowledge, enablement, and TPB variables for regular weighing*

	1	2	3	4	5	6
1. Knowledge	--	.13 (46)	.30* (45)	.22 (42)	.22 (46)	.13 (46)
2. Enablement		--	.22 (45)	.36* (42)	-.01 (46)	.14 (46)
3. Attitude			--	.79** (42)	.47** (45)	.30* (45)
4. PBC				--	.45** (42)	.32* (42)
5. Intention					--	.56** (46)
6. Behaviour						--

*p<.05 **p<.01

Table 33. *Spearman's correlations post-NICE booklet for knowledge, enablement, and TPB variables for taking medications as prescribed.*

	1	2	3	4	5	6
1. Knowledge	--	-.09 (47)	.18 (46)	-.14 (43)	-.02 (47)	.02 (47)
2. Enablement		--	-.03 (46)	.15 (43)	.08 (47)	-.11 (47)
3. Attitude			--	.43** (43)	.55** (46)	.64** (46)
4. PBC				--	.59** (43)	.42** (43)
5. Intention					--	.53** (47)
6. Behaviour						--

*p<.05 **p<.01

Table 34. *Bivariate correlations post-NICE booklet for baseline knowledge, enablement and attitude, PBC, intention and behaviour for planned physical activity.*

	1	2	3	4	5	6
1. Knowledge	--	-.09 (47)	.19 (46)[1]	-.06 (43)	-.10 (47)	-.04 (47)
2. Enablement		--	.22 (46)[1]	.16 (43)	.30* (47)	.20 (47)
3. Attitude			--	.31 (42)[1]	.40** (46)[1]	.34* (46)[1]
4. PBC				--	.47** (43)	.42**(43)
5. Intention					--	.66**(47)
6. Behaviour						--

*p<.05 **p<.01 [1] Spearman's rank order correlations

Table 35. *Bivariate correlations post-NICE booklet for knowledge, enablement, and TPB variables for restricting salt intake*

	1	2	3	4	5	6
1. Knowledge	--	-.09 (47)	.28 (47)[1]	-.07 (42)	.22 (46)	.19 (46)
2. Enablement		--	.13 (47)[1]	-.03 (42)	.22 (46)	.19 (46)
3. Attitude			--	.27 (42)[1]	.29* (46)[1]	.21 (46)[1]
4. PBC				--	.23 (42)	.25 (42)
5. Intention					--	.78** (46)
6. Behaviour						--

*p<.05 **p<.01

[1] Spearman's rank order correlations

Table 36. *Bivariate correlations post-NICE booklet for knowledge, enablement, and TPB variables for regular weighing*

	1	2	3	4	5	6
1. Knowledge	--	-.09 (47)	.27 (46)	.17 (43)	.28 (46)	.24 (47)
2. Enablement		--	-.10 (46)	.07 (43)	-.03 (46)	.09 (47)
3. Attitude			--	.57** (42)	.72** (45)	.64** (46)
4. PBC				--	.48** (42)	.54** (43)
5. Intention					--	.76** (46)
6. Behaviour						--

*p<.05 **p<.01

8.3.5 Informed Choice Analysis

Participants were categorised according to whether their choices to perform or not perform self-management behaviours were informed (see table 37). Uninformed choices were further sub-divided into choices which were completely uninformed or partly uninformed (see table 38). For taking medications as prescribed, 74.8% of participants had made informed choices, however, 25.2% had not made informed choices. Of the uninformed choices, 0.86% were completely uninformed, 2.56% were partly uninformed due to behaviour being inconsistent with attitude, and 21.76% were partly uninformed due to poor knowledge.

For engaging in planned physical activity, 52.3% of participants had made informed choices, while 47.7% had not made informed choices. Of the uninformed choices, 8.3% were completely uninformed, 24.8% were partly uninformed due to behaviour being inconsistent with attitude, and 14.7% were partly uninformed due to poor knowledge.

For restricting salt intake, about half of participants (54.4%) had made informed choices and half (45.6%) had not. Of the uninformed choices, 6.1% were completely uninformed, 22.8% were partly uninformed due to attitude being inconsistent with behaviour, and 16.7% were partly uninformed due to poor knowledge.

For regular weighing, about half of the choices made by participants were informed (54.7%) and half were uninformed (45.3%). Of the uninformed choices, 3.8% were completely uninformed, 25.5% were partly uninformed due to attitude being inconsistent with behaviour, and 16% were partly uninformed due to poor knowledge.

Table 37. *Informed and uninformed choices for the self-management behaviours*

	Informed choice		Uninformed choice
Self-management behaviour	Good knowledge, positive attitude & performance of behaviour	Good knowledge, negative attitude & no performance of behaviour	Choices based on poor knowledge and/or inconsistent with attitude
Taking medications	74.8% (86)	0.0% (0)	25.2% (29)
Physical activity	47.7% (52)	4.6% (5)	47.7% (52)
Reducing salt intake	51.8% (59)	2.6% (3)	45.6% (52)
Regular weighing	33.9% (36)	20.8% (22)	45.3% (48)

Taking medications as prescribed n=115, behaviour=always

Physical activity n=109, behaviour= always, almost always and sometimes

Reducing salt intake, n=114, behaviour = always, almost always

Regular weighing, n=106, behaviour= always, almost always and sometimes

Table 38. *Categorisation of uninformed choices*

Categorisation of informed choices	Self-management behaviours			
	Taking medication	Physical activity	Reducing salt intake	Regular weighing
	Completely uninformed choices			
Poor knowledge and behaviour inconsistent with attitude				
Negative attitude and behaviour performed	0.86% (1)	4.6% (5)	2.6% (3)	1.9% (2)
Positive attitude and no behaviour performed	0.0% (0)	3.7% (4)	3.5% (4)	1.9% (2)
	Partly uninformed choices			
Good knowledge and behaviour inconsistent with attitude				
Negative attitude and behaviour performed	1.7 % (2)	10.1% (11)	2.6% (3)	10.4% (11)
Positive attitude and no behaviour performed	0.86% (1)	14.7% (16)	20.2% (23)	15.1% (16)
Poor knowledge and behaviour consistent with attitude				
Positive attitude and behaviour performed	20.9% (24)	9.2% (10)	14.9% (17)	7.5% (8)
Negative attitude and no behaviour performed	0.86% (1)	5.5% (6)	1.8% (2)	8.5% (9)

8.3.6 Ad Hoc Sample Size Calculation

The sample size calculated for this trial was derived from a study which compared the effects of a booklet and control group on the knowledge of rheumatoid arthritis patients (Barlow & Wright, 1998). There were no relevant studies in the heart failure literature to draw upon. Therefore, the data collected during this trial could be used to inform an ad-hoc sample size calculation, and also to assess whether the trial conducted in this study was adequately powered. Two separate sample size calculations were conducted on the outcome of knowledge (primary outcome for this study): firstly for a trial which compared a booklet group to a control group, and secondly for a trial which compared two booklet interventions. A sample size (statistical method for determining trial size: Pocock, 1983) of 72 (36 per group) was required to achieve 80% power, with a significance level of 0.05, two tailed, for a trial which compared a booklet to a control group on the outcome of knowledge. In this trial there was a 13% loss of participants to follow-up, therefore a sample of 81 participants (approximately 40-41 participants per group) would be required to achieve this sample size. A sample size of 192 (96 per group) was required to achieve 80% power with a significance level of 0.05, two tailed, for a trial which compared two booklets and its effects on knowledge. This sample would be increased to 217 participants (108 participants per group) when the 13% of participants that may be lost to follow-up is incorporated.

8.4 Discussion

The primary aim of this pilot RCT was to ascertain whether a theory-based booklet would produce greater improvements in heart failure knowledge, compared to an atheoretical booklet and a control group. The results provided support for the primary hypothesis and secondary knowledge hypothesis, which was that the IHF booklet improved patients' knowledge significantly, compared to the control group and NICE booklet. This study adds to the growing literature demonstrating the potential of written information to influence knowledge (see Chapter 4). At present there are no quality research studies which evaluate the effectiveness of information materials alone on knowledge outcomes in heart failure patients. The majority of previous studies have incorporated written materials as one component within a broader multifaceted intervention. This exploratory trial indicated that a written intervention does have the potential to improve heart failure patients' knowledge.

A number of possible factors may have allowed the IHF booklet to produce greater improvements in knowledge. Firstly, the theory-based booklet was piloted with heart failure patients, and patient feedback was used to improve the booklet to meet patient needs. This process tested readability, patients' perceptions of content, and identified patients' information needs. Secondly, the theory-based booklet provided patients with information about the pharmacological and non-pharmacological management for heart failure. In contrast, the NICE booklet focused mainly on medical management, and did not provide adequate information on lifestyle changes and self-monitoring. Thirdly, the theory-based booklet had a lower readability level than the NICE booklet, and incorporated a variety of recommendations (e.g. question and answer format, personalising information). These factors combined may have enabled the IHF booklet to communicate information about heart failure, and its self-management, more effectively. The secondary aims of this study included exploration into whether the theory-based booklet produced greater improvements in enablement. Pre- and post-booklet results indicated an increase in enablement, however, there was no evidence to suggest that the IHF booklet was more effective than the NICE booklet.

A secondary aim of this study was to explore whether the IHF booklet exerted a greater influence on the determinants of behaviour, as proposed by the TPB, compared to the atheoretical NICE booklet. The findings from this trial indicated that the IHF booklet was significantly more effective in influencing the cognitive predictors of behaviour than the NICE booklet, for engaging in regular physical activity and regular weighing. The IHF booklet resulted in more favourable attitudes and increased PBC for engaging in regular physical activity, and influenced attitudes and intention for regular weighing compared to the NICE booklet. Although the NICE booklet also significantly influenced attitudes for regular weighing; the IHF booklet exerted a greater influence on attitude. This study demonstrated that influencing the beliefs which underlie behaviour can promote changes in the predictors of intention as proposed by the TPB. This study provides support, like previous research (Chatzisarantis & Hagger, 2005; Kelley & Abraham, 2004; Hoogstraten, de Haan, & ter Horst, 1985), for the ability of TPB-based written information to influence the determinants of behaviour change.

On examination of the means, the IHF booklet influenced all of the components of the TPB in the directions proposed by the model, influencing attitudes to be more favourable, increasing PBC, strengthening intention, and increasing behaviour. This indicates that even for the components of the TPB, which did not demonstrate significant improvements, the small improvements observed for the IHF booklet were in the desired direction. However, there were several instances in which the NICE booklet influenced the components of the TPB in the direction opposite to the one proposed by the TPB to influence behaviour. For example, the NICE booklet decreased PBC for engaging in regular physical activity, and decreased PBC and intention for reducing salt intake. This provides further support that the theory-based booklet IHF was more effective in influencing the cognitive determinants of behaviour, compared to the atheoretical NICE booklet.

The findings for the self-management behaviours of medication taking and reducing salt intake did not support the secondary hypotheses concerning the TPB variables. The lack of change in the TPB variables for medication taking could be accounted for by a ceiling effect. At baseline, participants already reported very positive attitudes, a high sense of PBC, very strong intentions, and performed the behaviour regularly; this did not leave much room for improvement. At baseline, and two week follow-up, the IHF booklet was found to improve salt restricting behaviour and intention, compared to the control group. This change in behaviour was not accompanied by any other changes in the determinants of behaviour as proposed by the TPB, therefore, the TPB could not account for this behaviour change. However, this improvement in salt restricted behaviour was not replicated at pre- and post- analyses which allowed a comparison between the two booklets in a larger sample. Thus, the findings indicate that the IHF booklet did not influence intention and behaviour more, compared to the NICE booklet. The lack of influence on the restricting salt behaviour is of interest, as there was some scope for improvement. There may be other influences on dietary behaviour; perhaps it is other family members, and not the patient who prepares food, or perhaps food choice is determined by habit. A more intensive intervention may be required to influence this behaviour. Previous research has indicated that in order to aid the performance of this behaviour (Bentley, De Jong, Moser, & Peden, 2005), patients request detailed dietary information, recipes for low sodium food, strategies for eating out, ways to improve palatability of food, and guidance on how to read a food label. This appears to indicate that for this self-management behaviour patients need more guidance, detailed instruction, and the acquisition of new skills, and that this was beyond the scope of the intervention developed for this research programme.

Exploratory correlation analyses enabled the identification of several trends within and across the self-management behaviours. Very small positive correlations existed between knowledge and attitude at baseline, and following distribution of both the booklets. However, the correlations between attitude and knowledge were greater following the booklets compared to baseline. The IHF booklet group had larger correlations between attitude and knowledge compared to the NICE booklet. At baseline, no trends were identified in the correlations between knowledge and PBC. However, differences were found in these correlations following the booklets. Correlations between knowledge and PBC were small but positive following the IHF booklet. In contrast, the correlations between knowledge and PBC were small and negative for all the self-management behaviours apart from regular weighing following the NICE booklet. This suggests that changes in the cognitive determinants of behaviours were in the desired direction for the IHF booklet, however, for the NICE booklet, increases in knowledge may be associated with changes in PBC which do not promote self-management behaviour.

Differences in the correlations between the TPB variables were found between the self-management behaviours. For regular weighing, significant correlations in all the TPB variables, in the desired directions proposed by the TPB, existed at baseline and following both the booklets. This trend was also observed for physical activity, with the exceptions of a small non-significant correlation between PBC and intention following the IHF booklet, and between attitude and intention following the NICE booklet. The correlations among the TPB variables reduced in strength for restricting salt intake following the booklets. This perhaps suggests that factors other than motivation may influence the dietary behaviour of patients. Diet behaviour in heart failure patients may be determined more by habits or social factors. The contrasts between the booklets for the correlations for medication taking were of interest. The NICE booklet had significant medium to large positive correlations for all the TPB variables, while the IHF had small positive correlations and a very small negative correlation between PBC and behaviour. This latter finding may be explained by the focus of the NICE booklet on the medical management of heart failure.

This study found that neither booklet influenced behaviour. The ineffectiveness of written information in producing behaviour change has been reported in previous research (e.g. Raynor et al., 2007). Like some previous TPB-based written information interventions, the IHF booklet produced changes in the behavioural determinants of behaviour, but not in actual behaviour (Chatzisarantis & Haggis, 2005; Hoogstraten et al., 1985). The greater effect of the IHF booklet on the cognitive determinants of behaviour is expected within the TPB. The TPB proposes that attitude, subjective norm, and PBC influence intention, and intention in turn influences behaviour. Therefore, informational messages targeting salient beliefs according to the model have a more direct effect on the cognitive determinants of intention, whereas, the influence of these theory-based messages is more indirect on intention and behaviour. In agreement with the TPB, this study found that the IHF booklet had more success in influencing attitude and PBC, rather than intention or behaviour. Therefore, to influence behaviour, the IHF booklet would need to be supplemented with specialist personal support.

There were differences in informed and uninformed choices between the self-management behaviours. Taking medications as prescribed had the highest level of informed choice. No participants made an informed decision not to take their medications as prescribed, perhaps indicating that participants perceived the importance and necessity of taking medication as part of their illness management. Only a quarter of heart failure patients made uninformed choices about taking medication as prescribed, and unlike the other self-management behaviours, only a minority of participants (2.56%) had attitudes that were inconsistent with their behaviour. For the remaining self-management behaviours, just less than half made uninformed choices and between 15-20% of patients did not engage in regular physical activity, reduce salt intake or weigh regularly, despite having positive attitudes and good knowledge. This suggests that a large proportion of patients may be experiencing barriers to performing these self-management behaviours for heart failure. As identified in this thesis (see chapter 7) patients mentioned their poor physical condition as a barrier to regular physical activity, and not knowing which foods were low in salt as a barrier to eating a low salt diet.

Of particular interest is the 20% of patients who had made an informed choice not to weigh regularly. These patients had made a choice based on adequate knowledge, and in accordance with their attitudes to not perform this self-management behaviour. This suggests that there are a proportion of heart failure patients who do not perceive regular weighing to be useful in the self-management of heart failure. Perhaps this finding could be explained by salient beliefs identified in the previous study (see chapter 7), where patients indicated that a stable weight could discourage regular weighing. Patients may have weighed regularly for a short while and found no change, which prompted less daily weighing. In addition, heart failure patients with mild heart failure may not be asked by their doctors to weigh regularly, as problems with fluid retention are less expected or frequent in this group. The informed choice analysis also indicated that of the 44% of patients who reported at baseline that they did not weigh regularly at least sometimes during the week, about 20% of these patients had made an informed choice not to.

This raises interesting questions about health behaviour as a measure of outcome, as these participants would form part of this group but would be distinctly different from patients who do not engage in self-management behaviour due to lack of knowledge and perceived barriers. The use of informed choice as a measure of booklet effectiveness has been increasing in momentum over recent years. Nicolson, Knapp, Raynor, Grime and Pollock (2006) found that stakeholders (e.g. patients, patient organisation groups) identified informed choice as an acceptable outcome from written information. More importantly, the concept of informed choice as an outcome for written information was not reflected in previous literature reviews on written patient information. Raynor and colleagues (2007) state that, if informed choice is considered an acceptable primary focus for written information, as opposed to behaviour change, then questions need to be addressed about the usefulness of adherence as an outcome measure to evaluate the effectiveness of written information.

Patients' self-reports of adherence to self-management behaviours for heart failure at baseline were reflective of estimates provided by previous research. At baseline 97.4% of patients reported taking their medication every day, 71.9% of patients reported restricting their salt intake every day or nearly every day, 67.8% of patients reported engaging in physical activity at least sometimes, and 56.1% of patients reported weighing themselves at least sometimes every week. A recent overview of patients' adherence with self-management behaviour reported adherence with medication at approximately 70%, 50 to 89% for restricted salt intake, 42 to 59% for recommendations on physical activity, and between 12% to 75% for regular weighing (van der Wal, Jaarsma, & van Veldhuisen, 2005).

The medication taking behaviour in this study seems considerably higher than the estimates provided by the review conducted by van der Wal, Jaarsma and van Veldhuisen (2005). However, the estimates for medication taking are similar to those reported in three questionnaire studies which found 98.6%, 96% and 93% adherence to medication taking respectively (van der Wal et al., 2006; Evangelista et al., 2001; Artinian, Magnan, Sloan, & Lange, 2002). There is some evidence in the area of medication adherence that self-report measures are concordant with other measures such as electronic devices (Garber, Nau, Erickson, Aikens, & Lawrence, 2004). The estimates from our study, and the other questionnaire studies, seem considerably higher that estimates of adherence obtained from medication event monitoring systems (MEMS). Two studies which have used the MEMS estimated adherence in heart failure populations at 84% (Bohachick, Burke, Sereika, Murali, & Dunbar-Jacob, 2002) and 72% (Chui et al., 2003). The discrepancy between self-report and more objective measures of medication taking, indicate that perhaps the high medication taking reported in this study was reflective of patients over-reporting their medication behaviour. Previous research in heart failure has found lack of knowledge and misunderstandings of medication regimens to be reasons for high reporting of adherence to medication regimens (Cline, Bjorck-Linne, Israelsson, Willenheimer, & Erhardt, 1999). The limitations of self-report measures will be discussed further below.

The measurement of knowledge in patients has received considerable attention in recent years (see Stromberg, 2005) primarily due to the difficulty of measuring this concept. At present there is no 'gold standard' for measuring knowledge in heart failure patients and, as outlined in the informed choice literature, there is no absolute standard against which knowledge can be categorised as good or poor (Michie et al., 2002; Marteau et al., 2001). Promisingly, within this study, the scale used to measure knowledge correlated very strongly with the Dutch Heart Failure Knowledge Scale which was published just prior to the commencement of this trial (van der Wal, Jaarsma, Moser et al, 2005). During its initial assessment, this scale established reliability and validity, and proved its ability to distinguish between patients who have or have not received heart failure education. This indicates that the scale used for this study was adequate to measure knowledge.

8.4.1. Limitations of the Study

This pilot trial enabled the methodology and measures designed for this trial to be tested. The theoretical and general limitations for this trial will be discussed below.

8.4.1.1 Theoretical limitations.

To limit the length of the IHF booklet, the booklet did not target normative beliefs due to findings in the literature that subjective norm was a less good predictor of intention, compared to attitude and PBC (Godin & Kok, 1996). Nonetheless, we have no evidence that the booklets did not influence subjective norm. The booklets made clear that health professionals supported the information they provided, giving patients an indication of what doctors (i.e. a significant other) expected from them. Furthermore, the IHF booklet states specifically that it is approved by local health professionals, and a cover letter providing information about the trial implied medical approval by doctors directly involved in their care. According to the TPB, changes in behaviour would be more likely when all three cognitive determinants of behaviour are influenced (Ajzen, 1991). A limitation of the IHF booklet is that it did not explicitly target subjective norm. Perhaps greater effects on intention may have been observed if the booklet had also targeted normative beliefs.

Implementation intentions were used in the IHF booklet to promote medication taking behaviour and increase regular weighing. For the former, implementation intentions were unlikely to have an effect due to a ceiling effect which has been discussed previously. However, for regular weighing, the IHF booklet did not exert a greater influence on behaviour than either the NICE booklet or the control group, despite positive intentions. Previous research has shown that implementation intentions have not improved medication taking, or fruit and vegetable consumption, over and beyond the provision of simple information and/or a TPB questionnaire (Jackson et al., 2006). In this study, due to the timing of regular weighing being important (e.g. prior to breakfast and after going to the toilet), patients did not create, but were provided with, an implementation intention. There is very little research investigating whether forming an implementation intention is more effective than being provided one by a health professional. One study which assessed the difference between forming an implementation intention oneself or being given an implementation intention by instruction, found implementation intentions to be ineffective in promoting antibiotic adherence over and beyond the standard provision of information (Jackson et al., 2006). The fact that more motivated patients were likely to have taken part in this study points to the possibility that implementation intentions may have been created spontaneously, as is likely in motivated individuals (Gollwitzer & Brandstatter, 1997). Goal setting was used to promote regular physical activity. Abraham and Sheeran (2003) suggest that PBC may be partly determined by levels of planning, such as goal setting. PBC for physical activity was increased, perhaps suggesting that goal setting prompts did have an influence on PBC, although this is only inferred. Kelley and Abraham (2004) found that goal setting was an important component, in their booklet, which influenced physical activity and healthy eating in older adults.

8.4.1.1 General limitations.

Despite every effort to try to increase recruitment to the trial, it was impossible to attain the sample required to adequately power this RCT. A sample size calculation for a more definitive trial based on this pilot study indicated that the trial was inadequately powered to fully determine differences between the two booklets. Therefore, this trial carries a considerable risk of being unable to demonstrate differences between the groups in this trial (Type II error; Pocock, 1983). The recruitment rate for this study was 20%, which is lower than the 30% reported in a recent heart failure study conducted in primary care in the UK (Barnes et al., 2005). However, it must be noted that we cannot estimate the exact number of patients who received information about the study, as some of the patient details provided by the hospital were inaccurate, with letters returned indicating a wrong address: therefore, it cannot be assumed that all letters sent were received by the addressee. A strategy adopted by other researchers in the field of heart failure in response to low recruitment has been to extend the recruitment period (Chang, Hendricks, Slawsky, & Locastro, 2004). However, this was not a feasible option due to the limited time period available for this research programme. This study reflects the difficulties already discussed in the literature, in relation to recruiting older adults and older adults with chronic ill health (see Barnes et al., 2005; Harris & Dyson, 2001; Petty et al., 2001). Research has suggested that older adults may either perceive taking part in, or understanding, a research study too difficult, or may consider themselves too old to take part (Harris & Dyson, 2001). This emphasises the importance of communication in research. This study only provided information to patients via an information sheet, and perhaps this was insufficient information. Some participants, particularly those in the control group, contacted the researcher, as they were confused as to why they had received the same questionnaire they had completed a few weeks previously, indicating that they did not understand the trial[10]. A flexible approach is advocated in the literature for the recruitment of older adults, where information is presented in a variety of different ways to facilitate understanding (Harris & Dyson, 2001). However, providing information face to face would have been beyond the resources available for this study.

Information about patients' severity of heart failure could not be collected in this trial. Therefore, questions need to be considered about the appropriateness of the IHF booklet for patients at different stages of their illness. The American Heart Association and American College of Cardiology developed the 'Stages of Heart Failure' (Hunt et al., 2001), and this system classifies heart failure in stages A through to D. Stage A classifies individuals at high risk of developing heart failure. Stage B refers to individuals who have a disorder of the heart but have never developed chronic heart failure symptoms. The stages of C and D are most applicable to this research study. Stage C includes individuals with an underlying heart disease and past or current heart failure symptoms whilst stage D refers to individuals with end-stage disease who are frequently hospitalised for chronic heart failure and require specialist treatments (e.g. heart transplant) or hospice care. According to the American Heart Association and

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[10] Participant's who made queries about the trial were provided with the information they required and reminded that they could withdraw from the study at any time.

American College of Cardiology, all stages would involve physical activity as part of therapy, and patients in stages C and D would be encouraged to restrict their dietary salt restriction (see Hunt et al., 2001). Therefore, the patients receiving a classification of C and D would be most suitable for the IHF booklet. The other most common classification system used in heart failure is developed by the New York Heart Association and assigns patients into one of four functional groups. This system includes: class I no limitation or symptoms from physical activity; class II slight limitation and symptoms resulting from ordinary exertion; class III marked limitation and symptoms resulting from less than ordinary exertion; class IV patients with symptoms of heart failure at rest. Taking this information into consideration it could be suggested that the IHF booklet would be most suitable for patients in stage C and with a functional status of class II and III. Patients in stage D and class IV would also be expected to perform self-management behaviours; however, their stage of illness could make these very difficult to perform due to physical limitations. For example, patients in stage D and class IV would have heart failure symptoms at rest. Details provided by families and patients about not participating in the study seemed to indicate that there was a proportion of patients who were in the end stages of the illness. In fact, a few patients died in the interim, between receiving the patient details and mailing the study information to patients. Therefore, within the population of patients contacted about the research there is likely to be a proportion that would have been too unwell to take part in the study. In regards to the IHF booklet this group of patients would not benefit from the IHF booklet, because of the severe nature of their symptoms. The IHF booklet would be most suitable for patients experiencing mild to moderate symptoms of heart failure. Furthermore, targeting this group would enable the booklet to provide information to patients who are most likely to benefit from lifestyle changes. Future interventions should take the stage of heart failure into account, in order, to assess the suitability of their intervention to the patient population. If researchers are attempting to design interventions for heart failure patients with a range of symptom severity, then consideration should be given as to whether the intervention would need to be amended to meet the needs and abilities of patients with different degrees of limitation.

The literature already acknowledges that heart failure patients may be too fatigued to fill in lengthy questionnaires (Stomberg, 2005). Within this study there was a need to strike a balance between collecting research data and burdening patients. Usually TPB questionnaires use more than one item to obtain a more reliable measure of each construct of the TPB (Ajzen, 2002). Due to the nature of heart failure and the various sensory changes that arise due to older age, every effort was made to keep the questionnaire as brief as possible. Therefore, a single item measure was employed for PBC, intention, and behaviour, in order to limit the length of the questionnaire. Comparing the correlations observed in this study with those reported in comprehensive meta-analyses is one method of determining whether the measures used in this study were performing in a similar manner to those used in other studies. This method has been adopted in other TPB research, which has been unable to use a full TPB questionnaire (see Kelley & Abraham, 2004). Armitage and Conner's (2001) comprehensive meta-analysis of the applications of the TPB reported the following correlations between the constructs within the TPB: 0.49 between attitude and intention, 0.43 between PBC and intention, 0.37 between PBC and behaviour, and 0.47 between intention and behaviour. Apart from the correlations which were very low for medication taking, the correlations for the other self-management behaviours at baseline are broadly comparable to those in other studies, providing some degree of construct validity for the measures of TPB in this study.

Nonetheless the implications of adopting only single-item measures for the constructs of PBC, intention, and behaviour in this study must be addressed. The adoption of single-item measures may restrict the ability of these measures to adequately measure the constructs of the TPB. This, therefore, may have weakened the relations between the variables in the TPB, and limited the ability of the trial to investigate the relationships between the TPB constructs for the self-management behaviours. These limitations of the TPB measures should be adequately addressed in future more definitive trials of the IHF booklet.

A further limitation in this study was the lack of an objective measure of patients' behaviour. Although there is some evidence in the area of medication adherence that self-report measures are concordant with other measures such as electronic devices (Garber et al., 2004), bias in self-reports of behaviour still remains a concern. It is possible that patients may have over reported their self-management behaviour, due to a tendency to give socially desirable responses. The high adherence for the self report of adherence has theoretical implications, particularly as self-report methods have been found to generate higher estimates of medication taking, compared to more objective measures in the heart failure population (see van der Wal., 2006). This would limit the ability of the TPB to predict this behaviour, and the relationships between the determinants of behaviour and reported behaviour. Future intervention evaluations should attempt to adopt more objective measures which would enable the TPB to more accurately predict this behaviour. In addition, patients may have perceived the response options differently and, therefore, there may be variation in how participants categorised their self-management behaviours. For example, the response options of 'sometimes' and 'rarely' may have different meanings to different participants. This could result in participants categorising similar practices of self-management in different response categories. Participants may also have not understood the questions, and this may have influenced their responses. For example, participants may not have understood how much six grams of salt is, and this is may have influenced their responses to questions. Future intervention development may benefit from gathering information about patients understanding of questionnaire items, and utilising objective measures to validate self-report measures. For example, the MEMS could be used to measure medication taking, a pedometer (counts steps taken) could provide some indication of activity (Evangelista et al., 2005), or exercise capacity could be estimated by the six-minute-walk test (Guyatt et al., 1985). For regular weighing and reducing salt intake more objective measures would be difficult to identify, but future research could incorporate a food diary to identify if participants were consuming foods high in salt, and participants could keep a chart detailing how often they weighed.

A limitation of the informed choice analysis was that the knowledge scale used was inadequate to provide knowledge scores separately for the different heart failure self-management behaviours. Future research should focus on developing a measure of knowledge that could be used in informed choice analyses, particularly as informed choice is becoming increasingly important as an outcome measure for interventions. This study only conducted follow-up two weeks after the booklet interventions. Although the results suggest that the IHF booklet initiated some changes in the predictors of behaviour, it is necessary to assess whether these changes were maintained.

Previous research using more comprehensive interventions, which incorporated longer periods of follow-up, reported short-term effects on behaviour change (see Jaarsma et al., 1999; Stromberg, 2001). Future studies should incorporate longer-term follow-up to investigate whether effects observed in the short-term are maintained over time.

Patients in this study were self-selecting. It is, therefore, possible that the patients who entered this trial were more motivated to change their self-management behaviour or were more eager to seek further information about their illness. Indeed, the high self-reports for taking medications as prescribed may be a reflection of the motivation of patients in this study. However, there was no means of identifying whether the patients who entered this trial differed from the general population of heart failure patients. The IHF booklet attempted to influence the management of heart failure by targeting four different behaviours. To promote change in all these behaviours simultaneously would require a substantial effort from patients. Possibly, decision-making and self-management could be more effectively promoted by the provision of information that addressed the self-management behaviours separately, and with the delivery of information staggered over time.

8.5 Clinical Implications

Written information has the potential to influence health related beliefs. This exploratory study suggests that a theory-based written information booklet can improve knowledge about heart failure, and initiate change in the cognitive predictors of behaviour to promote self-management behaviour. The developers of patient education materials need to consider beyond what information needs to be provided to patients. Consideration should be given to how information is presented, and the influence this may have upon readers' attitudes and PBC. Models of behaviour change can enable developers of patient education materials to consider ways of incorporating strategies that can help to promote health and self-management behaviours. More often than not, patient education materials are lost among a plethora of strategies within complex interventions to promote heart failure self-management (see Chapter 4). This study showed how a single theory-based booklet worked to improve knowledge and initiate change in the cognitive predictors of heart failure self-management. More evaluation is required of patient education materials before they are disseminated to a wider readership, and perhaps evaluation should consider variables important to behaviour change, rather than evaluating behaviour only. By incorporating this advice into the development of patient education materials, we may develop a more in-depth understanding of the reasons why written information interventions are successful or unsuccessful in promoting behaviour change.

The IHF booklet developed during this program of research could be utilised by health professionals to communicate information to patients about self-management which would be relevant to their management plan. There was no criterion available, however, to evaluate the implementation of the communication of the management plan. The absence of a written management plan in service provision prevented the evaluation of this recommendation. This programme of research has identified that healthcare professionals perceive a shortage of appropriate written materials (see Chapter 6), and that only a small proportion of patients reported receiving written information from healthcare professionals (see section 8.3). Furthermore, the majority of patients in this study requested further information about their heart condition (see section 8.3). The incorporation of this intervention into routine clinical practice would not disturb current practice or require additional input from health professionals, and could be easily sustainable. Most importantly, the IHF booklet has the potential to be used alongside other more complex interventions, to support heart failure self-management.

8.6 Chapter Summary

This pilot trial showed that a theoretically driven booklet could significantly improve knowledge, compared to an atheoretical booklet and control group. In addition, this theoretical booklet was able to significantly influence the cognitive predictors of behaviour for the self-management behaviours of physical activity and daily weighing, compared to an atheoretical booklet and control group. This pilot trial also gathered important information about the limitations of the methodology and measures employed in this trial. This information would prove useful in the development of a more definitive trial. The interpretation of the findings of this trial was limited, because of the small sample size. However, the findings of this pilot trial do suggest that this topic is worthy of further research in a larger sample. Further research is necessary to evaluate whether theoretically informed written information offers advantages over other forms of written information.

8.7 Conclusions

The results of this exploratory RCT suggest that the current lay guideline booklet developed by NICE may not be optimal in improving patients' knowledge, or promoting shared responsibility for heart failure self-management. The findings of this study suggest that incorporating theory and drawing upon an evidence base for producing patient education materials improves the ability of written information to improve patient outcomes. This study indicates that a theory-based booklet was more successful in improving knowledge and initiating change in the cognitive predictors of behaviour.

Chapter Nine: Discussion

9.1 Introduction

The programme of research presented in this thesis was intended to develop and evaluate a theory-based intervention, to implement the 'communicating the management plan' and the 'shared responsibility' guidelines for heart failure. This research programme investigated whether a theory-based booklet, which draws upon recommendations for producing written information and targets the modifiable psychological factors identified by the TPB, is more successful in influencing heart failure knowledge and self-management than an atheoretical booklet. This chapter will summarise the main findings of this research programme, discuss its strengths and weaknesses, discuss the development of theory-based interventions, consider the implication of these findings for patient educational interventions, and make suggestions for future research.

9.2 Overview of Thesis and Main Findings

9.2.1 Background

Chapter 2 provided an overview of the existing literature on interventions to influence health professional behaviour change. This literature showed that, while there was a substantial body of research, the vast heterogeneity between similar interventions hindered conclusions about the likely effectiveness of interventions. In particular, the lack of theory informed approaches hindered the emergence of evidence which could provide insights into the reasons why interventions have proven effective or ineffective in changing clinical behaviour.

Chapter 3 provided an overview of the existing literature detailing heart failure patients' knowledge and self-management practices, and outlined interventions designed to promote self-management. The literature showed that heart failure patients lacked knowledge and were unable to successfully manage their illness. As found in the implementation science literature, heart failure interventions also typically lacked a theoretical foundation. Therefore, as above, it was difficult to tell why interventions were effective or ineffective.

Chapter 4 introduced the main theoretical framework utilised throughout this research programme. In the first part of this chapter, the TPB was found to be a better model for predicting health professional behaviour compared to the TRA. The second part of this chapter reviewed studies which utilised the TPB as the principal framework for the development and evaluation of written interventions. This literature provided some evidence indicating that TPB-based written interventions could be more effective in improving patient outcomes than atheoretical interventions. This chapter highlighted the potential of the TPB to extend understanding about health professionals' behaviour, and to inform the development of written information materials.

Chapter 5 set out the rationale for using qualitative and quantitative research methods. It was argued that both methods were appropriate and necessary for the different research objectives addressed during the course of this programme of research. Semi-structured interviews and thematic analysis were considered the most suitable methods to identify health professionals' views concerning the implementation of clinical guidelines, and to identify patients' salient beliefs for heart failure self-management. The 'think aloud' method was used to identify patients views of the pilot theory-based booklet. Finally, a RCT was selected as the best method to evaluate the theory-based booklet, compared to an atheoretical booklet, and a no-booklet group

9.2.2 Healthcare professionals' Views of the Implementation of the NICE Guidelines for Heart Failure Management

Chapter 6 presented a qualitative study using a semi-structured interview schedule, which incorporated questions based on the TPB to identify health professionals' attitudes, beliefs, and perceived barriers, to implementing the NICE guidelines for heart failure and the communication of the management plan guideline. To the author's knowledge this was the first study which employed the TPB in an interview format to explore the factors and beliefs associated with the implementation of guidelines. Data was inductively analysed and then categorised according to the components of the TPB. A key goal of this study was to move beyond a descriptive account of implementing clinical guidelines, to a theory-driven identification of factors that might influence guideline implementation. The findings of this empirical study will first be discussed in relation to the NICE guidelines for heart failure management, and then in relation to the communication of the management plan guideline. Finally, the ability of the TPB to explain the findings that emerged from the qualitative analysis will be discussed.

The health professionals interviewed felt that service related barriers such as lack of resources and time constraints hindered the implementation of clinical guidelines. However, a key finding to emerge was that the delivery of evidence-based practice was not solely driven by organisational and professional factors; patient-related factors also exerted a considerable influence on health professionals' heart failure management. For example, health professionals may opt not to refer frail patients for echocardiogram investigations, because of the inconvenience it would cause them to attend the medical appointment.

With regards to the communication of the management plan guideline, a notable finding from the interviews was that a written management plan was rarely available, and information about heart failure usually comprised informal verbal communication. Health professionals felt that a number of patient related factors, such as distress, unwillingness to obtain information, or partake in decision-making could thwart attempts by them to provide information. Furthermore, health professionals' suggested that difficulties encountered by patients in the retention and comprehension of information about their management plan impeded self-management. Health professionals stated that they sometimes felt apprehensive disclosing a diagnosis of heart failure, or discussing prognosis with patients. The former stemmed from concerns that the use of the term 'heart failure' could result in patient distress, and the latter derived from the difficulty of determining prognosis because of the unpredictable trajectory of heart failure. Health professionals also appeared to be uncertain about the content and quantity of information to provide to patients.

Health professionals felt that they had insufficient time to deliver adequate information, advice, and instruction to patients. Written interventions were endorsed as a strategy to provide information to patients about their management plan. However, health professionals indicated that they did not regularly distribute written information, and reported a lack of suitable materials. Although the interviews did not seek to determine their views of patients' self-management, a relevant finding to emerge from this study was that health professionals apportioned some of the responsibility for heart failure management to patients. Health professionals' accounts, in particular, emphasised the shared partnership required with patients to successfully manage heart failure. These findings corresponded to a 'shared responsibility' guideline, which related primarily to the implementation of the management plan.

The majority of themes inductively identified in this study did correspond to the components of the TPB. The theory was able to account for themes deriving from the social influences on clinical practice (e.g. patients and colleagues), anticipated outcomes from guideline implementation (e.g. improvement in patient care, increase in demands), and the barriers and facilitators to performing evidence-based practice (e.g. resources, time). Most of the themes identified in relation to the implementation of the NICE guidelines for heart failure management, and the communication of the management plan guideline, fell within the construct of PBC. This perhaps suggests that PBC is the most salient factor for the implementation of the heart failure management guidelines in the healthcare context. The TPB, however, was unable to encompass all the themes identified during the analysis. Findings not accounted for by the theory included those referring to external influences which did not include a social interaction (e.g. local guidelines), the purpose of guidelines (e.g. threat to clinical freedom), and the views about NICE and its guidance (e.g. perceived motives of NICE). This study was the essential first step required before embarking on the development of an intervention to implement the communication of the management plan guideline. This stage also enabled a more thorough understanding of the healthcare context, within which the intervention would be delivered, and was used to inform its development.

9.2.3 Development of a Theory-Based Self-Management Booklet for Heart Failure Patients

Chapter 7 described the development of a theory-based booklet intervention, entitled 'Improving Heart Function', to implement the communication of the management plan and shared responsibility guidelines. The latter guideline also became a primary focus of this research programme, as findings from the first study emphasised the joint partnership required between practitioners and patients for the successful management of heart failure. To my knowledge, this is the first study to develop a TPB-based written intervention to promote heart failure self-management.

The theory-based IHF booklet was proposed for three reasons.

1. A written intervention was recommended and considered acceptable by health professionals in the first study.
2. Such an intervention would be deliverable and sustainable within current service provision. Although an intervention targeting health professionals had been initially intended at the outset of this thesis, the financial implications of reimbursing health professionals for their participation would be beyond the resource capabilities of this research programme. Therefore, a patient intervention therefore was deemed more appropriate, particularly as patients' responsibility in the management of heart failure was emphasised in the first study. In addition, patients were usually only supplied with verbal information about their illness and management plan. Augmenting this information with written materials could assist in improving patients understanding and retention.
3. Although NICE have produced a lay booklet version of the guidelines for heart failure management, it was still deemed necessary to develop another booklet intervention, primarily because the development and outcomes targeted by the NICE booklet were not based on a theoretical perspective. According to health psychology theory, merely providing information which targets knowledge is unlikely to influence behaviour. Taking all these factors into consideration, this research programme developed a booklet which incorporated psychological strategies and was intended to target the factors proven to influence behaviour. Alongside knowledge, the IHF booklet also specifically planned to target attitude and PBC, the theoretical predictors of intention and behaviour proposed by the TPB.

The content of the pilot booklet was derived from information about the management plan that healthcare professionals deemed important. This booklet provided information, and proposed behavioural strategies for four key management behaviours: taking medication as prescribed, regular physical activity, regular weighing, and restricting salt. Psychological theory was utilised to inform the design of the booklet.

Information in the booklet was structured around the five broad cognitive dimensions typical of illness representations. Implementation intentions were incorporated to strengthen the intention-behaviour relationship for medication taking and weighing regularly. Patients could also monitor their daily weighing on a chart within the booklet, and patients were encouraged to identify a behaviour change and develop goals to achieve its attainment in a lifestyle contract.

This chapter presented a qualitative study which had two parts. Firstly, this study elicited patients' salient beliefs about heart failure self-management. Patients identified a number of favourable and unfavourable outcomes, and barriers to the performance of self-management. A key finding to emerge was that patients did not understand the rationale behind daily weighing and salt restriction as part of their self-management regimen. Then, the second part of this study piloted the booklet on intended users, using the 'think aloud' method to determine whether the information and theoretical approaches in the booklet were understandable, acceptable and useful to patients, and met their informational needs. Patients' overall evaluations of the booklet were very positive: however all patients had difficulty identifying and setting goals in the lifestyle contact, and sections about restricting alcohol consumption and stopping smoking were considered irrelevant. This patient feedback was used to improve the booklet's content and patients' salient beliefs were targeted in the booklet, to promote a more positive attitude, and to increase patients' sense of PBC. A comparison of the NICE and IHF booklet found that the IHF booklet had better readability, and utilised a greater number of recommendations for producing patient written information, compared to the NICE booklet.

9.2.4 RCT Evaluation of a Theory-Based Booklet to Improve Knowledge and Promote Self-Management

Chapter 8 presented the main study, a pilot randomised controlled trial which assessed the effectiveness of the NICE and IHF booklets for improving the outcomes of knowledge, enablement, attitude, PBC, intention, and self-management behaviour. This study explored whether a theory-based booklet was more successful in increasing knowledge and influencing heart failure self-management behaviours, than an atheoretical booklet and control group.

This study was adequately powered to evaluate the main outcome of knowledge and, therefore, provides a definitive test of the primary hypothesis only - tests of the other hypotheses were secondary and exploratory. The primary hypothesis predicted that the IHF would improve knowledge more than the control condition. The three secondary hypotheses proposed that: (1) The IHF booklet would improve knowledge more than the NICE booklet; (2) The IHF booklet would improve enablement more than the NICE booklet and control condition; (3) The IHF booklet would produce greater improvements in the TPB components of attitude, PBC, intention, and behaviour compared to the NICE booklet and control group. In addition, patients' attitudes and knowledge were categorised to determine whether their self-management choices were informed or uninformed.

The study provided support for the primary and secondary hypotheses for knowledge. The IHF booklet was found to produce greater improvements in knowledge among heart failure patients, compared to the control condition and the NICE booklet. The IHF booklet was not more effective in improving enablement but was more effective in influencing the cognitive predictors of behaviour than the NICE booklet or the control condition, thus providing partial support for the secondary hypotheses. For engaging in regular physical activity, the IHF booklet resulted in more favourable attitudes and increased PBC. For regular weighing, the IHF booklet produced greater improvements in attitude and intention. Neither booklet influenced the cognitive predictors of taking medications as prescribed (which were already very positive), or restricting salt intake. The IHF booklet was found to influence all of the components of the TPB in the desired direction. However, in some instances, the NICE booklet was found to influence some components of the TPB in the direction opposite to the one proposed by the model to increase self-management behaviour. In summary, the pilot trial indicated that the theory-based IHF booklet was more effective in influencing the cognitive determinants of behaviour than the atheoretical NICE booklet. This study showed that influencing the beliefs which underlie behaviour can promote changes in the predictors of intention and behaviour as proposed by the TPB.

In addition, this study found that only a few patients made uninformed decisions about taking their medication as prescribed. However, for the remaining self-management behaviours, just less than half of the patients made uninformed choices and 15% to 20% of patients did not engage in these management behaviours, despite having positive attitudes and good knowledge. One fifth of patients had made an informed choice not to weigh regularly.

9.3 The Development of Theory-Based Interventions

The inadequate development and evaluation of interventions can result in researchers being uncertain about the mechanisms underlying the effectiveness or ineffectiveness of an intervention. For example, when an intervention is found to be ineffective, it is difficult to ascertain whether this is due to the intervention being inadequately developed, whether all similar interventions would also prove unsuccessful, or whether the intervention was applied to an unsuitable situation or target group. Complex interventions, such as those that aim to influence behaviour change, are inherently difficult to design and evaluate. They usually comprise of many different components, and it can be difficult to identify their components and how they are related (Campbell et al, 2000). In response to the difficulties posed in developing complex interventions, the Medical Research Council (MRC) developed a framework to aid researchers developing such interventions (MRC, 2000). This framework consists of five phases: pre-clinical/theoretical, modelling, exploratory trial, definitive trial, and long term implementation. The framework highlights the questions and issues that need to be considered by researchers during the process of developing an intervention. Each phase in the framework moves towards gathering further evidence on the effectiveness of the intervention, and gradually proceeds to the development of a definitive trial and long term pragmatic studies. This framework, in particular, emphasises the early phases of intervention design, and advocates a theoretical basis in the development and evaluation of interventions.

This research programme included elements that form parts of the first three phases proposed by the MRC framework. As recommended by the pre-clinical/theoretical phase, the development of the intervention was based on a review of the literature and underpinned by a theoretical framework. The first two studies in this research programme form part of the preclinical/theoretical and modelling phases. The qualitative exploration of health professionals' views towards the NICE guidelines for heart failure, based on a theoretical model of behaviour change, enabled the identification of health professionals' beliefs that underpinned their clinical behaviour. This study also enabled an identification of health professionals behaviours, and organisational factors, that informed the selection of a suitable intervention which could be delivered within the healthcare setting. The second qualitative study enabled a theoretical understanding of heart failure patients self-management, and how these key beliefs could be targeted in the booklet intervention. The acceptability of the booklet was also tested in this study and information from the target group was used to improve the booklet. An exploratory trial was then conducted in which the theoretically expected effects of the intervention on behaviour and its determinants were tested. This trial generated very useful information about the design, measures and effectiveness of the intervention, which could inform further intervention development and the design for a more definitive trial.

While the MRC framework stresses the importance of a theoretical basis for interventions, the process by which this can be achieved is unclear in the framework. Part way through this research programme, Hardeman and colleagues (2005) proposed a causal modelling approach which researchers could utilise to guide the development of behaviour change interventions. However, this thesis was unable to benefit from this approach, because the intervention and trial had already been designed. Causal modelling enables researchers to identify and link all elements of their intervention, and proposed evaluation by theoretical pathways. Researchers are able to pictorially represent theoretical pathways and how intervention techniques link to behaviour, or determinants of behaviour, and the measures by which these pathways will be tested. This enables researchers to identify points at which constructs from behaviour change theories can be utilised to influence change in outcomes. This is particularly useful when constructs from multiple theories are used within an intervention. This process ensures that theoretical components are incorporated into the evaluation of the intervention, and that the theoretical mechanisms via which an intervention is expected to influence outcomes is defined. Researchers using causal modelling, within the MRC framework, should be more readily able to identify (1) points along the causal framework where an intervention failed, or (2) the mechanisms by which an intervention was successful in influencing outcomes. This process would also enable researchers to communicate the theoretical elements of their research via a common framework. This model has been used in the development of an intervention, Proactive, which aims to improve physical activity behaviour (see Hardeman et al., 2005). While complex behaviour change interventions are difficult to plan and evaluate, the causal modelling approach could prove useful to researchers in planning interventions and evaluations that are more embedded within a theoretical framework. Future studies based on the research in this thesis would benefit substantially from incorporating the casual modelling approach in defining the theoretical elements of the intervention and its evaluation.

9.4 Limitations for this Programme of Research

There are some limitations that should be taken into account when interpreting the findings of this research programme and planning future research. This section summarises the general limitations present in the empirical studies. The limitations specific to each empirical study are discussed in more detail within their respective chapters.

Firstly, all participants involved in the empirical studies were self selecting. Health professionals in the first study gave their time voluntarily and, therefore, may have had a particular interest in guidelines or heart failure management. It is possible that their views may not represent the views held by professionals who did not participate in the study. In addition, heart failure patients who participated in the RCT may have been more motivated to seek further information, and to be more involved in their care. Indeed, the very high patient self-reports of intention and behaviour in all groups within the RCT may well reflect these higher levels of motivation. Therefore, the heart failure patients who participated in the RCT may not have been representative of the general medical population of people with heart failure.

Secondly, it is well recognised in the TPB literature that self-report measures may lead to an overestimation of intention and behaviour (Abraham, Clift, & Grabowski, 1999). Although objective measures for measuring self-management behaviours exist (e.g.

MEMS, food diaries), these measures would have required face-to-face contact with patients for their implementation. It was, therefore, beyond the scope of this thesis to use objective measures. The first study in this research programme relied on health professionals' self-reports of barriers to evidence-based practice, and at no point was the accuracy of these self-reports evaluated. Nonetheless, it could be argued that these barriers were real to the participants in the study.

Thirdly, the sample size required to adequately power the RCT was not achieved. This may have resulted in the trial being unable to detect differences between the groups that may have existed. The first study in this research programme failed to recruit adequate numbers of health professionals in some of the services responsible for heart failure management (cardiothoracic directorate and primary care), and in some health professional groups (nurses, junior doctors). It was, therefore, not possible to compare and contrast findings between different health professionals and healthcare services to ascertain whether views about the implementation of the NICE guidelines varied on these factors.

The fourth limitation in this research programme relates to the short-term follow-up enlisted in the RCT to evaluate the effectiveness of the booklet interventions on patient outcomes. This trial, therefore, was only able to identify effects on patient outcomes achieved shortly after the delivery of the intervention, and does not give an indication of whether changes in outcomes were maintained over time. The limited time available for this research programme hindered the prospect of employing a longer-term follow-up.

An overview of the limitations of the IHF booklet will now be presented. To limit the length of the booklet, some information about heart failure and its treatment was not incorporated (e.g. coping with depression, pacemakers). This information may have proved useful to patients. Although the second study identified that specialist support would have supported patients to initiate and plan their self-management, this was not possible in the resources available for this research programme. Therefore, psychological strategies could only be utilised in a very minimalist manner in the booklet. The IHF booklet did not address normative beliefs and concentrated only on control and behavioural beliefs. This may have reduced the effectiveness of the booklet to influence behaviour and intention. Finally, the absence of a written or more ideally computerised management plan available from patients' records, meant that it was impossible to deliver an educational intervention which was personalised to patients' circumstances.

9.5 Substantial Contribution, Implications, and Recommendations for Future Research

The contribution, theoretical, and clinical implications of this research programme will now be considered, and suggestions for future research presented. The studies in this research programme will be considered sequentially. Firstly the implications of this research programme on the implementation of clinical guidelines will be explored. Secondly, the implications of this research for information provision and doctor-patient communication will be examined, and finally the implications of this research for the development and evaluation of written interventions will be discussed.

9.5.1 Implementation of Clinical Guidelines

This research programme at the outset intended to develop a health professional intervention. To the authors knowledge, this is the first study to explore health professionals' perceptions and experiences of implementing the NICE guidelines for heart failure. Substantive findings were that, health professionals felt unsupported, lacked time, and had other more urgent clinical matters and competing demands that prevented the implementation of the guidelines. There was also variation in the applicability of the guidelines to clinical practice by different health professional groups. Health professionals in the healthcare setting for this study perceived clinical guidelines as tools for more senior clinicians. Nurses and junior doctors did not perceive guidelines as suitable for their clinical practice or decision making. This has implications for organisations, such as NICE, that design and disseminate guidelines for good practice, as these findings suggest that they may be failing to reach all health professional groups.

To the authors knowledge, this is the first study which has investigated the implementation of clinical guidelines, using a qualitative methodology which was informed by a behaviour change model. The TPB framework enabled a more specific understanding of the attitudes, social influences, and barriers that could influence clinical behaviour. This methodology proved useful in organising qualitative findings into theoretical constructs and, therefore, identified factors that could be potential targets for change in interventions. This methodology could be adopted by other researchers prior to the development of an intervention to influence clinical behaviour and would enable theory to be adopted at an early stage of intervention development.

9.5.2 Doctor- Patient Communication in Heart Failure

This thesis has contributed to the research on doctor-patient communication in heart failure, which is an under-researched area. Prior to the commencement of this thesis, there was some literature on heart failure patients' perceptions of information provision and communication from health professional's about their illness (e.g. Buetow & Coster, 2001; Rogers et al., 2000). However, no previous research that examined health professional's experiences and perceptions of communicating information to heart failure patients was identified. During this thesis, Barnes and colleagues (2006) published research which investigated primary healthcare professionals' experiences of communicating with heart failure patients. This thesis produced similar findings to the study by Barnes and colleagues (2006), and found that secondary care professionals also experienced difficulty in using the term 'heart failure', and communicating diagnosis. The research in this thesis on health professionals' views of communicating the care plan to patients adds further to this research area.

To the authors knowledge, this is the first study which utilised a theoretical model of behaviour change to investigate health professionals' communication behaviour. The theory of planned behaviour appeared useful for identifying and organising the themes that health professionals had identified as important, when communicating to heart failure patients. A substantive finding was that health professionals held a range of beliefs about patients which influenced the content and amount of information delivered to patients. These beliefs concerned health professionals perceptions about whether patients wanted, or could cope with, information. Health professionals also had beliefs about information being unhelpful to patients, and its potential to cause more patient distress. According to the TPB these beliefs are amenable and could be targeted in interventions to promote the communication of information by health professionals to patients. Future research could investigate whether interventions, that target the beliefs which hinder professionals from providing information to patients, influence their communication behaviour. Future research could also establish whether other theoretical models could be used to understand doctor-patient communication in heart failure consultations.

This was the first study to investigate doctor-patient communication in the field of heart failure, specifically relating to the delivery of information about the management plan to patients. This thesis found that health professionals perceived information giving as a tool to facilitate self-management among heart failure patients. Other substantive findings to emerge from this study indicate that health professionals did not perceive themselves to be equipped with the necessary skills to communicate effectively about important aspects of heart failure, and to deal with the potential reactions of patients to information about diagnosis and prognosis.

Another substantive finding was that health professionals were hesitant to provide patients with information about heart failure, because they were unsure what information patients wanted. This prevented an open dialogue between professionals and patients about heart failure and its management. These findings indicate that developments in doctor-patient communication models in heart failure are needed. Future research, therefore, should intend to gain a more in-depth understanding of doctor-patient communication in heart failure, and should aim to develop models of communication which can inform the development of interventions, to improve the provision of information to patients within the healthcare context. In particular, interventions to improve the communication skills of health professionals are required, and health professionals need guidance in communicating prognostic estimates to patients.

Future research should intend to develop simple and easy to use strategies within the consultation to enable health professionals to identify patients' knowledge deficits and information needs. Future research could also develop and investigate the use of aids in the consultation which would enable practitioners and patients to openly discuss the areas of heart failure that patients want information about. Such approaches could facilitate the provision of timely and relevant information which could assist patients to manage their own illness.

9.5.3 Development and Evaluation of Written Patient Information Materials

To the author's knowledge, this is the first study to develop and evaluate a theory-based booklet to promote heart failure self-management. This study made a significant contribution to the under-researched area of theory-based written interventions. The findings of this research programme indicate that written information alone has the potential to produce significant improvements in patient knowledge. This research programme also provided some preliminary findings which indicate that a theory-based booklet, which targeted the beliefs underlying behaviour, was able to produce greater improvements in the cognitive predictors of intention and behaviour, compared to an atheoretical booklet and control group. This suggests, as in previous research (see Chatzisarantis & Haggis, 2005; Kelly & Abraham, 2004; Quine & Rutter, 2001), that the adoption of theoretical approaches to the development of written information improves the ability of such materials to influence the theoretical predictors of behaviour. These findings further suggest that perhaps theory-based interventions are more effective, either as stand alone interventions, or in combination with other approaches to facilitate behaviour change. These findings have implications for practitioners, researchers, and organisations such as NICE, that are involved in the development of patient education materials or lay guidelines, which provide information to patients. To improve the ability of written materials to facilitate or change behaviour, developers of written interventions should incorporate a theory-base to their interventions. Previous evaluations of health promotion leaflets have concluded that the majority of patient education materials do not incorporate information targeting the modifiable predictors of behaviour identified by psychological research (Abraham et al, 2002, 2007). This research programme helps to bring these issues to the attention of practitioners, researchers, and organisations that are involved in patient education. Thus, it is proposed that the findings of this research programme, and those of previous research, could be used to refine recommendations designed to inform the development of health information materials. Perhaps such recommendations should advocate the use of a theoretical framework to guide the development of patient education materials.

The elicitation of salient beliefs underpinning behaviour comprises the first stage of developing any TPB intervention. To the authors knowledge, this is the first study which identified the salient beliefs which underpin self-management behaviour in heart failure. This stage within this research programme not only identified patients' behavioural and control beliefs, but also assisted in identifying the informational deficits among heart failure patients about their self-management. Future research should investigate the use of theoretically informed questions, in consultations, which may assist health professionals to identify misconceptions, attitudes, barriers, and facilitators to heart failure self-management. This information could then be used by the practitioner to address information needs, address barriers to self-management, and highlight facilitators for change. Therefore, the adoption of this stage alone could prove useful in patient education interventions could prove useful.

This research programme also enlisted a theory-based evaluation to test the effectiveness of the booklets. Evaluations of interventions which only assess end-points, such as knowledge, behaviour, and mortality, provide very little understanding of the mechanisms which contribute to the effectiveness (or lack of ineffectiveness) of interventions to promote behaviour change. Indeed, negative trials evaluating these outcomes would produce no information with which to improve the intervention or inform subsequent research (ICEBERG, 2006). Therefore, future research should adopt appropriate theoretical models to inform evaluations used to assess the effectiveness of interventions. Researchers, wishing to promote heart failure self-management, should continue to explore and evaluate the utility of social cognitive theories in the development of patient education materials, and conduct theory-based evaluations to assess their effectiveness.

Although a full evaluation of informed choice was not possible in this research programme, findings from this study nonetheless suggest that informed choice/decision models could prove useful as frameworks for the evaluation of patient information materials. This thesis was the first to investigate whether self-management decisions made by heart failure patients were informed. This thesis found that 20% of patients had made an informed choice, based on adequate knowledge and in accordance with their attitudes, not to perform daily weighing as part of their self-management regimen. This raises interesting questions about the appropriateness of behaviour/adherence as an indication of booklet effectiveness. Patients who have made an informed choice not to perform self-management would be distinctly different from patients who did not perform these behaviours due to lack of knowledge or barriers. Furthermore, this group of patients would have been identified as non-adherent in evaluations solely incorporating a behavioural outcome. The utilisation of informed choice as an evaluative outcome for written information has recently gained considerable attention in the literature (see Raynor et al, 2007; Nicolson et al, 2006). Raynor and colleagues (2007) reported that patients regarded an informed decision not to take medications as an acceptable outcome from the provision of information. These findings, along with the findings of this research programme, suggest that trials for evaluating patient education materials should perhaps also draw upon models of informed choice for their evaluations.

The complete application of the informed choice model was not possible in this research programme, because no knowledge scale existed which was able to provide separate knowledge scores for each of the self-management behaviours. Future research should seek to develop validated and reliable instruments to measure heart failure knowledge, and ideally develop measures which can also provide an indication of patients' knowledge for different management behaviours. The availability of such instruments would enable researchers to evaluate informed choice as an outcome measure, to assess the effectiveness of interventions. In addition, future research should seek to gain a greater insight into heart failure patients' comprehension and application of knowledge. This would help to determine whether heart failure patients understand the significance of changes in their symptoms, and whether they apply their understanding about heart failure self-management during healthcare incidents.

The exploratory RCT produced findings which were consistent with the TPB. The theory-based booklet intervention was found to exert a greater influence on the cognitive predictors of intention and behaviour, rather than on behaviour itself. This is consistent with the TPB, as influencing the more distal predictors of behaviour (attitude, subjective norm and PBC), by targeting salient beliefs, would have a weaker effect on behaviour. Future research should aim to determine the modifiable psychological factors which are more readily influenced by the provision of written information. The findings of this research programme support a number of studies which have produced mixed results, or found written information to be ineffective in producing behaviour change (see Coulter

& Ellis, 2007; Raynor et al, 2007). These findings may suggest that written interventions are likely to have a stronger influence on the motivational phase of behaviour, as opposed to the volitional phase. Strategies to influence the post-intentional phase were incorporated in the IHF booklet, and although these were not directly evaluated, the finding that the IHF did not influence behaviour suggests that perhaps these strategies were insufficient to promote self-management behaviour. Other studies have found that strategies such as implementation intentions within TPB-based written interventions have been ineffective at producing effects over and beyond those of comparison leaflets (Hill et al., 2007; Murgraff et al., 2007). These findings combined, alongside the previous literature which indicates that heart failure patients experience considerable difficulty in performing self-management (van der Wal, Jaarsma & van Veldhuisen., 2005), suggest that perhaps personal support is required alongside written interventions, to assist in the initiation, planning, and maintenance of self-management in heart failure patients.

This research programme achieved a preliminary evaluation of a theory-based booklet to promote heart failure self-management. This trial provides a strong justification for the evaluation of the IHF booklet in a larger trial, to test more definitively it's effects on patient outcomes. Future research, therefore, should seek to replicate and explore these findings in more detail than has been possible in this research programme. Future evaluations could also consider the evaluation of this booklet alongside more personal support (e.g. face-to-face education, telephone support). Subsequent trials should seek to incorporate a longer follow-up period, in order, to establish whether the short-term effectiveness of the intervention, observed in this research programme, is maintained over a longer duration.

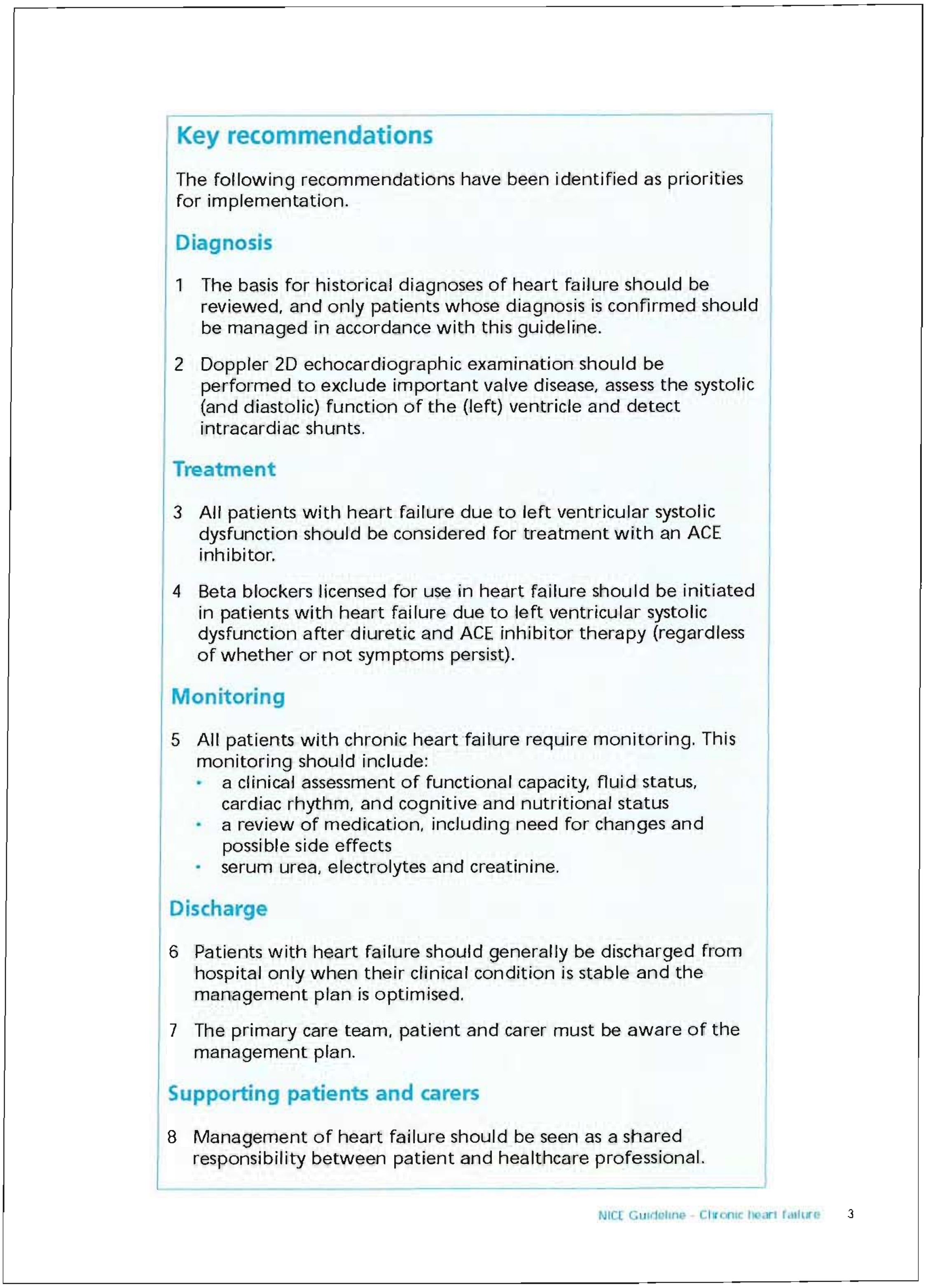
9.6 Concluding Comments

This thesis set out to investigate whether a theory-based intervention was more effective in improving patient outcomes than an atheoretical intervention. To the author's knowledge, this research programme was the first to develop and evaluate a theory-based written booklet intervention, intended to promote self-management in heart failure patients. This research programme showed that a theory-based booklet was more effective in improving patients' knowledge, and initiating change in the cognitive predictors of intention and behaviour, as identified by the Theory of Planned Behaviour. The availability of self-management resources that are rigorously developed and evaluated, have the potential to be a valuable resource that can be used by the growing population of heart failure patients.

Appendices

Appendix A: Key recommendations proposed by NICE for the management of heart failure

NICE (2003a)



Key recommendations

The following recommendations have been identified as priorities for implementation.

Diagnosis

1 The basis for historical diagnoses of heart failure should be reviewed, and only patients whose diagnosis is confirmed should be managed in accordance with this guideline.

2 Doppler 2D echocardiographic examination should be performed to exclude important valve disease, assess the systolic (and diastolic) function of the (left) ventricle and detect intracardiac shunts.

Treatment

3 All patients with heart failure due to left ventricular systolic dysfunction should be considered for treatment with an ACE inhibitor.

4 Beta blockers licensed for use in heart failure should be initiated in patients with heart failure due to left ventricular systolic dysfunction after diuretic and ACE inhibitor therapy (regardless of whether or not symptoms persist).

Monitoring

5 All patients with chronic heart failure require monitoring. This monitoring should include:
- a clinical assessment of functional capacity, fluid status, cardiac rhythm, and cognitive and nutritional status
- a review of medication, including need for changes and possible side effects
- serum urea, electrolytes and creatinine.

Discharge

6 Patients with heart failure should generally be discharged from hospital only when their clinical condition is stable and the management plan is optimised.

7 The primary care team, patient and carer must be aware of the management plan.

Supporting patients and carers

8 Management of heart failure should be seen as a shared responsibility between patient and healthcare professional.

NICE Guideline - Chronic heart failure 3

Appendix B: Audit criterion and recommended implementation of the shared responsibility guideline for heart failure management

(NICE 2003a)

Key recommendations	Denominator	Other relevant recommendations	Exceptions	Definition of terms
1.4.2.1: Patients with heart failure should generally be discharged from hospital only when their clinical condition is stable and the management plan is optimised. 1.4.2.2: The primary care team, patient and carer must be aware of the management plan	6. Discharge planning a. % of patients with heart failure who have a pre-discharge management plan in place b. % of patients discharged from hospital with a (primary or secondary) diagnosis of heart failure for whom a management plan has been rapidly communicated to the primary care team	–	Patient choice	'Rapidly' will need to be defined locally for audit purposes
1.5.1.6: Management of heart failure should be seen as a shared responsibility between patient and healthcare professional	7. Patient understanding All patients with heart failure receive a copy of the version of this guideline written for patients, their carers and the public	–	–	–

Appendix C: Interview Schedule used for study in chapter 6

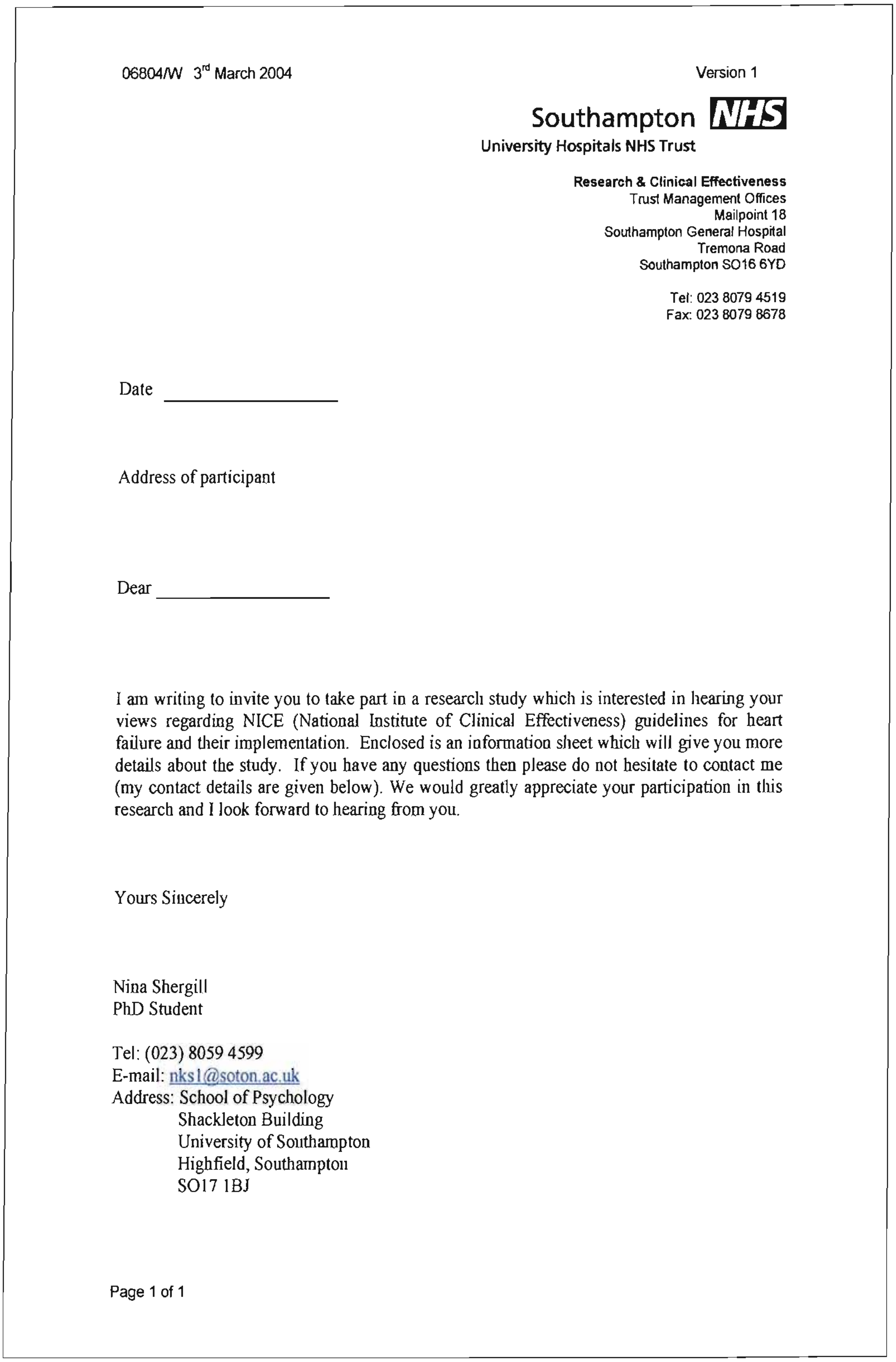
Section A.

1) Have you heard about the NICE guidelines for heart failure?
2) Have you had a chance to read them?
3) IF NO - There is a key recommendations page that could be given to them. And we can ask them the additional questions such as
    (a) Do you intend to read them?
4) What are your views of the guidelines?
5) What recommendations do you think are most important?
6) In what ways (if any) do they differ from your own practice?
7) What do you think other people think of the guidelines? (Can give clarification that 'other people'= anyone they think is important and who these people may be).
8) Do you see any problems in using these guidelines?
9) What might hinder their use- either by yourself or by your colleagues?
10) Is there anything that could help?
11) Are there any changes in the way the hospital/clinic/surgery is organised that could help?
12) Do you get any help in using the guidelines?
13) Do you have any plans to make any changes as a result of these guidelines?
14) Have any other guidelines influenced your management of heart failure?
    a) If so, which and why?
    b) What was it about them or their implementation that made them more helpful?
15) Would you like to make any further comments
    a) ...about these guidelines?
    b) ...about the role of this kind of guideline in clinical practice?
    c) ...about the demands and constraints that affect the implementation of such guidelines?

Section B: Communicating care plans guidelines.

16) What are your views of these guidelines?
17) What do you think other people think of these guidelines?
18) Do you see any problems in using these guidelines?

Appendix D: Invitation letter and information sheet used for study in chapter 6



06804/W 3rd March 2004 Version 1

Southampton NHS
University Hospitals NHS Trust

Research & Clinical Effectiveness
Trust Management Offices
Mailpoint 18
Southampton General Hospital
Tremona Road
Southampton SO16 6YD

Tel: 023 8079 4519
Fax: 023 8079 8678

Date ________________

Address of participant

Dear ________________

I am writing to invite you to take part in a research study which is interested in hearing your views regarding NICE (National Institute of Clinical Effectiveness) guidelines for heart failure and their implementation. Enclosed is an information sheet which will give you more details about the study. If you have any questions then please do not hesitate to contact me (my contact details are given below). We would greatly appreciate your participation in this research and I look forward to hearing from you.

Yours Sincerely

Nina Shergill
PhD Student

Tel: (023) 8059 4599
E-mail: nks1@soton.ac.uk
Address: School of Psychology
Shackleton Building
University of Southampton
Highfield, Southampton
SO17 1BJ

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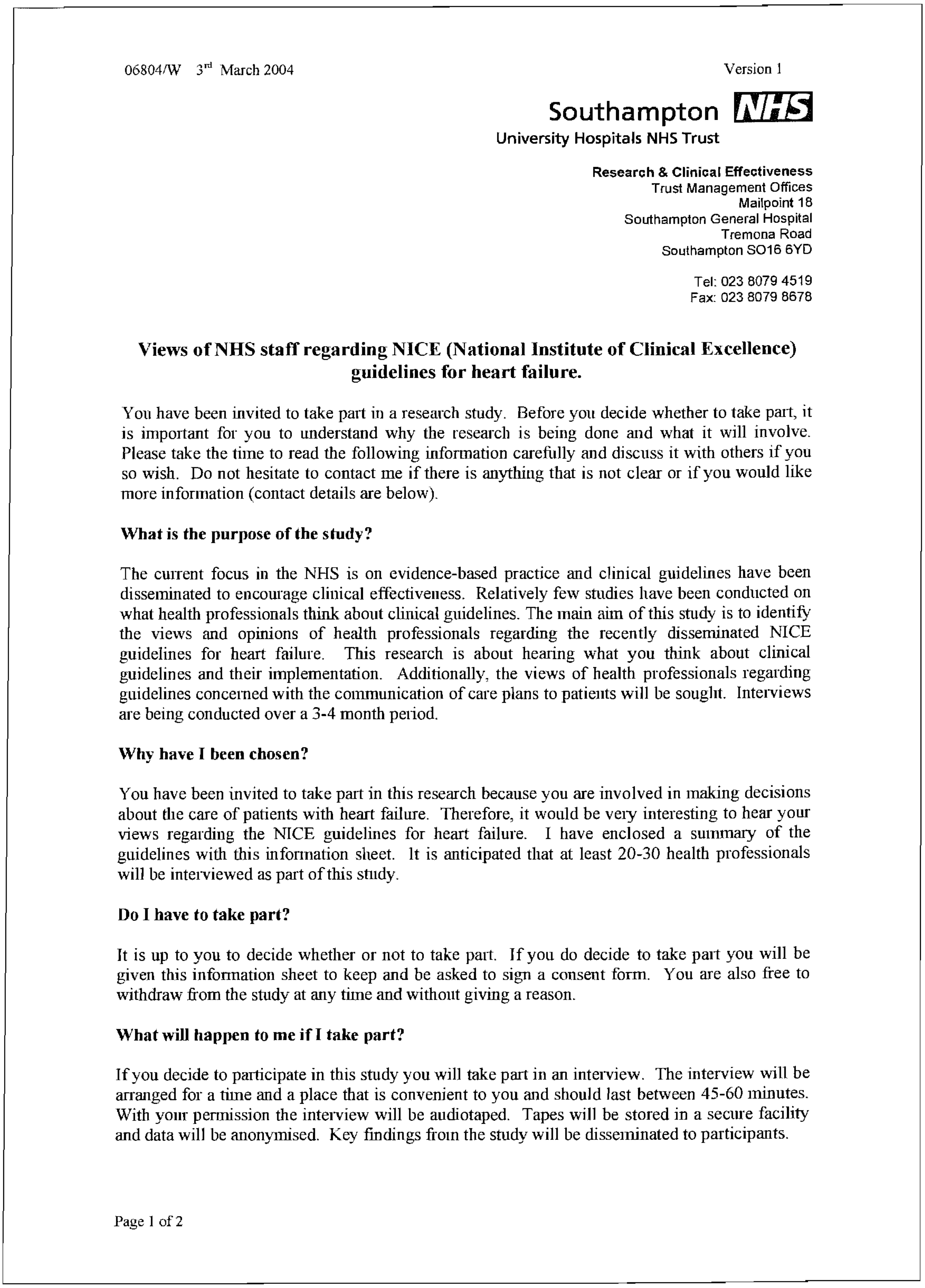
Appendix D



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Tremona Road
Southampton SO16 6YD

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Fax: 023 8079 8678

Views of NHS staff regarding NICE (National Institute of Clinical Excellence) guidelines for heart failure.

You have been invited to take part in a research study. Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you so wish. Do not hesitate to contact me if there is anything that is not clear or if you would like more information (contact details are below).

What is the purpose of the study?

The current focus in the NHS is on evidence-based practice and clinical guidelines have been disseminated to encourage clinical effectiveness. Relatively few studies have been conducted on what health professionals think about clinical guidelines. The main aim of this study is to identify the views and opinions of health professionals regarding the recently disseminated NICE guidelines for heart failure. This research is about hearing what you think about clinical guidelines and their implementation. Additionally, the views of health professionals regarding guidelines concerned with the communication of care plans to patients will be sought. Interviews are being conducted over a 3-4 month period.

Why have I been chosen?

You have been invited to take part in this research because you are involved in making decisions about the care of patients with heart failure. Therefore, it would be very interesting to hear your views regarding the NICE guidelines for heart failure. I have enclosed a summary of the guidelines with this information sheet. It is anticipated that at least 20-30 health professionals will be interviewed as part of this study.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. You are also free to withdraw from the study at any time and without giving a reason.

What will happen to me if I take part?

If you decide to participate in this study you will take part in an interview. The interview will be arranged for a time and a place that is convenient to you and should last between 45-60 minutes. With your permission the interview will be audiotaped. Tapes will be stored in a secure facility and data will be anonymised. Key findings from the study will be disseminated to participants.

Appendix D

06804/W 3rd March 2004 Version 1

What are the possible benefits of taking part?

This research will provide a forum within which NHS staff can express their views and discuss their experiences regarding clinical guidelines.

Will my taking part in this study be kept confidential?

All information, which is collected, about you during the course of the research will be kept strictly confidential. Personal information will not be released or viewed by anyone other than my supervisors or myself. Only investigators in the study will have access to the raw data. Any information about you that leaves this hospital or surgery will have your name and address removed so that you cannot be recognised from it.

What will happen to the results of the research study?

The findings from this study will be published in a journal and be part of a report for the Clinical Effectiveness Department at Southampton University Hospitals NHS Trust. It is hoped that this study will provide an insight into the role NICE guidelines play in encouraging clinical effectiveness within the health care setting. Results of this study will not include your name or any other identifying characteristics and you will not be identified in any of the reports/publications. Furthermore if any of the quotes from your interview are selected for use in reports/publications, you will be notified and your permission for their use will be sought. Copies of subsequent reports or publications can be obtained by contacting Nina Shergill, whose details are below.

Who is organising and funding the research?

The research is part of a PhD that is partly funded by the ESRC (Economic and Social Research Council) and partly funded by the clinical effectiveness department at Southampton Hospital University NHS Trust.

Who has reviewed the study?

The study has been reviewed by the ESRC (Economic and Social Research Council).

Contact for further information?

If you would like to take part in the research or if you have any questions or require any further information then please do not hesitate to contact me. If you are willing to participate in this study would you kindly contact me on the number, e-mail address or address below. I will then contact you in the near future to arrange a mutually convenient time and venue for the interview.

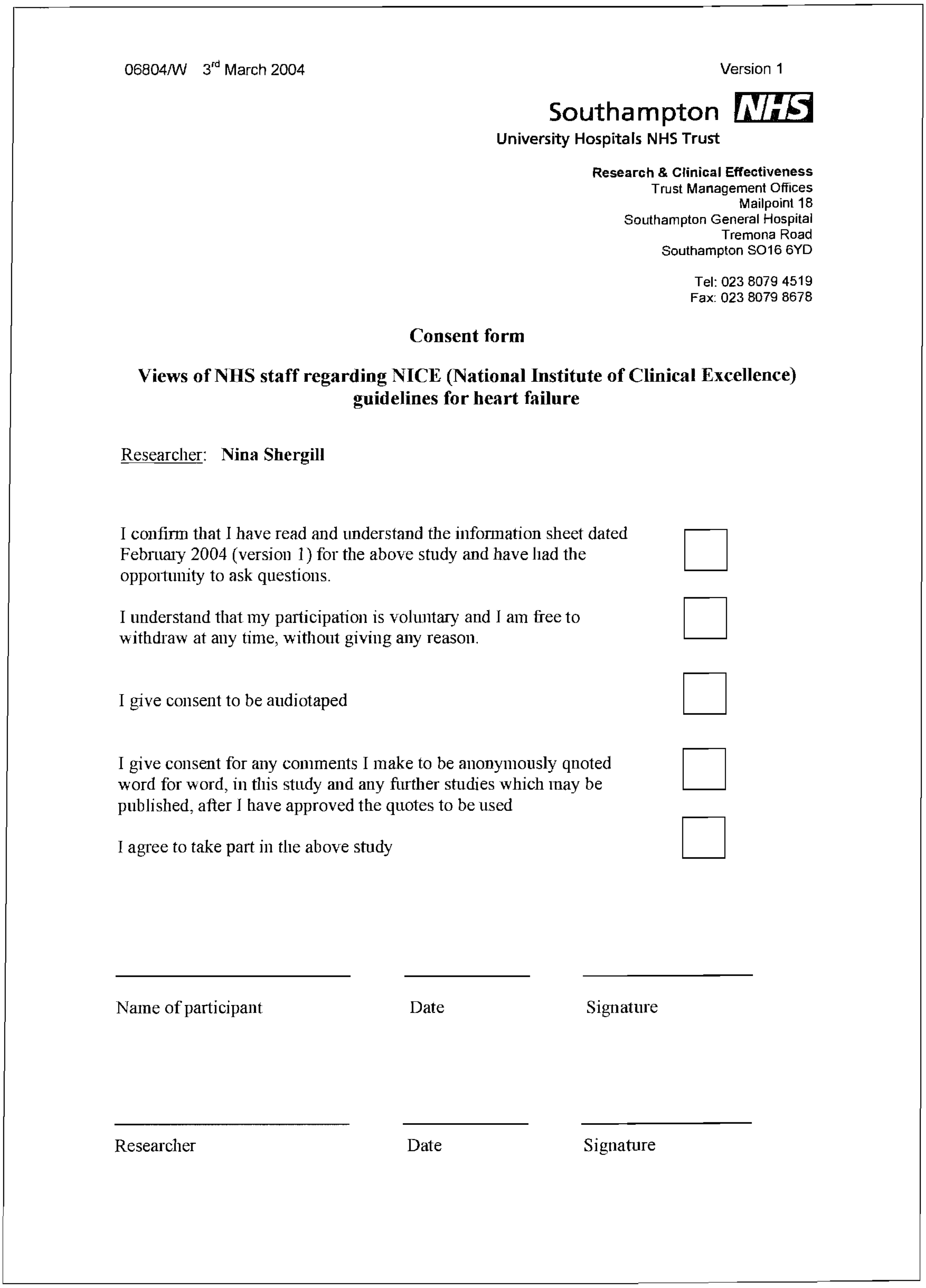
Nina Shergill

Tel: (023) 8059 4599
E-mail: nks1@soton.ac.uk
Address: School of Psychology
Shackleton Building
University of Southampton
Highfield, Southampton
SO17 1BJ

Thank you for taking time to read this information sheet

Page 2 of 2

Appendix E: Consent form used for study in chapter 6



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Research & Clinical Effectiveness
Trust Management Offices
Mailpoint 18
Southampton General Hospital
Tremona Road
Southampton SO16 6YD

Tel: 023 8079 4519
Fax: 023 8079 8678

Consent form

Views of NHS staff regarding NICE (National Institute of Clinical Excellence) guidelines for heart failure

Researcher: **Nina Shergill**

I confirm that I have read and understand the information sheet dated February 2004 (version 1) for the above study and have had the opportunity to ask questions. ☐

I understand that my participation is voluntary and I am free to withdraw at any time, without giving any reason. ☐

I give consent to be audiotaped ☐

I give consent for any comments I make to be anonymously quoted word for word, in this study and any further studies which may be published, after I have approved the quotes to be used ☐

I agree to take part in the above study ☐

____________________	__________	______________
Name of participant	Date	Signature
____________________	__________	______________
Researcher	Date	Signature

Appendix F

Appendix F: Summary of the thematic codes for health professionals' views of the NICE guidelines for heart failure

Views of NICE and its guidelines	**Views of the NICE guidelines for heart failure**	**Barriers to seeking and reading guidelines**	**Barriers and factors that promote the implementation of guidelines**	**Outcomes from guidelines**	**Other influences on clinical practice**
Nice is important and influential in clinical practice Motives and external influences on NICE Authors in 'ivory towers' Just guidance Threat to clinical freedom Insufficient to change practice	Sensible Nothing new Not detailed enough Limited application Very evidence-based Questionable evidence base Heart failure not a priority	Awareness Accessibility Relevance to clinical work Guideline fatigue Length of guidelines	Barriers *Service-related:* Fragmented service Lack of resources Lack of time and other clinical demands *Health professional:* Uncertainty *Patient-related:* Patient requests Patient characteristics Adverse patient consequences Promoters: Support Heart failure clinics and nurses	Improved patient outcomes and care Promotes changes within the service audit	Clinical experience Colleagues and local experts Local guidelines and contracts

Appendix G

Appendix G: Coding manual for the NICE guidelines for heart failure analysis

1) Views of NICE and its guidelines

Code name	Description	Example of quotes
NICE is important and influential	Suggestions that NICE were an influential and important body within the NHS for promoting evidence base practice. The guidance provided support to health professionals in managing illness.	*'Think we have pretty much developed our practice around the guidelines' (Consultant, 1.85.1)* *'Because this is the gold standard, this is approved good practice' (Consultant, 2.18.11)*
Motives and external influences on NICE	Suggestions that NICE had their own motives to produce guidelines and external forces were at work that influenced NICE and its guidance.	*'Your always weighing up in your own mind, well you know, just what is the driver here, particularly when the evidence is a bit iffy' (Consultant, 7.38.9-10)*
Authors in 'ivory towers'	Authors of NICE were professionals who were removed from the clinical environment and the guidelines produced were mainly relevant to the ideal world.	*'People in ivory towers who don't have clinical practice, [they] impart information[when] they're not really part of the clinical scene' (GP, 9.68.1-3)*
Just guidance	Guidelines are just guidance	*'No I think guidelines are guidelines they are not a rigid 'you must' (Consultant, 13.21.1)*
Threat to clinical freedom	Guidelines reduced the autonomy of health professionals	*'Specialists don't like to be told what to do' (Junior doctors, 16.42.9-10)*
Insufficient to change practice	Guidelines alone are insufficient to change practice	*'The paper guidelines alone are not enough' (GP, 20.40.12)* *'That guidelines are a useful reference but if you're going to influence how you go and alter behaviour you have to do more' (GP, 20.90.1-2)*

Appendix G

2) Views of the NICE guidelines for heart failure management

Code name	Description	Example of quotes
Sensible	Health professionals perceived the guidelines as sensible and straightforward	*'So the heart failure ones as I say are very straight forward cause there is very little that I think is contentious in there' (Consultant, 2.16.1-2)*
Nothing new	The guidelines did not present anything new that would change current clinical practice.	*'They made common sense and none of it was sort of new to me or rocket science, it was just good common sense' (Consultant, 8.6.1-2)* *'I think a lot of what was in the guidelines I was already doing' (Consultant, 8.44.1-2)*
Not detailed enough	The guidelines lacked detail about certain aspects of managing heart failure.	*'There are a fair amount of people who actually die from their heart failure and there aren't any palliative issues' (Nurse, 19.36.2-4)*
Limited application	Guidelines limited in their applicability. They were more useful for younger patients and for those with only heart failure.	*'I find the guidelines apply much better to younger fitter patients' (Junior doctor, 67.1-2)* *'They are good for monopathologies and lots of my patients have got lots and lots of different things going on so its much harder to apply' (Junior doctor, 6.67.8-9)*
Very evidence-based	Guidelines were based on very strong research evidence	'NICE guidelines are very solidity researched and if your prepared to look at the evidence, its pretty hard hitting stuff, you know, with each evidence graded according to its sort of certainty and whether it was based on what sort of trial and stuff' (GP, 15.120.1-4)

2) Views of the NICE guidelines for heart failure management continued

Code name	Description	Example of quotes
Questionable evidence base	The guidelines lack an evidence base. Majority of previous research based on untypical heart failure patients and in settings with ample resources and manpower.	'I think one of the big problems with any guideline like this, is that actually when you look into it the evidence on which our guidelines is based is pretty thin in most cases' (Consultant, 1.34.5-34.6)
Heart failure not a priority	Heart failure was not considered a priority	*'We all sat round and we discussed each of the, chronic care disease categories in turn, didn't discuss heart failure because there were other ones that took precedence' (GP, 20.40.6-8)*

3) Barriers to seeking and reading guidelines

Code name	Description	Example of quotes
Awareness	A lack of awareness existed about the guidelines	*'But I hadn't specifically heard they'd introduced guidelines for heart failure.' (Junior doctor, 18.8.1)* *'I'm not sure if everybody else on the ward is aware of them to be quite honest' (Nurse, 11.15.1-2)*
Accessibility	Guidelines are not easy to access	*'I try to get on during the night shift but it wouldn't let me access them at all I couldn't find them' (Nurse, 11.43.1-3)*
Relevance to clinical work	Guidelines were more relevant for the work of certain health professionals.	*'If they go into great detail then obviously its more on a doctors side than it is for a nursing side' (Nurse, 11.41.1-2)*
Guideline fatigue	Boundless guidelines existed for different illnesses and from a variety of sources	*'The other problem is that there is a wealth of guidelines not only from NICE, but from all sorts of hospitals, local hospitals, local PCTs, clinical governance leads, researchers...they are all churning out guidelines and I think there can[be] a bit of a feeling sometimes of guideline over kill' (GP, 15.79.4-9)*
Length of guidelines	Guidelines too lengthy to read	*'It's a big booklet not terribly friendly if you wanted to look back, not terribly friendly to do that' (GP, 9.140.1-2)* *'Also when you try and read then you have to read through pages and pages and pages of text that no-one is going to do' (Consultant, 1.99.1-2)*

4) Barriers and factors the promote the implementation of guidelines

a) Barriers

i) Service related

Code name	Description	Example of quotes
Fragmented service	The delivery of continuity of care was difficult. Management of heart failure spanned both primary and secondary care and involved a number of different healthcare services and health professionals.	*'What will happen, heart failure is being managed by all sorts of people in primary care, secondary care, its all a bit of a mess cause there's a lot of it about, so everybody does a bit' (Consultant, 7.24.4-6)* *'Its just the system is not good enough to actually do what the guidelines recommend' (Consultant, 7.30.6-7)*
Lack of resources	Resources inadequate to implement guidelines	*'We do not have the capacity to refer everybody for Echocardiogram so therefore, not everybody has had an*

		Echocardiogram. Now there is an understanding that it (patients) will be referred but there's a lot of wait' (GP, 20.30.2-4) *'I mean the only help that would be useful is if there are sufficient resources there to implement the guidelines in full or to even improve our current limitation' (Consultant, 5.38.2-4)*
Lack of time and other clinical demands	Inadequate time to plan the implementation of guidelines and other clinical demands took precedence.	*'I think it would be something that I would do if I get a chance but sometimes with some of the demands of my role its just actually having the time to properly update yourself a bit more' (Nurse, 12.6.1-3)*

ii) Health professional

Code name	**Description**	**Example of quotes**
Uncertainty	Uncertainty about a recommendation leads to its variable uptake. Uncertainty could arise from clashes between clinical guideline recommendations, previous experience and current opinion	*'So I suppose in a way that sort of goes slightly against my experience' (GP, 15.19.8-9)* *'Only last week the other doctors in the practice were telling me how Beta Blockers were now out of favour' (GP, 20.32.12-13)*

iii) Patient related

Code name	**Description**	**Example of quotes**
Patient requests	Addressing patient goals even if in conflict with clinical guidelines	*'If you say to someone I think you ought to go onto beta blockers, they'll say "oh not another tablet doctor', 'I'm already on three, I don't want four", is that a barrier to implementing the guidelines? It is.' (GP, 15.48.2-5)*
Patient characteristics	Patient characteristics, such as the frailty, could influence whether some guidelines were implemented	*'I've got some old person whose dragged all the way up to the Royal South Hants, if I fill in the form, they'll get another appointment. They have to drag all the way back for an echo and I know they've got heart failure, its not worth putting them through all this, so some of it just practical difficulties' (Consultant, 7.30.2-6)*
Adverse patient consequences	Anticipation of adverse patient reactions could hinder implementation of guidelines	*'Cause you've got someone whose very frail or be it they've got heart failure their probably going to get worse if I pour beta blockers and ACE inhibitors and whatever else into them' (Junior doctors, 6.88.3-5)*

Appendix G

b) Promoters

Code name	Description	Example of quotes
Support	Support from colleagues, audit departments and management needed to successfully implement guidelines	*'We could do with having more support from the management side in order to support us to get the newest guidelines and get it developed into a simple audit form'(Consultant, 4.66.1-2)* *'Its just making sure that we've got enough support from everyone involved including the juniors, management team and the audit departments themselves because we cannot, one person cannot take it aboard' (Consultant, 4.74.3-6)*
Heart failure clinics and nurses	The development of specialist heart failure clinics and nurses would improve the implementation of guidelines	*'We're all doing I think as best as we can within the system but I think there is scope for an heart failure clinic to be set up and run properly'(Consultant, 4.116.6-7)* *'Community heart failure nurse would really [be helpful], for older people it would be so useful for somebody to go and visit that patient at home'(Consultant, 8.64.9-11)*

5) Outcomes from guidelines

Code name	Description	Example of quotes
Improved patient outcomes and care	The implementation of guidelines would improve the patient outcomes and the care experienced by heart failure patients	*'Hopefully improve mortality and morbidity from heart failure I mean that can be the only sort of reason for setting up guidelines' (Consultant, 4.20.1-2)* *'Its there to improve the quality of patient care, to make sure that we practice things which have a proper evidence base' (Consultant, 2.24.1-3)*
Promotes changes within the service	Guidelines could be used to as levers for change and present an argument for greater resources and manpower to enable their implementation.	*'I would think that because of guidelines, people do try to allocate their resources differently in order to comply or to try to implement the guidelines so it has influenced the practices to a certain extent' (Junior doctor, 14.52.1-3)*
Audit	Guidelines assisted audit and allowed health care professionals/services to measure their performance against a standard	*'It helps you to audit whether what your actually doing is effective' (Consultant, 2.8.12-13)* *'Would like to audit my practice, how I am using them, audit before the guidelines and then afterwards, and see how better patients are treated'(Consultant, 3.70.1-2)*

6) Other influences on clinical practice

Code name	Description	Example of quotes
Clinical experience	Health professionals past experience influenced their current clinical practice	*'Most of my practice is based on my own experience and my own clinical knowledge of the disease itself' (Junior doctor, 14.40.1-2)* *'And we've all had bad experiences with individual drugs, you know, which would perhaps influence what we do' (Consultant, 1.81.7-8)* *'I think it may have been experience that has taught them (nurses) rather than looking at a piece of paper, rather than looking at the evidence behind it' (Nurse, 19.12.5-7)*
Colleagues and local experts	The discussions and information provided by colleagues could influence clinical practice.	*'Consultant comes in and talks about a particular condition and says you should do this but that is not quite effective as your colleagues saying, this is what I do' (GP, 20.40.14-16)* *'My algorithms in my brain have come from working with a series of consultants and their personal views as much as anything I've read' (Junior doctor, 6.71.1-3)*
Local guidelines and contracts	Guidelines produced locally also influenced clinical practice. These guidelines were perceived as more locally owned and took into consideration local resources and services.	*'Guidelines should be locally produced and tailored to the needs of the local patients based on the resources available in a specific trust otherwise it may not mean anything' (Junior doctor, 14.50.1-5)*

Appendix H

Appendix H: Summary of the thematic codes for health professionals' views of the communication of the management plan guideline

View of the guideline communicating the care plan	Barriers to implementing the guideline	Patient influences on communication and information giving	Outcomes from communication	Other influences on patient's management of illness	Written information
Unnecessary	*External service barriers:*	*Factors the hinder communication:*	*Undesirable patient outcomes:*	Patient self-management	*Present situation*
Unrealistic					Written care plans not always available
	Time constraints	Psychological state and distress	Lack of understanding	Carer support	
Increase demands					
Important	Lack of health professionals	Health status of patients	Difficulty retaining information		GP letters and discharge letters
	Other clinical demands	Faith and trust in doctor	Patient becomes disempowered		Hand written
	Fragmented service	Patient does not want to know			Not available
			Lack of compliance		
	Health professional information-giving barriers:				*Perceptions of written information*
		Factors that promote communication:	*Desirable patient outcomes:*		
					Causes distress and promotes confusion
	Difficult concepts	Patient seeks information	Patient has understanding of their illness and its condition		
	Large volume of information				Good way to provide, share and aid the retention of information
	Using the term 'heart failure'				
	Giving prognosis				
	Partial responsibility				

Appendix I

Appendix I: Coding manual for the communication of the management plan guideline analysis

1) View of the guideline 'communicating the care plan'

Code name	Description	Example of quotes
Unnecessary	The guideline was not required, and the inclusion of this guideline was patronising	*'I think as long as people are taught good communication skills then there should be no need for a formal guideline for it' (Consultant, 1.16.2-4).* *'In some ways I find it slightly patronising to have guidelines like that' (Junior doctor, 6.100.1)*
Unrealistic	Guidelines devised with the perfect patient and health service in mind	*'So the reality of communicating is often a lot more difficult than the theory' (Consultant, 1.20.5-6)* *'I often think something that things like guidelines can e drawn up with the idea of the perfect patient in mind' (Consultant, 2.250.5-6)*
Increase demands	Guideline about communication would increase the demands on health professionals	*'I don't think they can underestimate the importance of good communication but it shouldn't be at the expense of other good clinical practice' (Consultant, 1.26.1-2)*
Important	The guideline is required as communication is an important aspect of health care	*'At the end of the day you know, if we need a guideline to ensure that it happens, then it's a good thing' (Consultant, 1.16.4-5)*

2) Barriers to implementation the guideline

a) External service barriers

Code name	Description	Example of quotes
Time constraints	Inadequate time to provide information to patients	*'I haven't got time to go through a full explanation of heart failure, the management, complications and prognosis' (Consultant, 8.136.3-4)*
Lack of health professionals	The manpower in the NHS was insufficient manpower provide adequate information to patients. Furthermore, no specific professional group or service was responsible for the provision of information to heart failure patients.	*'More doctors then we would be able to spend more time with each one (patient)' (Consultant, 1.32.6-7)* *'In the current situation without having extra people around to help that is very difficult' (Consultant, 5.83.5-6)*
Other clinical demands	Other clinical demands impinged upon health professionals' behaviour and this reduced the time available for communicating with patients.	*'Unfortunately what tends to happen is that when you get busy you try and shorten that time and I suspect that the thing that might suffer in some cases is the communication*

		to the patient' (Consultant, 1.32.3-6)
Fragmented service	The service spanned both primary and secondary care and involved a variety of health professionals, this hindered the delivery of information to patients	*'There's no continuity so no-one accepts responsibility if you like for that continuity' (Consultant, 7.96.28-29)* *'The average person is admitted, they spin round admission, [go to] five different other wards, they get moved and [meet] different doctors' (Consultant, 7.96.26-28)*

b) Health professional information giving barriers

Code name	**Description**	**Example of quotes**
Difficult concepts	Difficulty experienced in communicating difficult concepts in layman terms	*'Some of them can be quite difficult concepts' (Junior doctor, 6.108.4)*
Large volume of information	The information about heart failure management was vast	*'There's a lot of information thrown at them all at once' (Junior doctor, 6.108.4-5)*
Using the term 'heart failure'	Apprehensive about using the term heart failure because of the distress and confusion it may evoke in patients	*'Sort of even saying to somebody "well you've got a failing heart", the questions is should we be using terms like that?' (Consultant, 2.62.9)*
Giving prognosis	Apprehensive about discussing prognosis because of the difficulty in its estimation and the potential patient distress it could provoke	*'That's a key thing prognosis, that's another thing, we're very bad at telling patients' (Consultant, 8.136.5)* *'There's a lot of junior doctors and a few senior doctors who don't realise you know the prognosis is as bad as some of the common cancers' (Consultant, 8.148.3-4)*
Partial responsibility	Health professionals perceived themselves to have only a 'partial' role in providing information and in promoting self-management. Patients were also responsible for heart failure management.	*'There's only so much [you can] do...I'm afraid we can't be responsible for everything' (Consultant, 4.1647.1-2)*

3) Patient influences on communication and information giving

a) Factors that hinder communication

Code name	**Description**	**Example of quotes**
Psychological state and distress	Patients' psychological status and distress could thwart any intention by health professionals to provide information. Furthermore, patients in denial would not accept any attempt to provide information	*'Its very difficult for people to sometimes understand this is as good as your going to get, and the treatments aren't going to get any better, its (medicine) just going to control it' (Junior doctor, 16.79.8-10)*
Health status of patient	The severity of the illness could influence health	*'In terms of communicating the care plan, obviously with*

	professionals' decision to provide information. .	*the elderly and people who are ill its quite hard, they get confused easily and they forget things' (GP, 9.173.1-3)*
Faith and trust in doctor	Patients do not want information because they prefer the doctor to take responsibility	*'And we say well look this is what you might like to do and they say 'well you tell me doc', most people don't want it (information) I have to say. (GP, 9.146.1-2)*
Patient does not want to know	Patients does not want information	*'They don't actually want to know anymore about it and they're not gonna listen if I explain things' (Consultant, 7.92.14-15)* *'I think some patients don't want too much information actually because they find it quite frightening' (Consultant, 4.126.2-3)*

b) Factors that promote communication

Code name	**Description**	**Example of quotes**
Patient seeks information	The patients who wants information	*'There are some patients that are very involved in their care and they tend to make the extra effort to do that as well', (Junior doctor, 17.53.7-8)* *'The vast majority of my older patients do actually want to know exactly why their on a certain drug and what it does' (Nurse, 10.74.6-8)*

4) Outcomes from communication

a) Undesirable patient outcomes

Code name	**Description**	**Example of quotes**
Lack of understanding	Health professionals perceived patients to lack understanding about their illness	*'I would imagine a lot of patients and relatives would say that they don't know enough about their condition and how its managed' (Nurse, 19.28.2-5)*
Difficulty retaining information	Health professionals perceived patients to encounter difficulty in retaining information	*'A lot of what we say isn't remembered anyway, only about 20%' (Consultant, 4.122.3-4)*
Patient becomes disempowered	Health professionals perceived disempowerment as a possible outcome from the provision of information to patients	*'The government at the moment is talking a lot about patient choice and particularly with the generation that I'm dealing with [older], it doesn't give them a choice, it just kind of causes bewilderment', (Consultant, 2.55.6-9)*
Lack of compliance	Health professionals perceived patients to lack adherence with their medication	*'Its much harder to ensure that they will take their tablets regularly so its basically an educational issue'*

		(Consultant, 5.69.13-14)

b) Desirable patient outcomes

Code name	Description	Example of quotes
Patient has awareness of their illness and its management	Health professionals perceived patients to have an awareness of their illness	'I get patients who've been on the net and they've had a look at what's current treatment for 'x' and 'y'' (Consultant, 7.92.10-11)

5) Other influences on patient's management of illness

Code name	Description	Example of quotes
Patient responsibility	The patient who takes responsibility for meeting information needs and managing their illness	*'I think it puts responsibility on both sides as well, the more responsible patient has a better idea about their care' (Junior doctor 17.53.8-9)*
Carer support	Health professionals perceived that carers had an influence on patients management of heart failure	*'A lot of patients with heart failure have a husband or wife or a concerned relative who could be involved and will actually help enhance and improve their care' (GP, 20.68.11-13)*

6) Written information

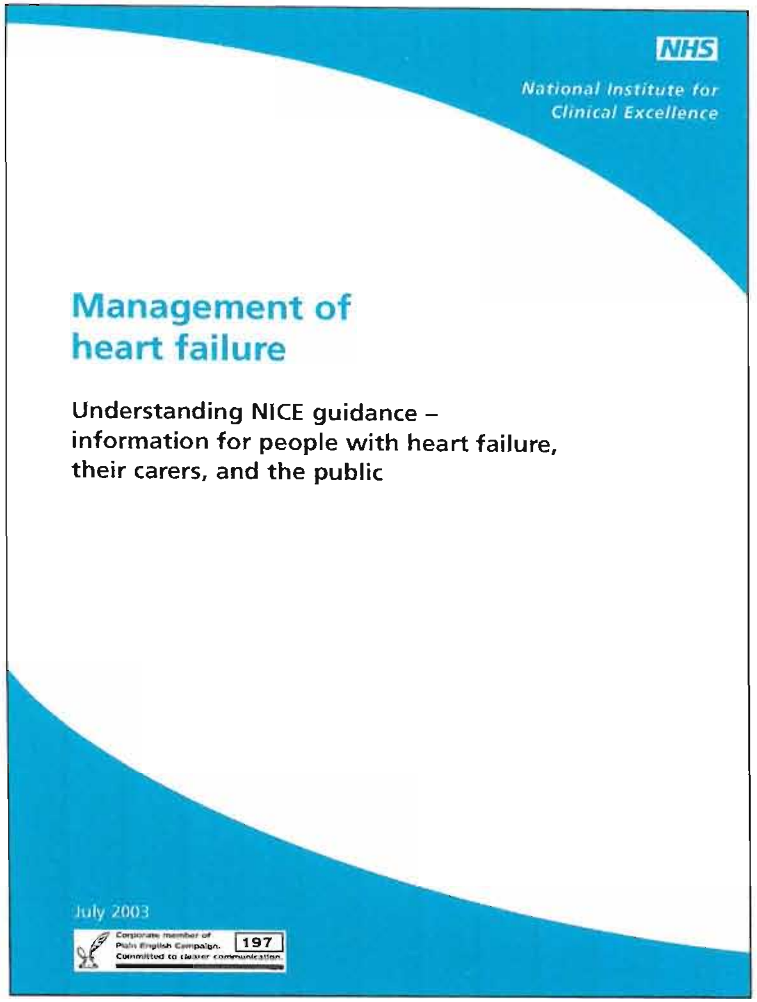
a) Present situation

Code name	Description	Example of quotes
Written management plans not always available	Not all patients have a written management plan	*'Usually there's no clear management plan that comes out of the hospital' (GP, 20.68.3-4)*
GP letters and discharge letters	Patients sent copies of correspondence with other health professionals	*'Where a lot of clinical communication about a patient...are actually sent [out] to the patients so that they get a better understanding of what's going on with their chronic disease management' (Consultant, 5.73.3-73.5)*
Hand written notes	Hand written notes sometimes provided	*'Occasionally I'll write things down, if someone looks a bit muddled on what drugs to take, I'll write that down but I won't do anything more than that' (Junior doctor, 6.110.1-3)*
Not available	Suitable written information materials not available or easily accessible	*'I haven't seen any leaflets about' (Junior doctor, 10.93.4)*

b) Perceptions of written information

Code name	Description	Example of quotes
Causes distress and promotes confusion	Health professionals perceived that written information could cause distress	*'and they (booklets/leaflets) can* ***really*** *scare the patient' (Junior doctor, 10.101.1)*
Good way to provide and share information	Health professionals perceived written materials as a useful method to provide patients with information to improve their understanding about their illness	*'I think its very helpful for them if they have something they can read after they have seen you so that they can refresh their memory about what you said' (Consultant, 5.77.5-77.7)* *'Patients would be a lot more wiser about their condition [if provided with written information] (Consultant, 8.132.2)*

Appendix J: NICE booklet on the management of heart failure



NHS

National Institute for
Clinical Excellence

Management of heart failure

Understanding NICE guidance –
information for people with heart failure,
their carers, and the public

July 2003

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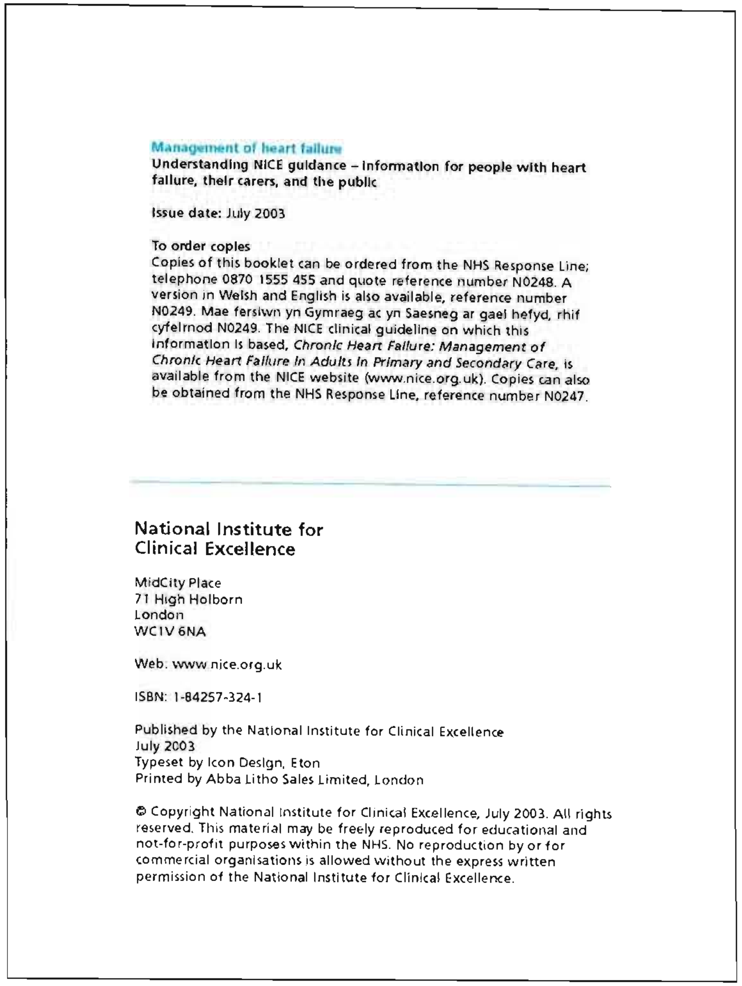

Management of heart failure
Understanding NICE guidance – information for people with heart failure, their carers, and the public

Issue date: July 2003

To order copies
Copies of this booklet can be ordered from the NHS Response Line; telephone 0870 1555 455 and quote reference number N0248. A version in Welsh and English is also available, reference number N0249. Mae fersiwn yn Gymraeg ac yn Saesneg ar gael hefyd, rhif cyfeirnod N0249. The NICE clinical guideline on which this information is based, *Chronic Heart Failure: Management of Chronic Heart Failure in Adults in Primary and Secondary Care*, is available from the NICE website (www.nice.org.uk). Copies can also be obtained from the NHS Response Line, reference number N0247.

National Institute for
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MidCity Place
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London
WC1V 6NA

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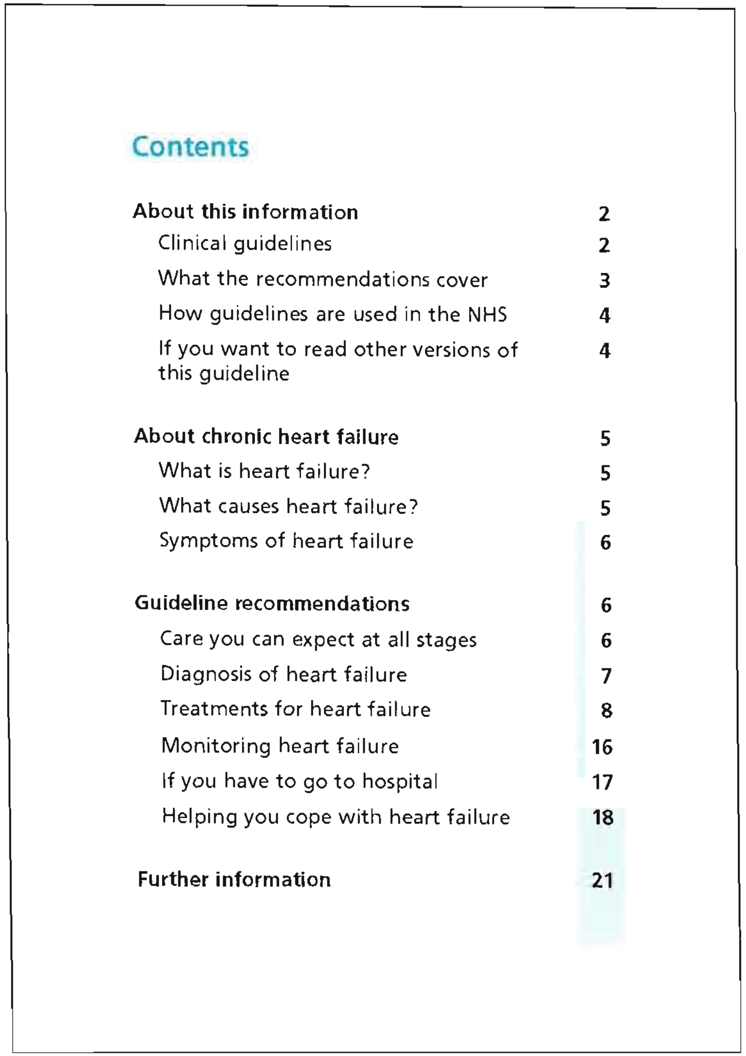

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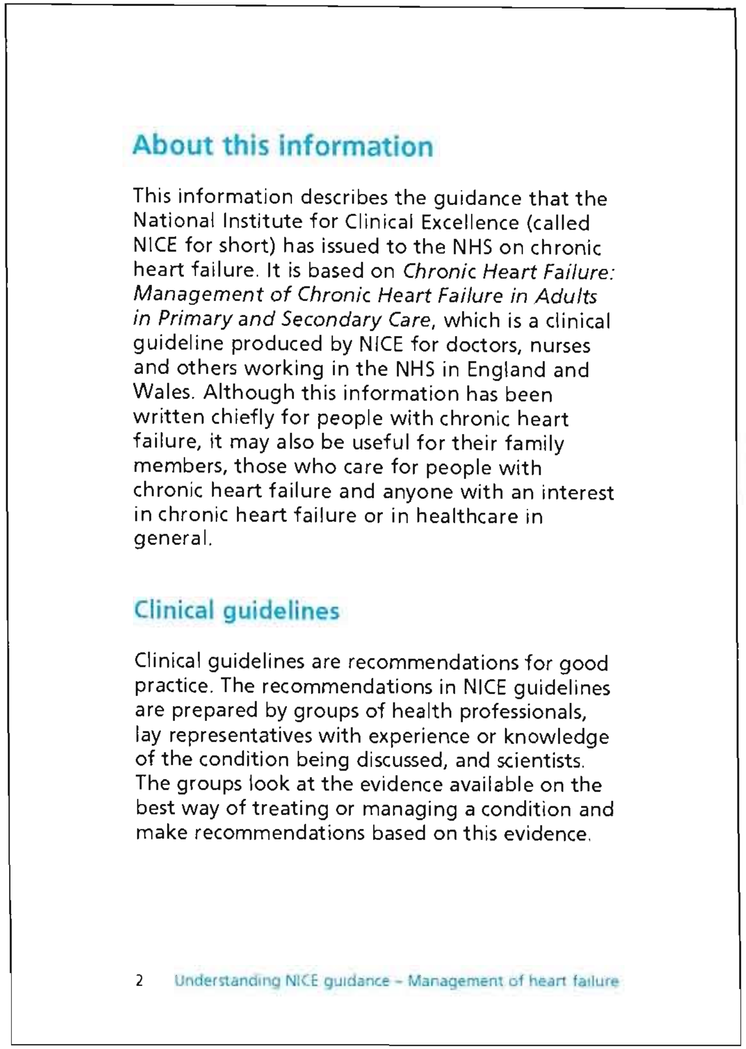
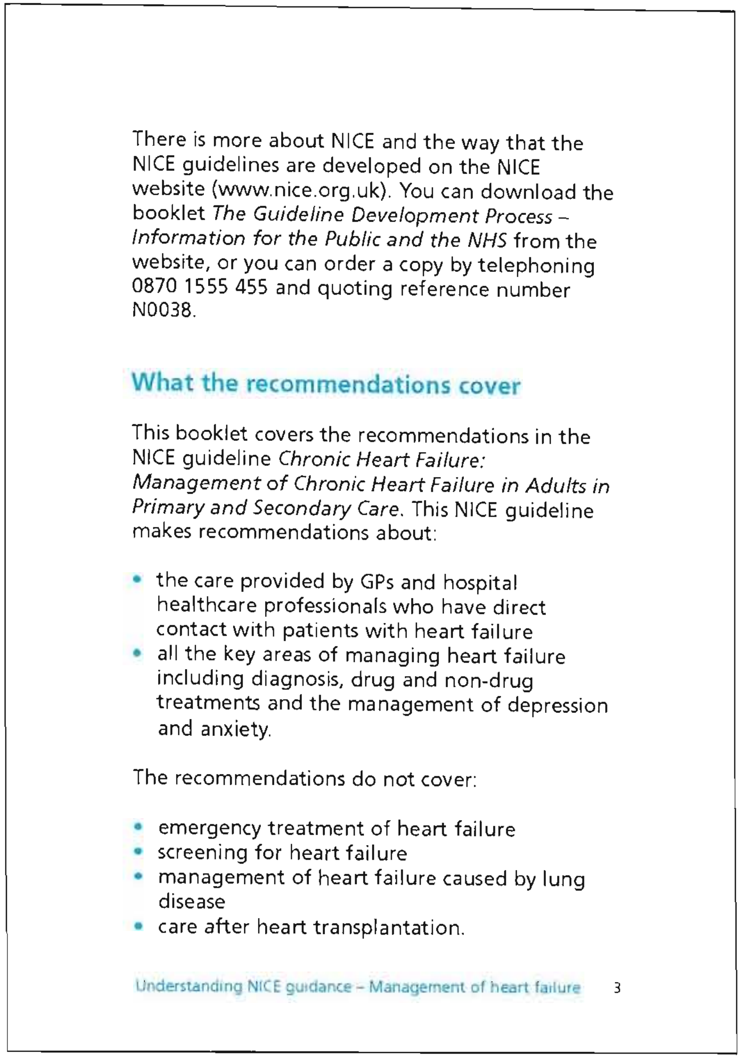


About this information

This information describes the guidance that the National Institute for Clinical Excellence (called NICE for short) has issued to the NHS on chronic heart failure. It is based on *Chronic Heart Failure: Management of Chronic Heart Failure in Adults in Primary and Secondary Care*, which is a clinical guideline produced by NICE for doctors, nurses and others working in the NHS in England and Wales. Although this information has been written chiefly for people with chronic heart failure, it may also be useful for their family members, those who care for people with chronic heart failure and anyone with an interest in chronic heart failure or in healthcare in general.

Clinical guidelines

Clinical guidelines are recommendations for good practice. The recommendations in NICE guidelines are prepared by groups of health professionals, lay representatives with experience or knowledge of the condition being discussed, and scientists. The groups look at the evidence available on the best way of treating or managing a condition and make recommendations based on this evidence.



There is more about NICE and the way that the NICE guidelines are developed on the NICE website (www.nice.org.uk). You can download the booklet *The Guideline Development Process – Information for the Public and the NHS* from the website, or you can order a copy by telephoning 0870 1555 455 and quoting reference number N0038.

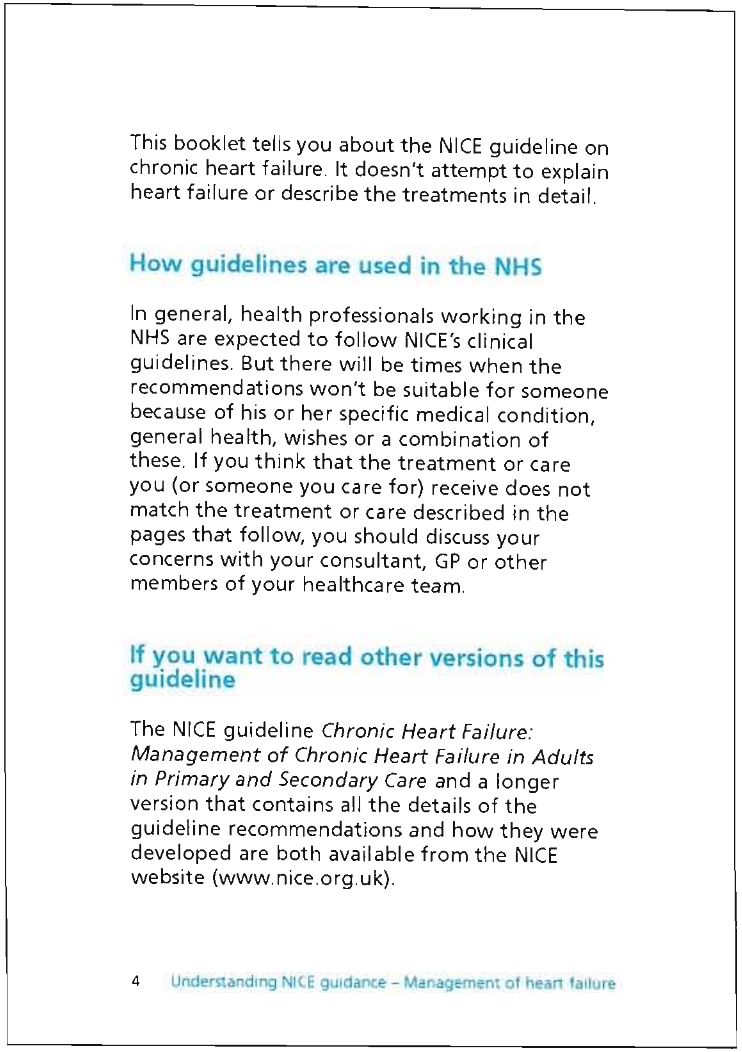
What the recommendations cover

This booklet covers the recommendations in the NICE guideline *Chronic Heart Failure: Management of Chronic Heart Failure in Adults in Primary and Secondary Care*. This NICE guideline makes recommendations about:

- the care provided by GPs and hospital healthcare professionals who have direct contact with patients with heart failure
- all the key areas of managing heart failure including diagnosis, drug and non-drug treatments and the management of depression and anxiety.

The recommendations do not cover:

- emergency treatment of heart failure
- screening for heart failure
- management of heart failure caused by lung disease
- care after heart transplantation.



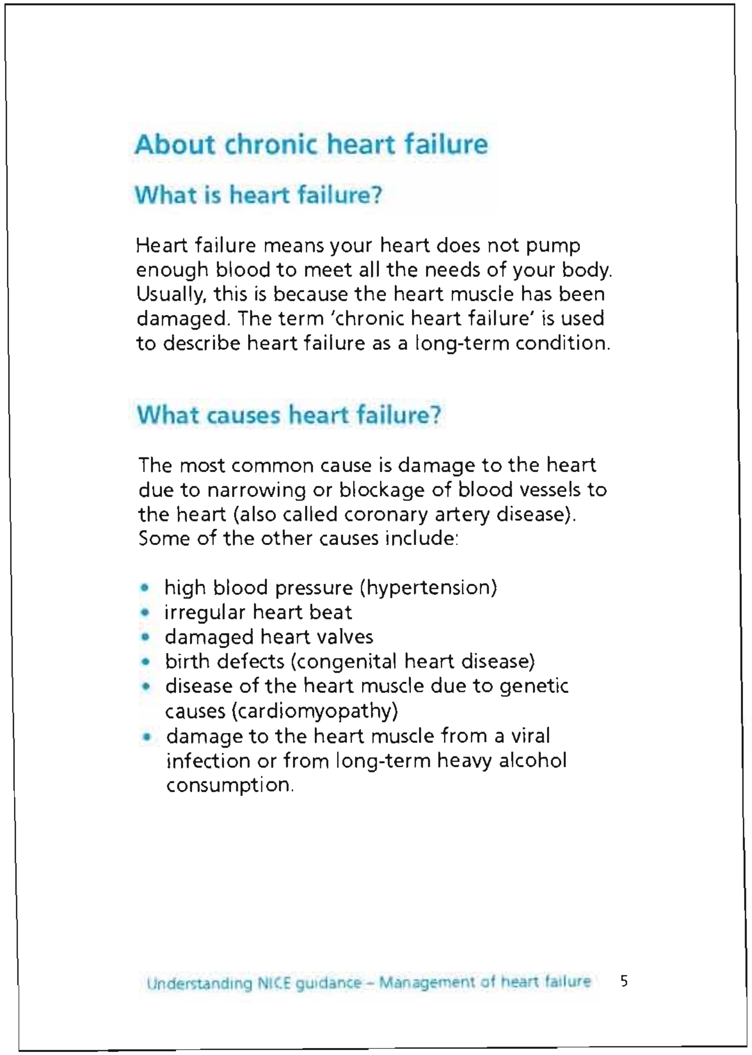
This booklet tells you about the NICE guideline on chronic heart failure. It doesn't attempt to explain heart failure or describe the treatments in detail.

How guidelines are used in the NHS

In general, health professionals working in the NHS are expected to follow NICE's clinical guidelines. But there will be times when the recommendations won't be suitable for someone because of his or her specific medical condition, general health, wishes or a combination of these. If you think that the treatment or care you (or someone you care for) receive does not match the treatment or care described in the pages that follow, you should discuss your concerns with your consultant, GP or other members of your healthcare team.

If you want to read other versions of this guideline

The NICE guideline *Chronic Heart Failure: Management of Chronic Heart Failure in Adults in Primary and Secondary Care* and a longer version that contains all the details of the guideline recommendations and how they were developed are both available from the NICE website (www.nice.org.uk).



About chronic heart failure

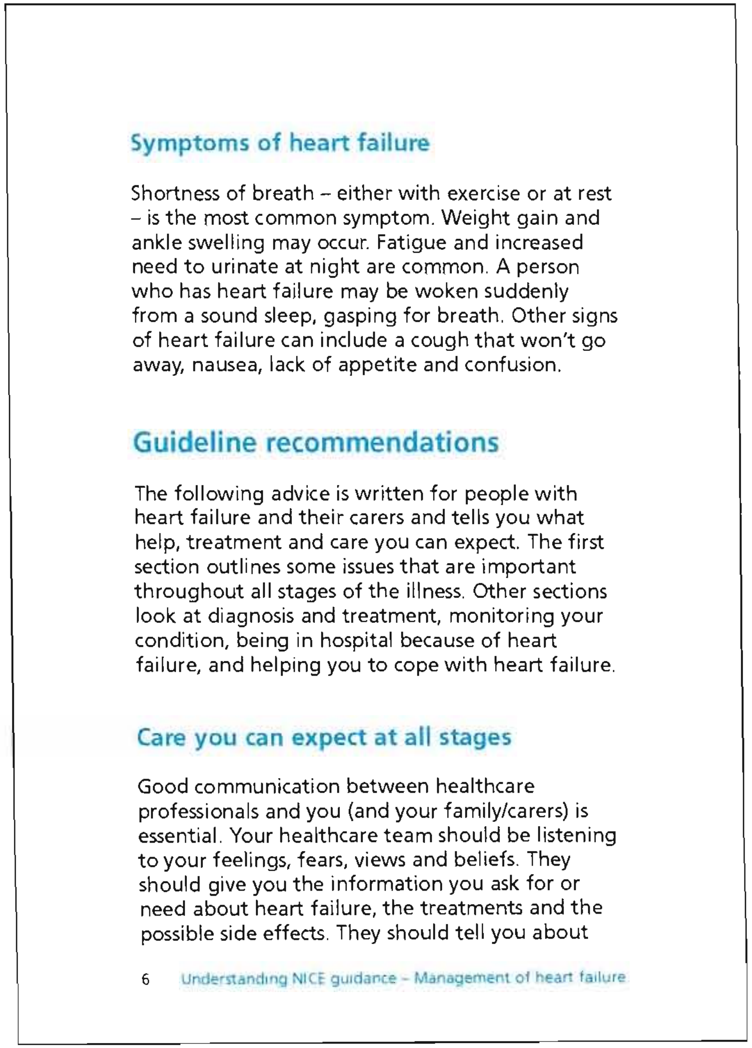
What is heart failure?

Heart failure means your heart does not pump enough blood to meet all the needs of your body. Usually, this is because the heart muscle has been damaged. The term 'chronic heart failure' is used to describe heart failure as a long-term condition.

What causes heart failure?

The most common cause is damage to the heart due to narrowing or blockage of blood vessels to the heart (also called coronary artery disease). Some of the other causes include:

- high blood pressure (hypertension)
- irregular heart beat
- damaged heart valves
- birth defects (congenital heart disease)
- disease of the heart muscle due to genetic causes (cardiomyopathy)
- damage to the heart muscle from a viral infection or from long-term heavy alcohol consumption.



Symptoms of heart failure

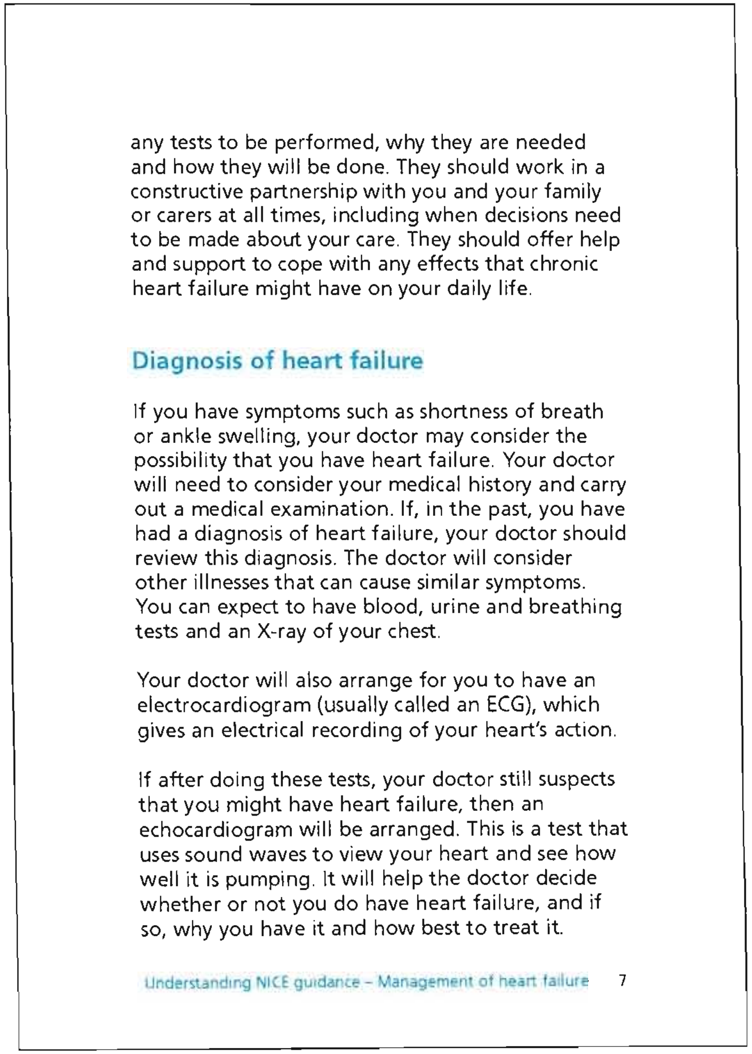
Shortness of breath – either with exercise or at rest – is the most common symptom. Weight gain and ankle swelling may occur. Fatigue and increased need to urinate at night are common. A person who has heart failure may be woken suddenly from a sound sleep, gasping for breath. Other signs of heart failure can include a cough that won't go away, nausea, lack of appetite and confusion.

Guideline recommendations

The following advice is written for people with heart failure and their carers and tells you what help, treatment and care you can expect. The first section outlines some issues that are important throughout all stages of the illness. Other sections look at diagnosis and treatment, monitoring your condition, being in hospital because of heart failure, and helping you to cope with heart failure.

Care you can expect at all stages

Good communication between healthcare professionals and you (and your family/carers) is essential. Your healthcare team should be listening to your feelings, fears, views and beliefs. They should give you the information you ask for or need about heart failure, the treatments and the possible side effects. They should tell you about



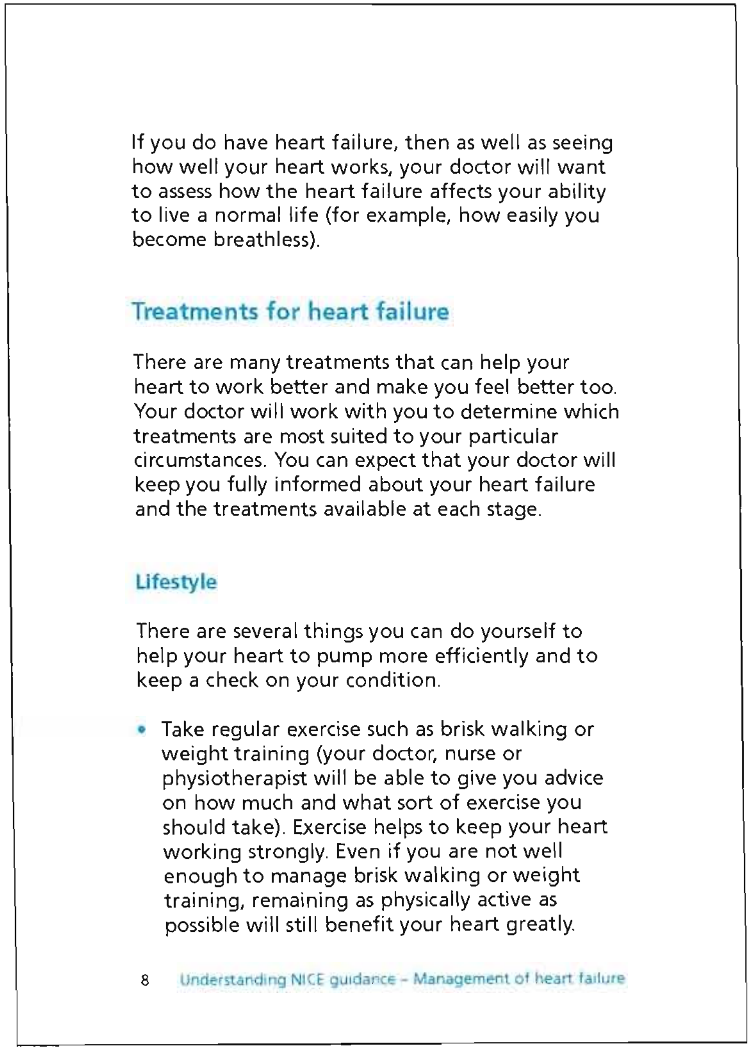
any tests to be performed, why they are needed and how they will be done. They should work in a constructive partnership with you and your family or carers at all times, including when decisions need to be made about your care. They should offer help and support to cope with any effects that chronic heart failure might have on your daily life.

Diagnosis of heart failure

If you have symptoms such as shortness of breath or ankle swelling, your doctor may consider the possibility that you have heart failure. Your doctor will need to consider your medical history and carry out a medical examination. If, in the past, you have had a diagnosis of heart failure, your doctor should review this diagnosis. The doctor will consider other illnesses that can cause similar symptoms. You can expect to have blood, urine and breathing tests and an X-ray of your chest.

Your doctor will also arrange for you to have an electrocardiogram (usually called an ECG), which gives an electrical recording of your heart's action.

If after doing these tests, your doctor still suspects that you might have heart failure, then an echocardiogram will be arranged. This is a test that uses sound waves to view your heart and see how well it is pumping. It will help the doctor decide whether or not you do have heart failure, and if so, why you have it and how best to treat it.



If you do have heart failure, then as well as seeing how well your heart works, your doctor will want to assess how the heart failure affects your ability to live a normal life (for example, how easily you become breathless).

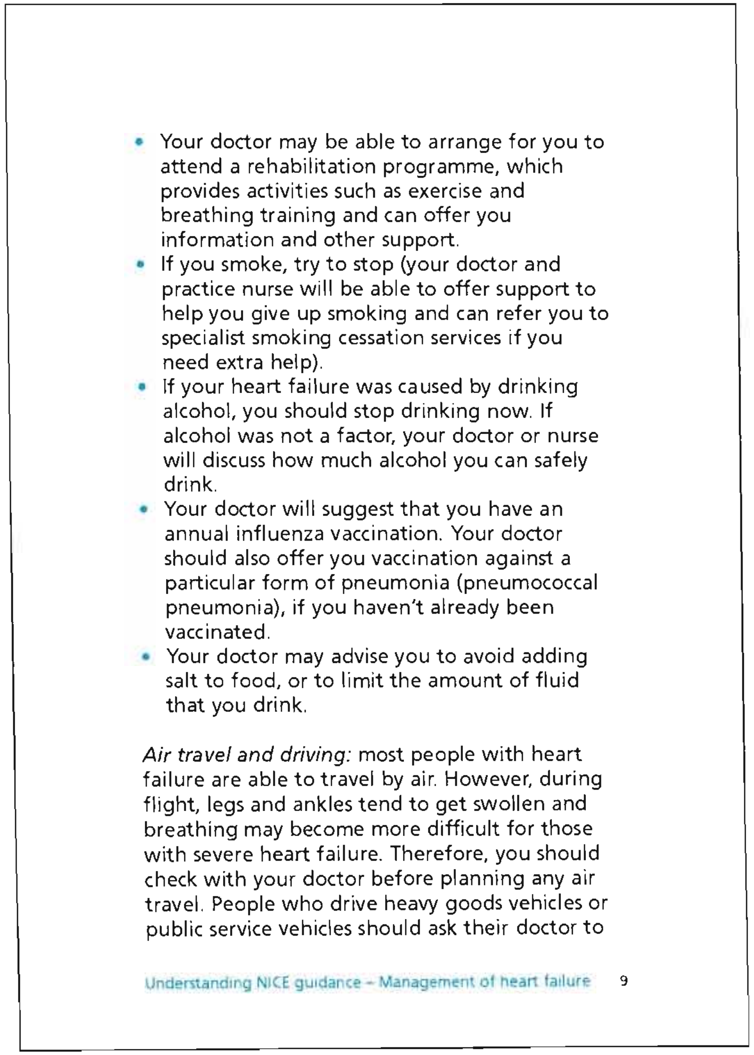
Treatments for heart failure

There are many treatments that can help your heart to work better and make you feel better too. Your doctor will work with you to determine which treatments are most suited to your particular circumstances. You can expect that your doctor will keep you fully informed about your heart failure and the treatments available at each stage.

Lifestyle

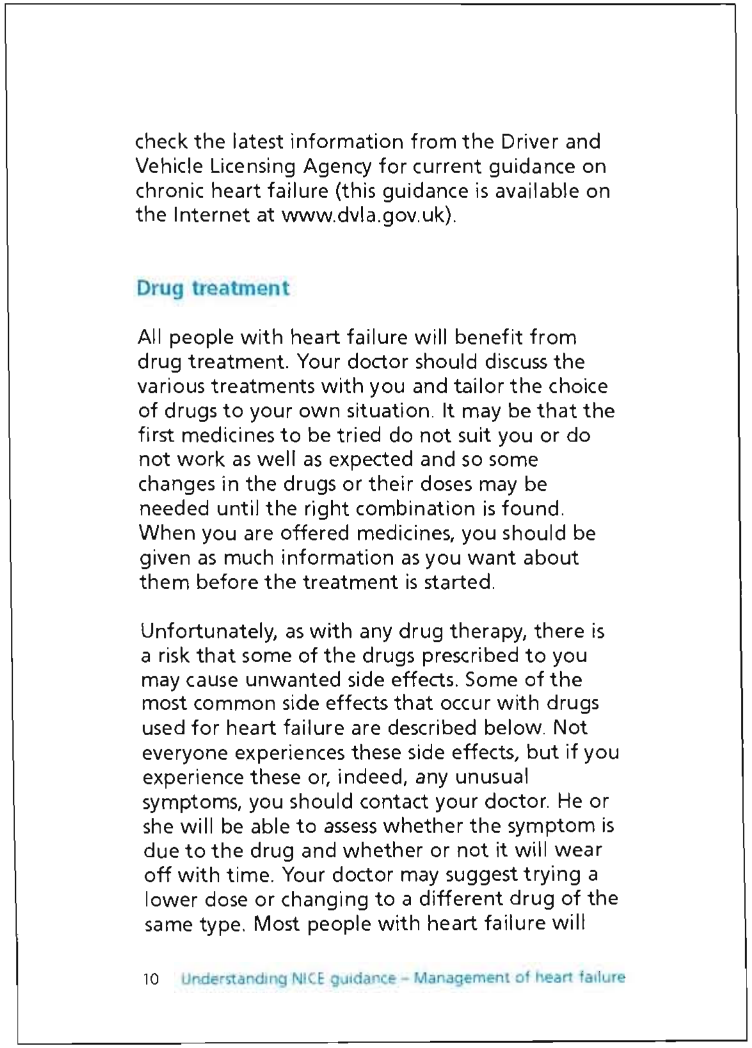
There are several things you can do yourself to help your heart to pump more efficiently and to keep a check on your condition.

- Take regular exercise such as brisk walking or weight training (your doctor, nurse or physiotherapist will be able to give you advice on how much and what sort of exercise you should take). Exercise helps to keep your heart working strongly. Even if you are not well enough to manage brisk walking or weight training, remaining as physically active as possible will still benefit your heart greatly.



- Your doctor may be able to arrange for you to attend a rehabilitation programme, which provides activities such as exercise and breathing training and can offer you information and other support.
- If you smoke, try to stop (your doctor and practice nurse will be able to offer support to help you give up smoking and can refer you to specialist smoking cessation services if you need extra help).
- If your heart failure was caused by drinking alcohol, you should stop drinking now. If alcohol was not a factor, your doctor or nurse will discuss how much alcohol you can safely drink.
- Your doctor will suggest that you have an annual influenza vaccination. Your doctor should also offer you vaccination against a particular form of pneumonia (pneumococcal pneumonia), if you haven't already been vaccinated.
- Your doctor may advise you to avoid adding salt to food, or to limit the amount of fluid that you drink.

Air travel and driving: most people with heart failure are able to travel by air. However, during flight, legs and ankles tend to get swollen and breathing may become more difficult for those with severe heart failure. Therefore, you should check with your doctor before planning any air travel. People who drive heavy goods vehicles or public service vehicles should ask their doctor to

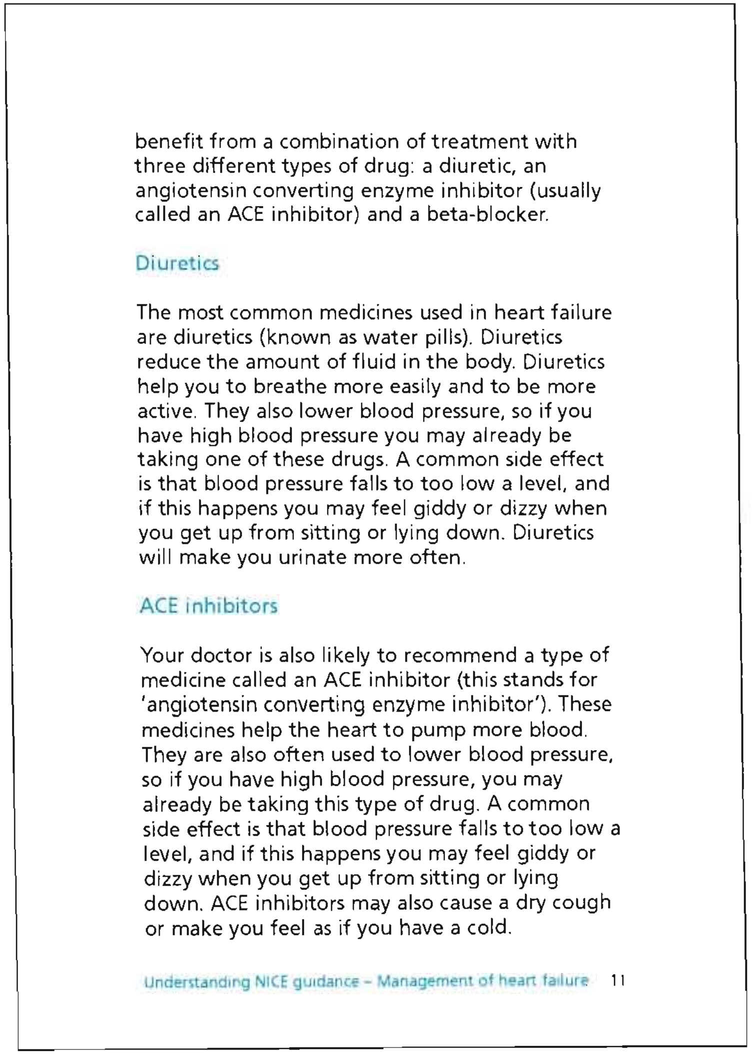


check the latest information from the Driver and Vehicle Licensing Agency for current guidance on chronic heart failure (this guidance is available on the Internet at www.dvla.gov.uk).

Drug treatment

All people with heart failure will benefit from drug treatment. Your doctor should discuss the various treatments with you and tailor the choice of drugs to your own situation. It may be that the first medicines to be tried do not suit you or do not work as well as expected and so some changes in the drugs or their doses may be needed until the right combination is found. When you are offered medicines, you should be given as much information as you want about them before the treatment is started.

Unfortunately, as with any drug therapy, there is a risk that some of the drugs prescribed to you may cause unwanted side effects. Some of the most common side effects that occur with drugs used for heart failure are described below. Not everyone experiences these side effects, but if you experience these or, indeed, any unusual symptoms, you should contact your doctor. He or she will be able to assess whether the symptom is due to the drug and whether or not it will wear off with time. Your doctor may suggest trying a lower dose or changing to a different drug of the same type. Most people with heart failure will



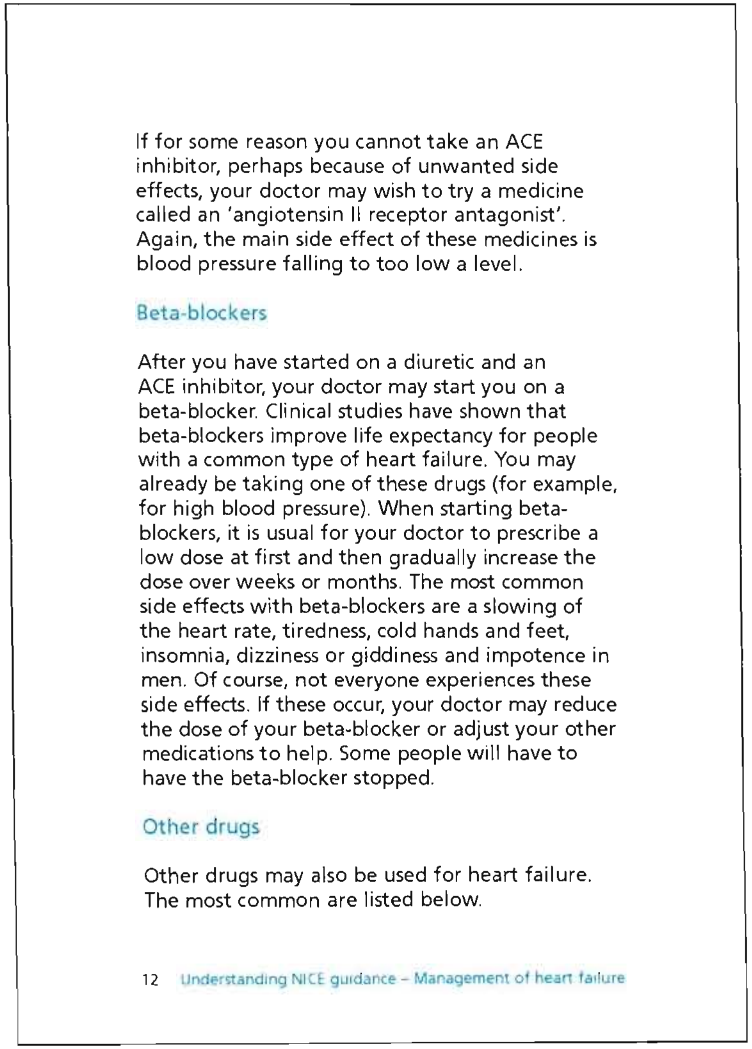
benefit from a combination of treatment with three different types of drug: a diuretic, an angiotensin converting enzyme inhibitor (usually called an ACE inhibitor) and a beta-blocker.

Diuretics

The most common medicines used in heart failure are diuretics (known as water pills). Diuretics reduce the amount of fluid in the body. Diuretics help you to breathe more easily and to be more active. They also lower blood pressure, so if you have high blood pressure you may already be taking one of these drugs. A common side effect is that blood pressure falls to too low a level, and if this happens you may feel giddy or dizzy when you get up from sitting or lying down. Diuretics will make you urinate more often.

ACE inhibitors

Your doctor is also likely to recommend a type of medicine called an ACE inhibitor (this stands for 'angiotensin converting enzyme inhibitor'). These medicines help the heart to pump more blood. They are also often used to lower blood pressure, so if you have high blood pressure, you may already be taking this type of drug. A common side effect is that blood pressure falls to too low a level, and if this happens you may feel giddy or dizzy when you get up from sitting or lying down. ACE inhibitors may also cause a dry cough or make you feel as if you have a cold.



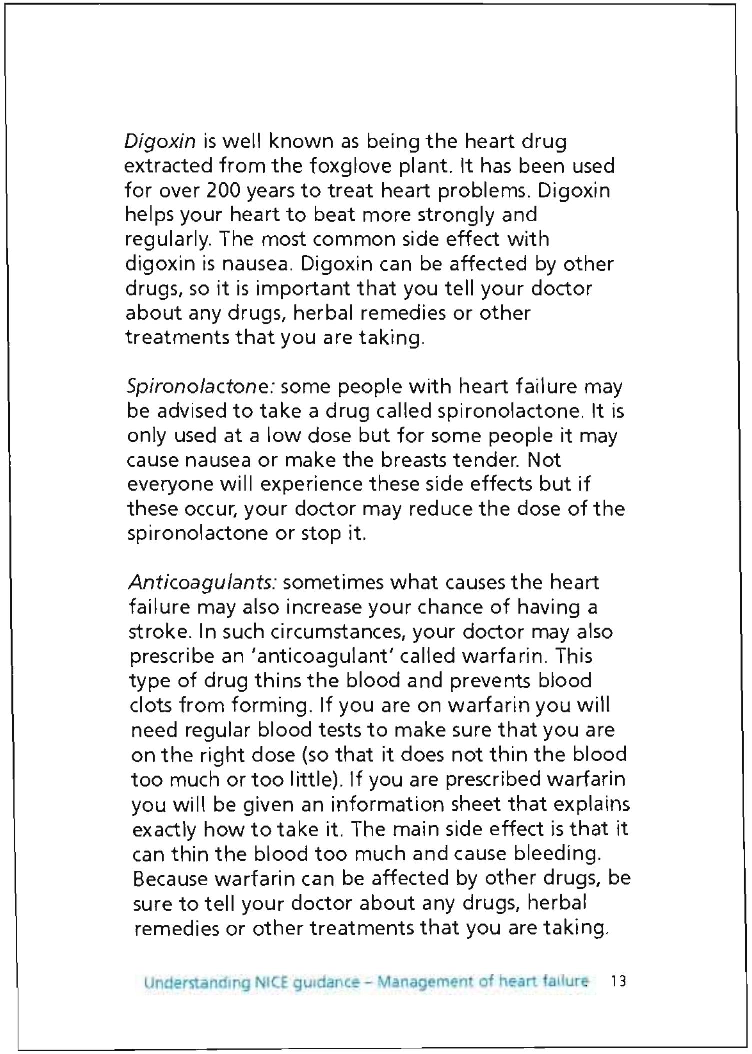
If for some reason you cannot take an ACE inhibitor, perhaps because of unwanted side effects, your doctor may wish to try a medicine called an 'angiotensin II receptor antagonist'. Again, the main side effect of these medicines is blood pressure falling to too low a level.

Beta-blockers

After you have started on a diuretic and an ACE inhibitor, your doctor may start you on a beta-blocker. Clinical studies have shown that beta-blockers improve life expectancy for people with a common type of heart failure. You may already be taking one of these drugs (for example, for high blood pressure). When starting beta-blockers, it is usual for your doctor to prescribe a low dose at first and then gradually increase the dose over weeks or months. The most common side effects with beta-blockers are a slowing of the heart rate, tiredness, cold hands and feet, insomnia, dizziness or giddiness and impotence in men. Of course, not everyone experiences these side effects. If these occur, your doctor may reduce the dose of your beta-blocker or adjust your other medications to help. Some people will have to have the beta-blocker stopped.

Other drugs

Other drugs may also be used for heart failure. The most common are listed below.



Digoxin is well known as being the heart drug extracted from the foxglove plant. It has been used for over 200 years to treat heart problems. Digoxin helps your heart to beat more strongly and regularly. The most common side effect with digoxin is nausea. Digoxin can be affected by other drugs, so it is important that you tell your doctor about any drugs, herbal remedies or other treatments that you are taking.

Spironolactone: some people with heart failure may be advised to take a drug called spironolactone. It is only used at a low dose but for some people it may cause nausea or make the breasts tender. Not everyone will experience these side effects but if these occur, your doctor may reduce the dose of the spironolactone or stop it.

Anticoagulants: sometimes what causes the heart failure may also increase your chance of having a stroke. In such circumstances, your doctor may also prescribe an 'anticoagulant' called warfarin. This type of drug thins the blood and prevents blood clots from forming. If you are on warfarin you will need regular blood tests to make sure that you are on the right dose (so that it does not thin the blood too much or too little). If you are prescribed warfarin you will be given an information sheet that explains exactly how to take it. The main side effect is that it can thin the blood too much and cause bleeding. Because warfarin can be affected by other drugs, be sure to tell your doctor about any drugs, herbal remedies or other treatments that you are taking.

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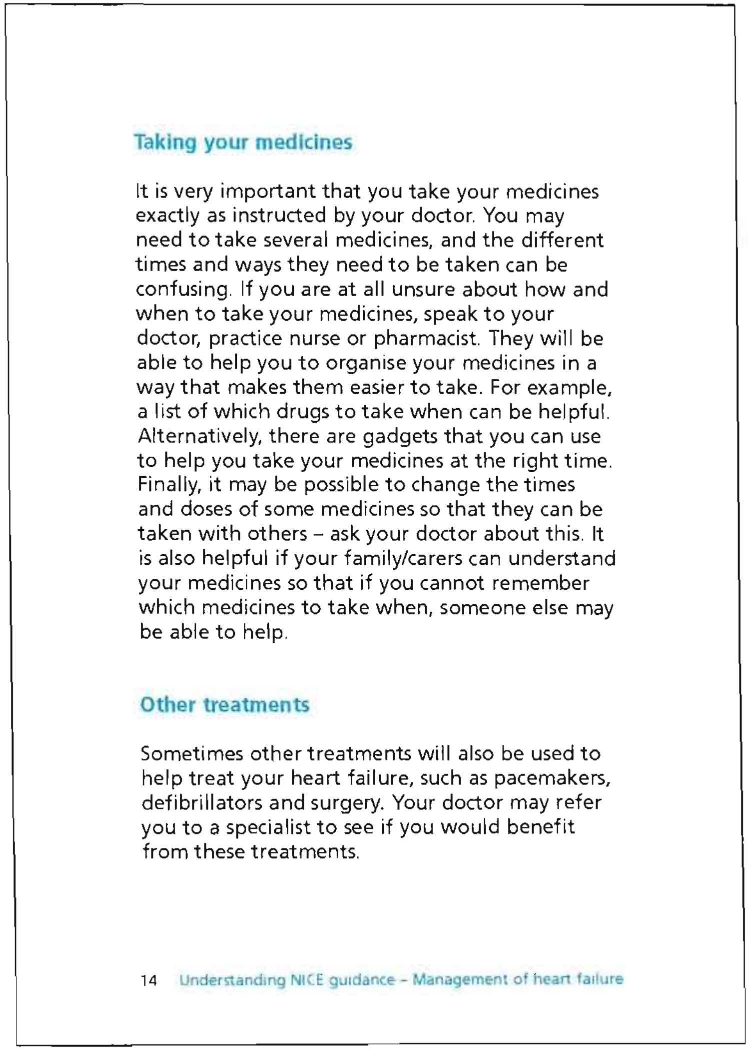

Taking your medicines

It is very important that you take your medicines exactly as instructed by your doctor. You may need to take several medicines, and the different times and ways they need to be taken can be confusing. If you are at all unsure about how and when to take your medicines, speak to your doctor, practice nurse or pharmacist. They will be able to help you to organise your medicines in a way that makes them easier to take. For example, a list of which drugs to take when can be helpful. Alternatively, there are gadgets that you can use to help you take your medicines at the right time. Finally, it may be possible to change the times and doses of some medicines so that they can be taken with others – ask your doctor about this. It is also helpful if your family/carers can understand your medicines so that if you cannot remember which medicines to take when, someone else may be able to help.

Other treatments

Sometimes other treatments will also be used to help treat your heart failure, such as pacemakers, defibrillators and surgery. Your doctor may refer you to a specialist to see if you would benefit from these treatments.

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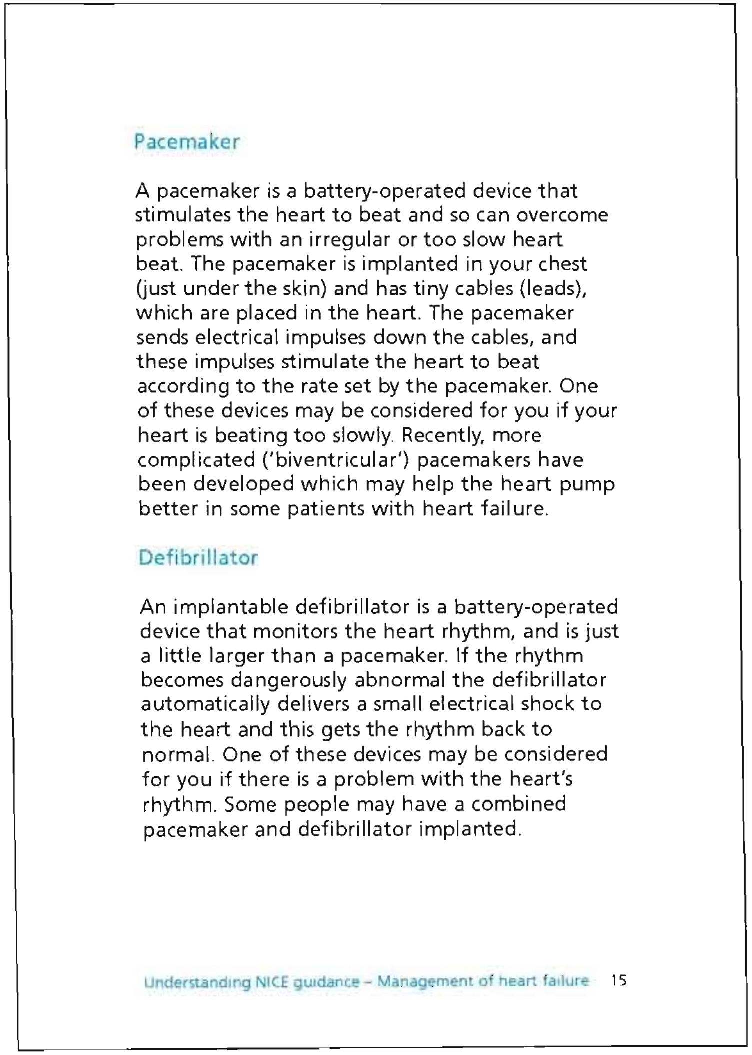
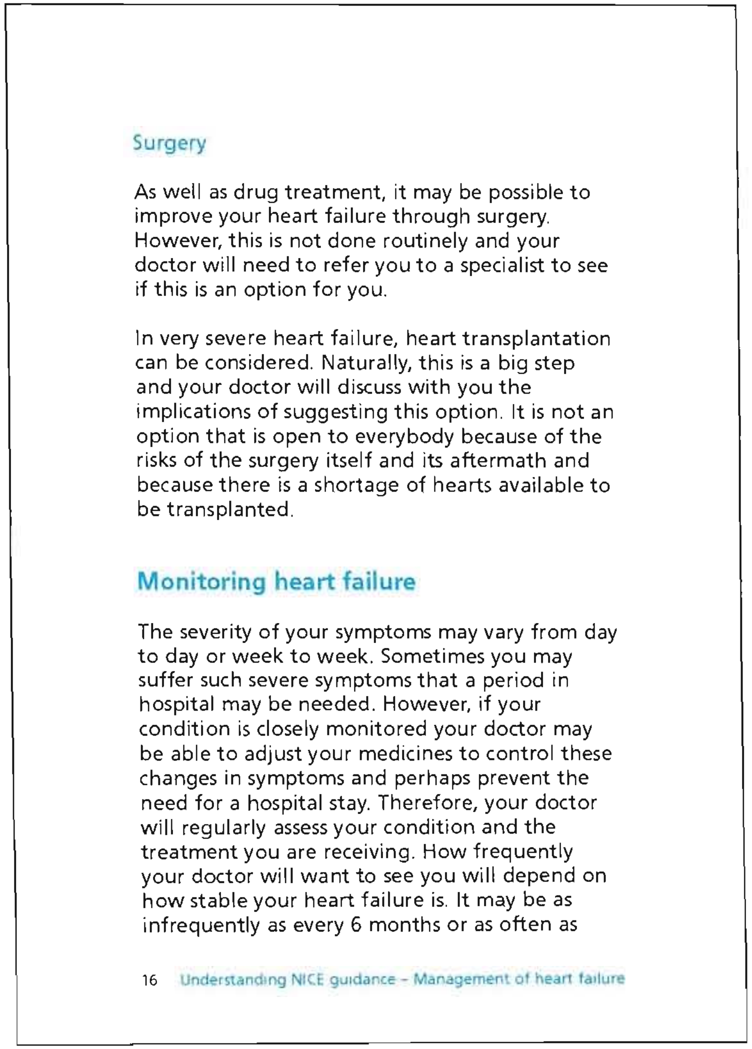


Pacemaker

A pacemaker is a battery-operated device that stimulates the heart to beat and so can overcome problems with an irregular or too slow heart beat. The pacemaker is implanted in your chest (just under the skin) and has tiny cables (leads), which are placed in the heart. The pacemaker sends electrical impulses down the cables, and these impulses stimulate the heart to beat according to the rate set by the pacemaker. One of these devices may be considered for you if your heart is beating too slowly. Recently, more complicated ('biventricular') pacemakers have been developed which may help the heart pump better in some patients with heart failure.

Defibrillator

An implantable defibrillator is a battery-operated device that monitors the heart rhythm, and is just a little larger than a pacemaker. If the rhythm becomes dangerously abnormal the defibrillator automatically delivers a small electrical shock to the heart and this gets the rhythm back to normal. One of these devices may be considered for you if there is a problem with the heart's rhythm. Some people may have a combined pacemaker and defibrillator implanted.



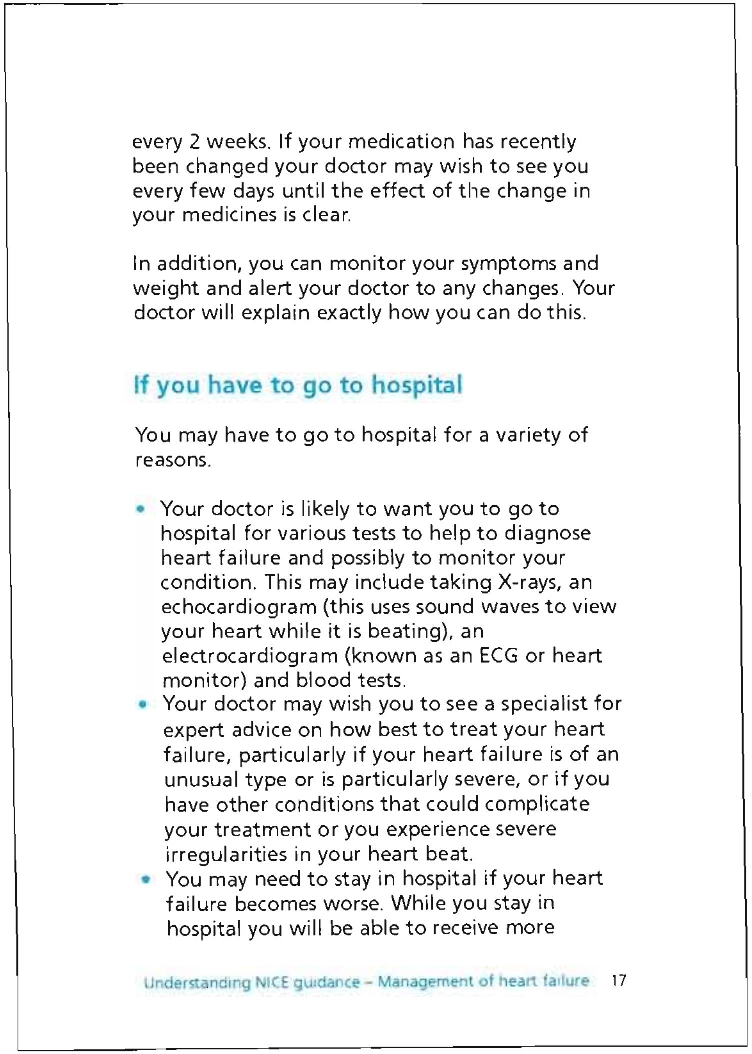
Surgery

As well as drug treatment, it may be possible to improve your heart failure through surgery. However, this is not done routinely and your doctor will need to refer you to a specialist to see if this is an option for you.

In very severe heart failure, heart transplantation can be considered. Naturally, this is a big step and your doctor will discuss with you the implications of suggesting this option. It is not an option that is open to everybody because of the risks of the surgery itself and its aftermath and because there is a shortage of hearts available to be transplanted.

Monitoring heart failure

The severity of your symptoms may vary from day to day or week to week. Sometimes you may suffer such severe symptoms that a period in hospital may be needed. However, if your condition is closely monitored your doctor may be able to adjust your medicines to control these changes in symptoms and perhaps prevent the need for a hospital stay. Therefore, your doctor will regularly assess your condition and the treatment you are receiving. How frequently your doctor will want to see you will depend on how stable your heart failure is. It may be as infrequently as every 6 months or as often as



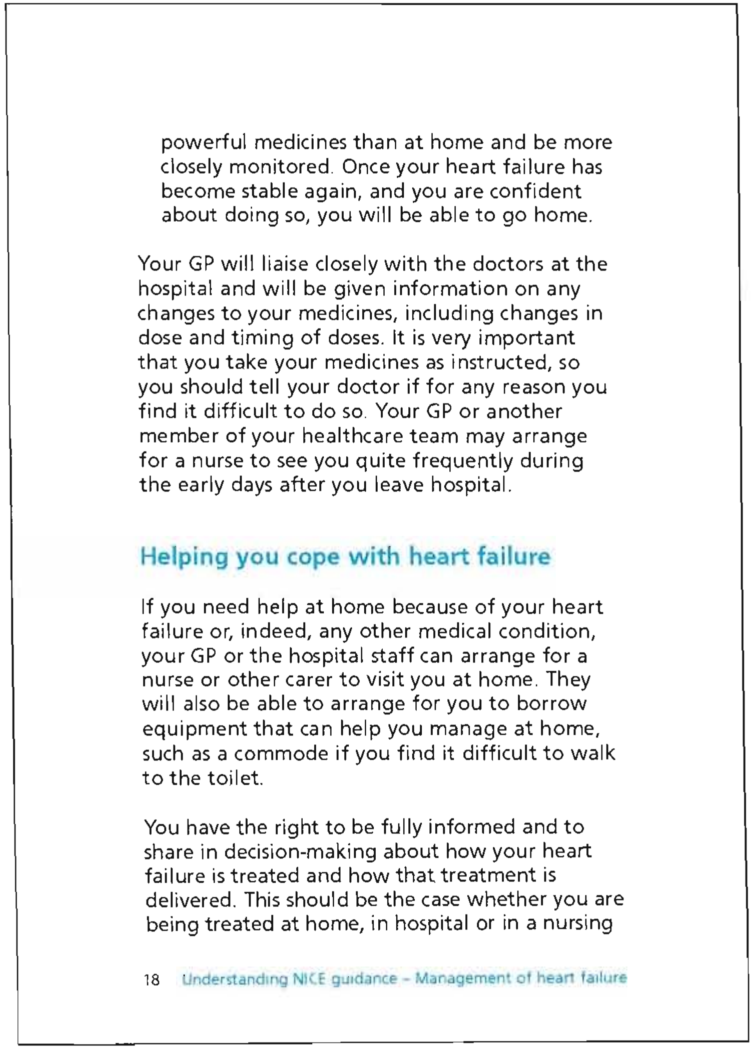
every 2 weeks. If your medication has recently been changed your doctor may wish to see you every few days until the effect of the change in your medicines is clear.

In addition, you can monitor your symptoms and weight and alert your doctor to any changes. Your doctor will explain exactly how you can do this.

If you have to go to hospital

You may have to go to hospital for a variety of reasons.

- Your doctor is likely to want you to go to hospital for various tests to help to diagnose heart failure and possibly to monitor your condition. This may include taking X-rays, an echocardiogram (this uses sound waves to view your heart while it is beating), an electrocardiogram (known as an ECG or heart monitor) and blood tests.
- Your doctor may wish you to see a specialist for expert advice on how best to treat your heart failure, particularly if your heart failure is of an unusual type or is particularly severe, or if you have other conditions that could complicate your treatment or you experience severe irregularities in your heart beat.
- You may need to stay in hospital if your heart failure becomes worse. While you stay in hospital you will be able to receive more powerful medicines than at home and be more closely monitored. Once your heart failure has become stable again, and you are confident about doing so, you will be able to go home.

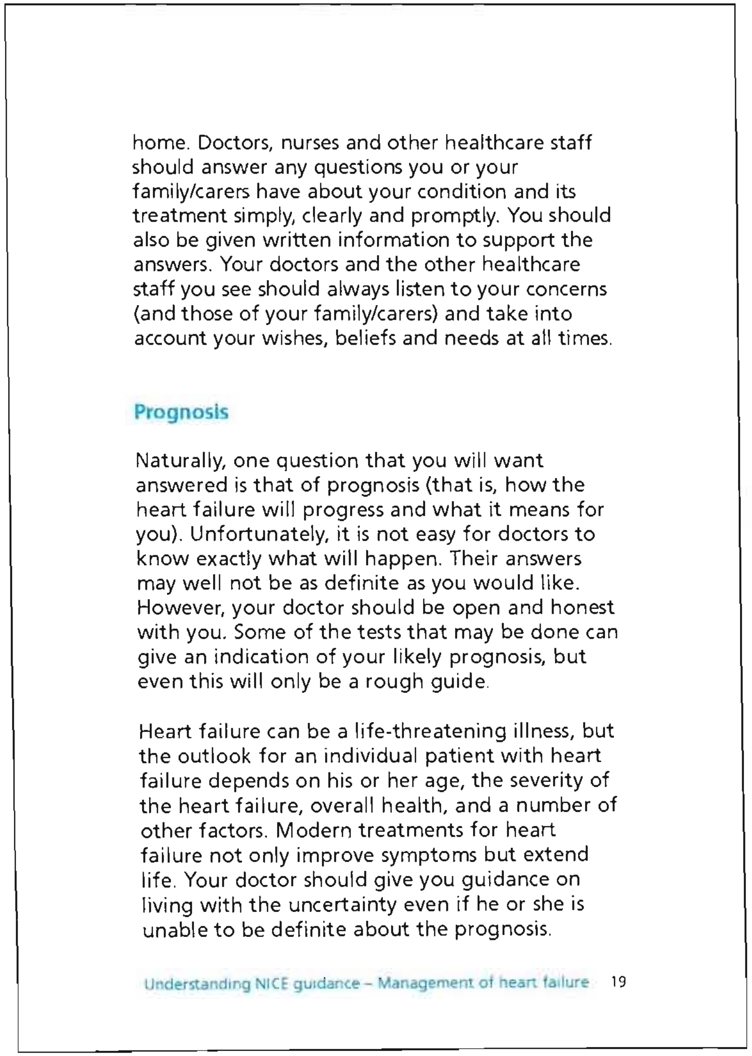


Your GP will liaise closely with the doctors at the hospital and will be given information on any changes to your medicines, including changes in dose and timing of doses. It is very important that you take your medicines as instructed, so you should tell your doctor if for any reason you find it difficult to do so. Your GP or another member of your healthcare team may arrange for a nurse to see you quite frequently during the early days after you leave hospital.

Helping you cope with heart failure

If you need help at home because of your heart failure or, indeed, any other medical condition, your GP or the hospital staff can arrange for a nurse or other carer to visit you at home. They will also be able to arrange for you to borrow equipment that can help you manage at home, such as a commode if you find it difficult to walk to the toilet.

You have the right to be fully informed and to share in decision-making about how your heart failure is treated and how that treatment is delivered. This should be the case whether you are being treated at home, in hospital or in a nursing

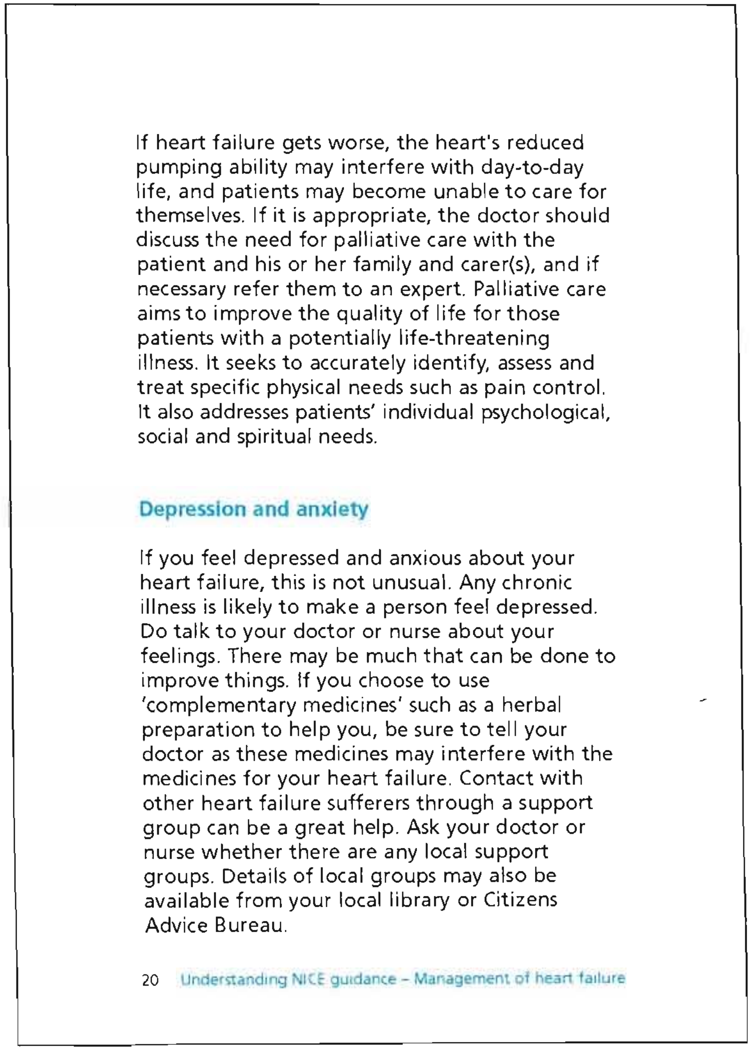


home. Doctors, nurses and other healthcare staff should answer any questions you or your family/carers have about your condition and its treatment simply, clearly and promptly. You should also be given written information to support the answers. Your doctors and the other healthcare staff you see should always listen to your concerns (and those of your family/carers) and take into account your wishes, beliefs and needs at all times.

Prognosis

Naturally, one question that you will want answered is that of prognosis (that is, how the heart failure will progress and what it means for you). Unfortunately, it is not easy for doctors to know exactly what will happen. Their answers may well not be as definite as you would like. However, your doctor should be open and honest with you. Some of the tests that may be done can give an indication of your likely prognosis, but even this will only be a rough guide.

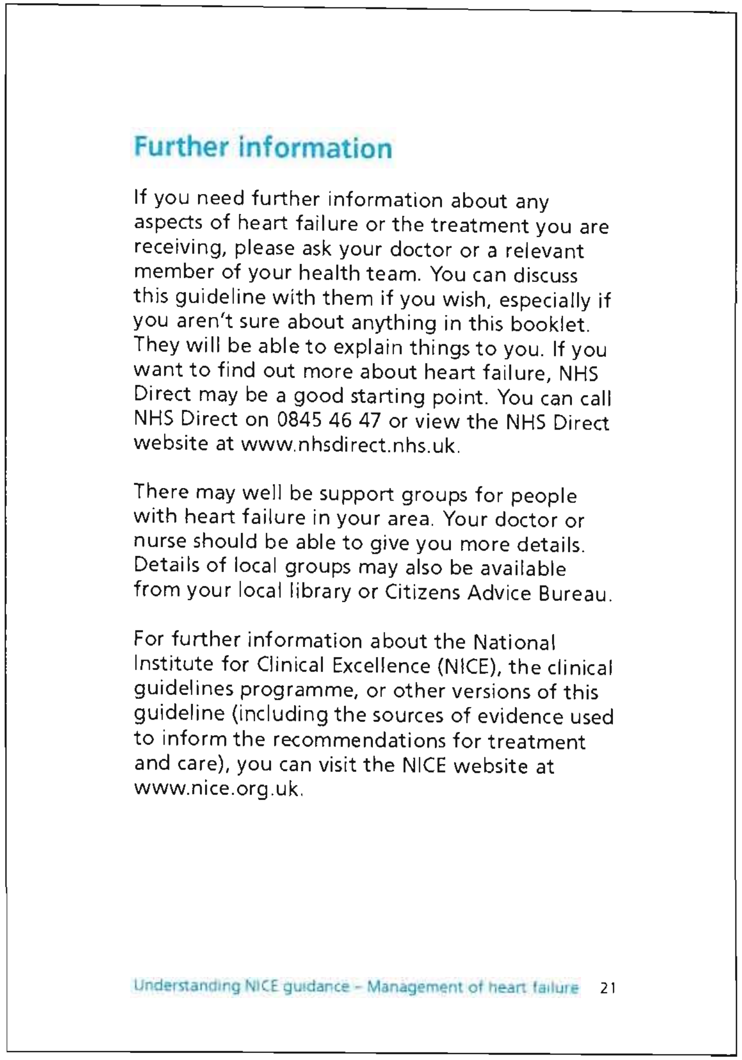
Heart failure can be a life-threatening illness, but the outlook for an individual patient with heart failure depends on his or her age, the severity of the heart failure, overall health, and a number of other factors. Modern treatments for heart failure not only improve symptoms but extend life. Your doctor should give you guidance on living with the uncertainty even if he or she is unable to be definite about the prognosis.



If heart failure gets worse, the heart's reduced pumping ability may interfere with day-to-day life, and patients may become unable to care for themselves. If it is appropriate, the doctor should discuss the need for palliative care with the patient and his or her family and carer(s), and if necessary refer them to an expert. Palliative care aims to improve the quality of life for those patients with a potentially life-threatening illness. It seeks to accurately identify, assess and treat specific physical needs such as pain control. It also addresses patients' individual psychological, social and spiritual needs.

Depression and anxiety

If you feel depressed and anxious about your heart failure, this is not unusual. Any chronic illness is likely to make a person feel depressed. Do talk to your doctor or nurse about your feelings. There may be much that can be done to improve things. If you choose to use 'complementary medicines' such as a herbal preparation to help you, be sure to tell your doctor as these medicines may interfere with the medicines for your heart failure. Contact with other heart failure sufferers through a support group can be a great help. Ask your doctor or nurse whether there are any local support groups. Details of local groups may also be available from your local library or Citizens Advice Bureau.

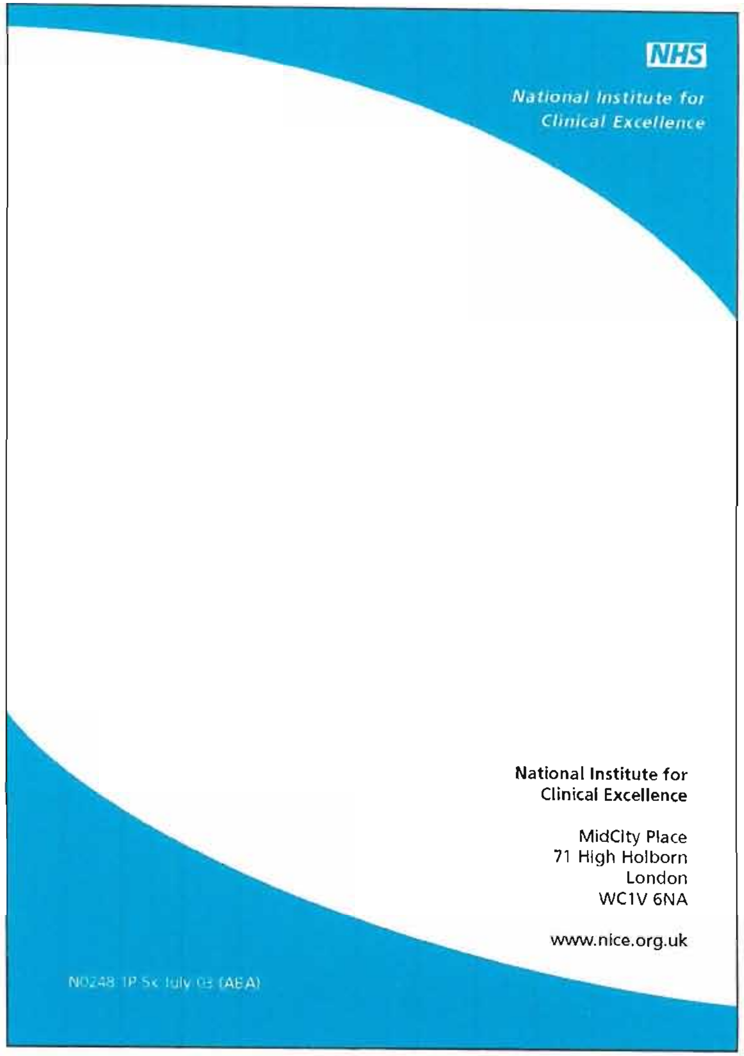


Further information

If you need further information about any aspects of heart failure or the treatment you are receiving, please ask your doctor or a relevant member of your health team. You can discuss this guideline with them if you wish, especially if you aren't sure about anything in this booklet. They will be able to explain things to you. If you want to find out more about heart failure, NHS Direct may be a good starting point. You can call NHS Direct on 0845 46 47 or view the NHS Direct website at www.nhsdirect.nhs.uk.

There may well be support groups for people with heart failure in your area. Your doctor or nurse should be able to give you more details. Details of local groups may also be available from your local library or Citizens Advice Bureau.

For further information about the National Institute for Clinical Excellence (NICE), the clinical guidelines programme, or other versions of this guideline (including the sources of evidence used to inform the recommendations for treatment and care), you can visit the NICE website at www.nice.org.uk.



NHS

National Institute for
Clinical Excellence

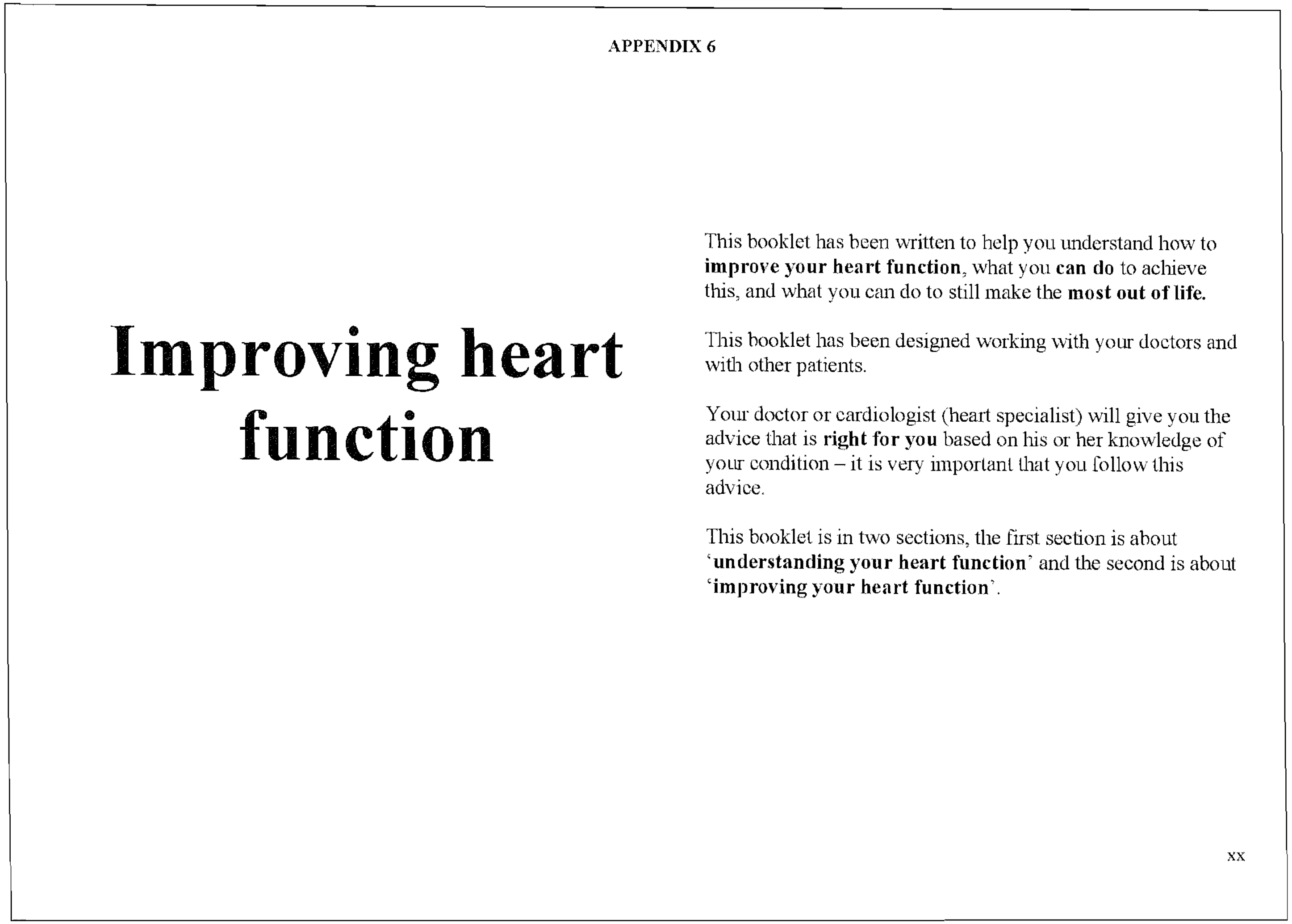
**National Institute for
Clinical Excellence**

MidCity Place
71 High Holborn
London
WC1V 6NA

www.nice.org.uk

N0248 1P 5k July 03 (ABA)

Appendix K: Pilot Improving Heart Function booklet



APPENDIX 6

Improving heart function

This booklet has been written to help you understand how to **improve your heart function**, what you **can do** to achieve this, and what you can do to still make the **most out of life.**

This booklet has been designed working with your doctors and with other patients.

Your doctor or cardiologist (heart specialist) will give you the advice that is **right for you** based on his or her knowledge of your condition – it is very important that you follow this advice.

This booklet is in two sections, the first section is about '**understanding your heart function**' and the second is about '**improving your heart function**'.

UNDERSTANDING YOUR HEART FUNCTION

How does my heart work?

The heart is a muscle that beats. Each heartbeat is made of two actions. The muscle relaxes so that the heart can fill with blood. It then pumps or squeezes the blood out of the heart and round the body. Blood carries the oxygen and nutrients, or food, the body needs to keep working.

What is wrong with my heart?

Your heart is having some **problems with pumping enough blood round the body** to carry out normal activities. This is why you may experience symptoms such as shortness of breath, tiredness and swelling (particularly in the ankles). We will look at these in more detail later. By following a few simple guidelines and understanding your condition, you can improve the quality of your life and feel better.

What has caused it?

There are a number of things that can decrease the function of your heart: e.g. high blood pressure, narrow or leaking heart valves, heart attacks in the past, excessive alcohol intake, viral heart infections. Sometimes it is not easy to know, or find out, what has caused the symptoms of heart failure.

BUT....

Whatever the cause, **heart function can be improved** by a range of medications that are designed to reduce the work the heart has to do and help it to pump as well as it can. There are also some **lifestyle changes** that will help to **reduce any symptoms** you may have and **improve your heart function.**

How will I feel?

Here is a list of some of the symptoms that may affect you. Remember that **not everyone has the same symptoms** and **not everyone will have all of them.**

The main symptoms you are likely to experience are: -

- **Breathlessness:** either at rest or when doing normal every day activities such as washing and dressing, walking short distances or when lying flat in bed. The heart is not able to pump blood into the arteries as well as it should, this can cause fluid to build up in the lungs, which leads to breathlessness.
- **Fluid retention:** your legs and ankles may become swollen because the heart is not strong enough to pump all the fluid in your body back to the heart. The swelling is due to the body holding extra salt and water.
- **Weight gain:** this is due to the build-up of fluid in legs and ankles and other areas of the body.
- **Tiredness or general lack of energy:** this can happen with even a small amount of activity and may make it harder to carry out your normal tasks. This is because of the reduced blood flow to some parts of the body, especially the leg muscles when you walk.
- **Other symptoms** include dizziness, coughing, poor memory and problems sleeping.

The onset of these symptoms may be gradual. If any of your symptoms get worse or you experience any new symptoms, **contact your doctor right away**, as they may be able to help to reduce the symptoms.

What type of care can I expect?

Specialist doctors, GPs and nurses will manage your care. Your doctor will provide you with information that is right for you and will monitor your symptoms, adjusting your medicines to improve your symptoms and heart function. Your doctor will also regularly check your condition. How often you see your doctor depends on what is right for you and your condition.

There may be times when you may have to go into hospital and this can happen for a variety of reasons including:

- going to hospital for special tests
- going to the hospital to see a specialist doctor
- if your heart function becomes weaker, then you may have to go into hospital until you feel stable again.

In order to help your doctors and nurses to improve your heart function, **it is very important that you tell them about your symptoms** and if any changes have occurred in your symptoms. If your symptoms begin to get worse or you develop any new symptoms, or feel that you may be experiencing side effects from your medication, then contact your doctor or nurse right away. **The doctor can use the information to help improve your heart function.**

You must help your doctor to help you. Please use this booklet to **share information** with your doctors. When you fill in the tables in the back of this booklet you will be able to show this information to your doctors and help them to provide you with the best care for your heart.

IMPROVING YOUR HEART FUNCTION

What can be done?

There is much that can be done to improve your heart function- by a combination of making changes to your lifestyle and getting good treatment from your doctors. Unfortunately the damage to the pump function of your heart cannot be cured. But careful monitoring of your condition by your G.P., specialist doctors and nurses, together with you and your family, can allow you to have a good quality of life. **It makes good sense to do everything you can to improve the function of your heart.**

What can you do to help yourself?

A little extra care and a few simple lifestyle changes can make a **big difference** to how well you will feel. On the following pages are tips and guidelines that you should follow to take good care of yourself.

You should remember these basic points:

- Take your medication **regularly and carefully**
- Make sure you do **not** run out of tablets
- Report any **sudden** weight changes (over 2-3lbs/day) to your GP or nurse.
- Report any **increase** in breathlessness to your GP or nurse
- Report any **increase** in the swelling of your ankles to your GP or nurse.
- Live a **healthy lifestyle**- this booklet will help you to achieve this.

Improve your heart function: Take your medications as prescribed.

Taking your medication as prescribed every day is very important. Your medication will help to **control symptoms** and **support your heart's pumping action.**

- You may have to take several tablets at different times. If you **write down** the medications you are taking and at **what times** in the table at the back of this booklet, then this can help you to **remember** to take your medicine **correctly**. Go to the back of this booklet **right away and write them down**. If you are unsure about when and how to take your medications, talk to your doctor, nurse or pharmacist and they can help you to organise your tablets to make them easier to take.
- You **MUST** keep taking your tablets until you are told to stop by your doctor or nurse. If you stop taking your tablets without speaking to your nurse or doctor, your condition may deteriorate rapidly and you may have to go to hospital.
- You must make sure you **never** run out of tablets
- **Do not** take medication 'bought over the counter' without telling your doctor or nurse, as it may interfere with the tablets you are already taking and affect your heart function.

At the back of this booklet you will find some information about the medicines commonly used to improve heart function. You may be prescribed all of the drugs described in this booklet or you may need only some of them. Your doctor or nurse will explain why a particular drug is prescribed and how the doses of some will be increased over a period of time.

Remember:

Most people take these medications without any problems but sometimes side effects can occur. If you have problems, **DO NOT STOP** taking your tablets, contact your doctor.

Life style changes can improve heart function

There are several things you can do to help your heart pump more efficiently.

- **Weigh yourself regularly**

It is important to check your weight everyday because this will tell you whether you are retaining too much fluid.

Weigh yourself every morning after going to the toilet and before you eat, and **keep a daily record**. (You will find it helpful to write down your weight everyday in the chart provided with this booklet). Make copies of this chart, so that you can always keep a daily record of your weight.

Ask your doctor or nurse if you are unsure how to do this. If your weight seems to be increasing over a number of days, you may be retaining too much fluid. You must report any weight gain to your doctor.

The extra fluid that is being retained is more than your body needs and will add to the workload of your heart. It is important that you get help dealing with water retention early as it helps to prevent your symptoms from getting worse.

- **Be physically active, within the limits advised by your doctor**

It is important to keep as active as possible and discuss this with your doctor.

By being inactive you will gradually feel weaker and feel less able to do things. Exercise helps to keep your heart **working strongly**. You can do many things to increase your activity levels, such as walking, swimming or gentle exercise at the gym.

If you have been unwell and activity has been limited it is a good idea to set yourself small goals so that you can return to your normal levels of activity. Gentle exercising of arms and legs whilst sat on a chair for short periods of time will improve your fitness and make it easier for you to continue doing all of the things that you like to do. Make sure you always feel like you would be able to talk while you're exercising, **do not over exert yourself**.

- **Monitor your symptoms**

The way you feel will vary over time. However, you can help your doctor to maintain and improve your heart function by monitoring your symptoms and **telling your doctor of any changes.**

- **Eat less salt**

If you have a lot of salt in your diet your body is **more** likely to retain water. For this reason you should cut down on the salt in your diet. This is not just the salt that you add to your food but also the salt that is in many processed foods.

It is best not to add salt to your food after it is cooked. You may find that food tastes good with just a pinch of salt added during cooking.

Please seek advice before using a salt substitute as it may cause a problem with some of your medication. Other seasonings, such as pepper, herbs, lemon or onion are all safe.

Some processed foods are high in salt and are best avoided or limited in your diet; please check the labels on cans and packets. Salt appears as sodium on food packaging, choose foods that contain less salt or sodium.

To help you understand the labels on processed foods, you need to look at the 'amount per serving' or check the 'per 100g' information.

- Foods that have 1.25g of salt or 0.5g of sodium or more per 100g are high in salt and include foods like crisps, bacon, cheese, sausages, tinned meat, tinned fish in brine, smoked food, soups, canned foods, ready made meals.

- Foods that have 0.25g of salt or 0.1g of sodium per 100g are low in salt and include foods like rice, pasta, poultry, meat, eggs, potatoes, vegetables and fruit.

You will soon get used to eating foods with less salt and will not notice the difference.

- **Eat a healthy diet:** eating a healthy diet will help you to feel better and lose weight if you need to. Leaflets on healthy eating should be available from your GP surgery.

Following the points below will improve your diet.

- reduce the amount of fat in your diet and eat starchy foods like bread, pasta, rice, cereals and potatoes.
- aim to eat at least five portions of vegetables and fruit a day
- eat fish twice a week, one portion should be an oily fish such as herring, salmon, mackerel or sardines.
- Saturated fats are 'harmful' cholesterol in your blood while monounsaturated and polyunsaturated fats are 'protective' cholesterol. Cut down on saturated fats (found in butter, biscuits, cakes cheese, lard, coconut oil and palm oil) and instead have small amounts of polyunsaturated fats (found in cornflower oil, sunflower oil, Soya oil and fish oil) and monounsaturated fats (olive oil, walnut oil, rapeseed oil and in some margarines and spreads).

- **Smoking is harmful for the heart!** If you smoke, stop smoking. This will improve your general health and fitness as well as lessening risks to your heart. If you feel that you would like help to stop smoking then you can ring the NHS Smoking Helpline 0800 169 0 169.

- **Alcohol:** you should check with your doctor before drinking alcohol, to see whether it would be safe for you. Some medicines may react differently if alcohol is taken and alcohol can reduce the strength of the heart pumping action.

- **Get immunised:** flu can make you feel very unwell and it puts an extra strain on your heart. It is best to have a flu jab every year. You can discuss this with your doctor or practice nurse.

Turn to the back of the book now to choose how you can make a lifestyle change that will help improve your heart function.

Getting support.

It is **very important** to talk to others about how you are feeling, whether this is with family, friends or carers. They can also **support you to make any changes** you want to make to your lifestyle to improve your heart function.

When you have filled in the back of this booklet about what lifestyle changes you are going to make to improve your heart function, ask a close relative or friend to sign the contract too this will help you keep to it.

You may also want to join a 'heart support group' and talk to people who are experiencing the same things as you. Details of support groups can be obtained from the British Heart Foundation on 02074877110.

Lifestyle changes- your contract

Everyone's lifestyle is different, so choose which lifestyle change will be right for you. Use the questions below to help you make the lifestyle change, **go from thinking to doing, and improve your heart function!**

Tick which of the lifestyle changes you would like to make

☐ Increase physical activity
☐ Stop smoking
☐ Reduce/stop alcohol
☐ Eat less salt
☐ Eat a healthier diet

What is your final target?
(E.g. doing 30 minutes of exercise a day, eating five portions of fruit and vegetables, stop smoking)

1)……………………………………………………………………
2)……………………………………………………………………
3)……………………………………………………………………

What steps would you like to take to reach this target?
It is a good idea to start slowly, so set small goals to reach your target. (E.g. ring the smoking helpline for help, look at the salt content in foods, put time aside to exercise each day, gradually increase your exercise time each week, reduce your units of alcohol or cigarettes each week)

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You can reward yourself- it can help you to stick to your plan!
Write down what your reward will be when you reach your small goals and final target.

1)……………………………………………………………………
2)……………………………………………………………………
3)……………………………………………………………………

Support from others. Write down the name of someone who will either make the changes with you or who will support you in doing it.

………………………………………………………………………
………………………………………………………………………
………………………………………………………………………

Your signature ……………………………………

Date ………………………………………………

Medication chart

It really helps to write down what medications you are taking and at what times, by using the table below you are making a specific plan that you can commit to. You can also use the table to remind you of your medication and times!

Date started	Medication	When and where to be taken

Checking your weight

I agree to weigh myself every morning, after going to the toilet and before I eat.

Keeping a daily diary: You should fill this in immediately after you have weighed yourself.
Photocopy this table so you can use it once it is finished

Date	Weight	**Are there any changes? If there is a change of a couple of pounds over a few days please contact your doctor right away.**

Medications used to improve your heart function

ACE inhibitors (Angiotensin Converting Enzyme)

ACE inhibitors (Perindopril, Ramipril or any name ending in 'pril') can help to improve your symptoms and heart function. They relax blood vessels, making it easier for the heart to pump. ACE inhibitors reduce the amount of work the heart has to do and you may find you are able to do much more when taking this medication. ACE inhibitors are started at a low dose and gradually increased to a level that is right for you.

Beta Blockers

Beta blockers slow the rate that your heart pumps and, like ACE inhibitors, reduce the work that your heart has to do. This allows it to pump better. They are started at a low dose and gradually increased to the maximum dose or the highest level that is right for you. It may take weeks or months to reach the right level.

Diuretics (water tablets)

Diuretics (such as Frusemide or Bumetanide) work on the kidneys so that more water and salt are removed from the body in urine. In this way they reduce the amount of fluid that can build up in your body, so they are a great help in relieving any ankle swelling and breathlessness. The dose of your diuretic may change over time. By weighing yourself regularly you will notice if you suddenly put on weight and need to take an extra water tablet. The heart failure nurse or your doctor will explain this further to you.

Other drugs

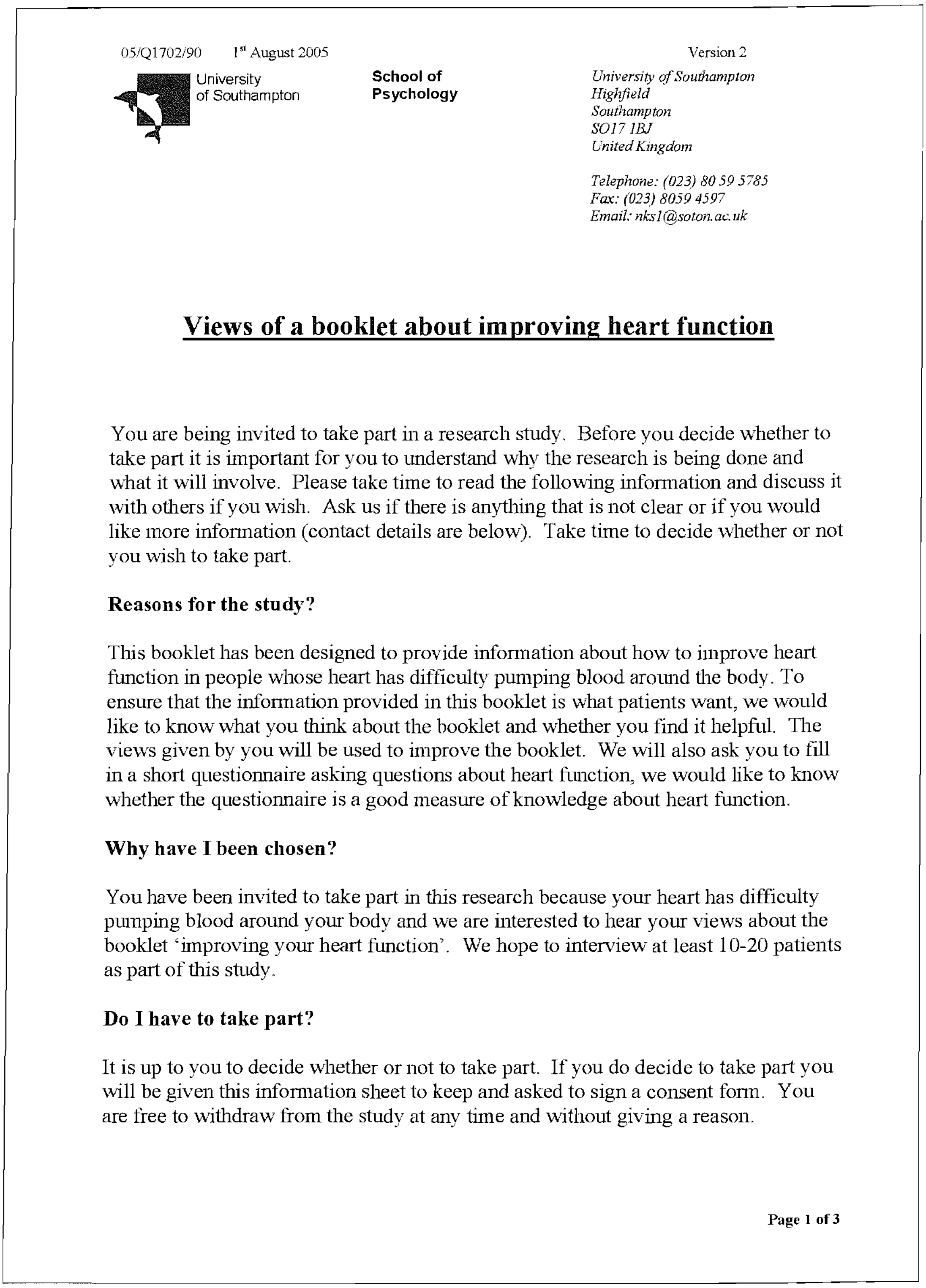
Digoxin: This slows and steadies the heart rate in some people and helps the heart to pump better. **Spironolactone:** This helps to reduce the salt and water retention in the body.
Warfarin or Aspirin: If you have an irregular heart rate, then you may be prescribed Warfarin or Aspirin, as it reduces the risk of a blood clot.

Write down any questions you want to ask your G.P. or your specialist doctor/nurse.

Notes

	Useful numbers
G.P	
Specialist nurse	
Hospital	

Appendix L: Information sheet used for study in chapter 7



05/Q1702/90 1st August 2005 Version 2

University of Southampton
School of Psychology

University of Southampton
Highfield
Southampton
SO17 1BJ
United Kingdom

Telephone: (023) 80 59 5785
Fax: (023) 8059 4597
Email: nks1@soton.ac.uk

Views of a booklet about improving heart function

You are being invited to take part in a research study. Before you decide whether to take part it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information (contact details are below). Take time to decide whether or not you wish to take part.

Reasons for the study?

This booklet has been designed to provide information about how to improve heart function in people whose heart has difficulty pumping blood around the body. To ensure that the information provided in this booklet is what patients want, we would like to know what you think about the booklet and whether you find it helpful. The views given by you will be used to improve the booklet. We will also ask you to fill in a short questionnaire asking questions about heart function, we would like to know whether the questionnaire is a good measure of knowledge about heart function.

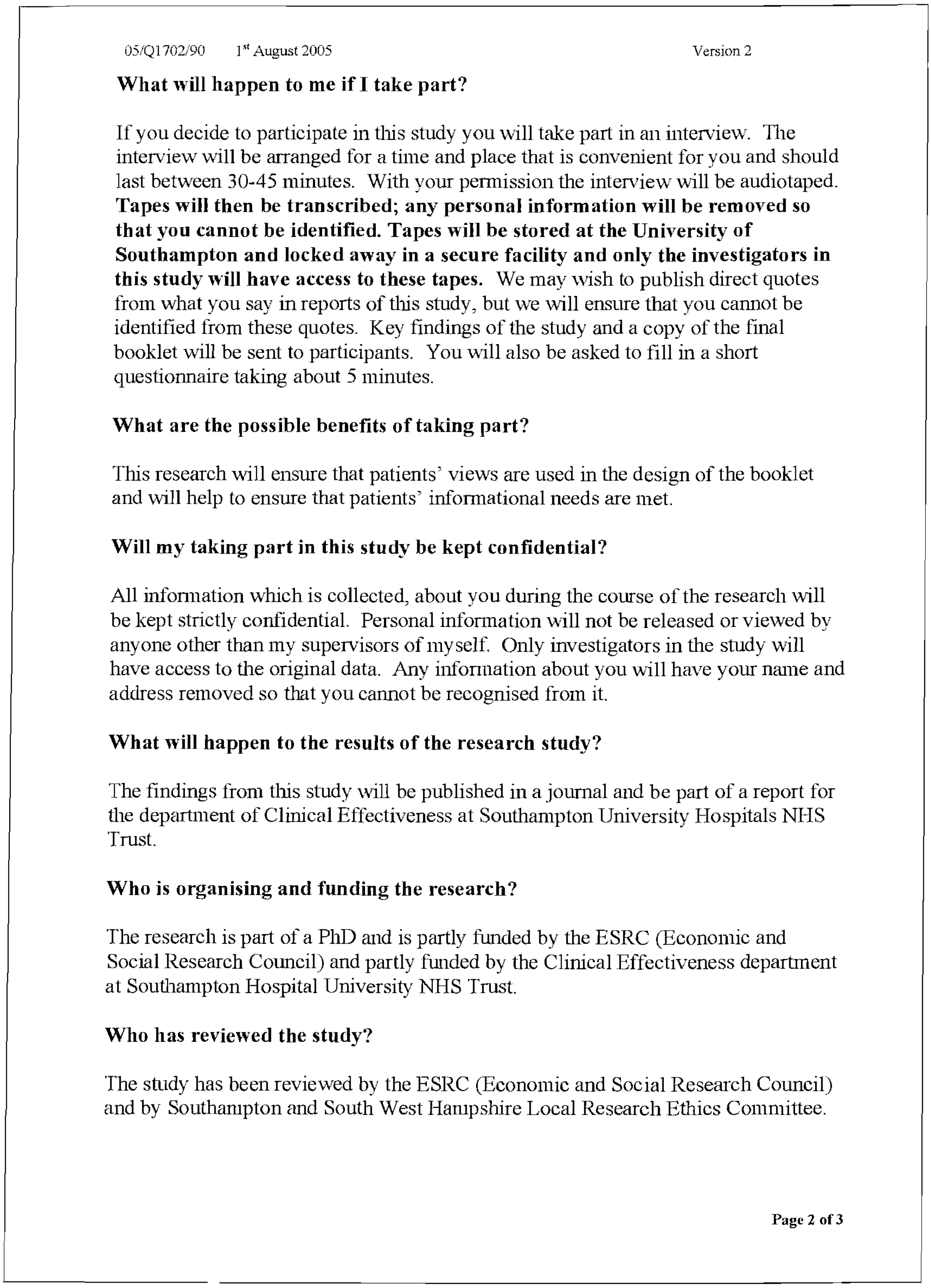
Why have I been chosen?

You have been invited to take part in this research because your heart has difficulty pumping blood around your body and we are interested to hear your views about the booklet 'improving your heart function'. We hope to interview at least 10-20 patients as part of this study.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and asked to sign a consent form. You are free to withdraw from the study at any time and without giving a reason.

Appendix L



05/Q1702/90 1st August 2005 Version 2

What will happen to me if I take part?

If you decide to participate in this study you will take part in an interview. The interview will be arranged for a time and place that is convenient for you and should last between 30-45 minutes. With your permission the interview will be audiotaped. **Tapes will then be transcribed; any personal information will be removed so that you cannot be identified. Tapes will be stored at the University of Southampton and locked away in a secure facility and only the investigators in this study will have access to these tapes.** We may wish to publish direct quotes from what you say in reports of this study, but we will ensure that you cannot be identified from these quotes. Key findings of the study and a copy of the final booklet will be sent to participants. You will also be asked to fill in a short questionnaire taking about 5 minutes.

What are the possible benefits of taking part?

This research will ensure that patients' views are used in the design of the booklet and will help to ensure that patients' informational needs are met.

Will my taking part in this study be kept confidential?

All information which is collected, about you during the course of the research will be kept strictly confidential. Personal information will not be released or viewed by anyone other than my supervisors of myself. Only investigators in the study will have access to the original data. Any information about you will have your name and address removed so that you cannot be recognised from it.

What will happen to the results of the research study?

The findings from this study will be published in a journal and be part of a report for the department of Clinical Effectiveness at Southampton University Hospitals NHS Trust.

Who is organising and funding the research?

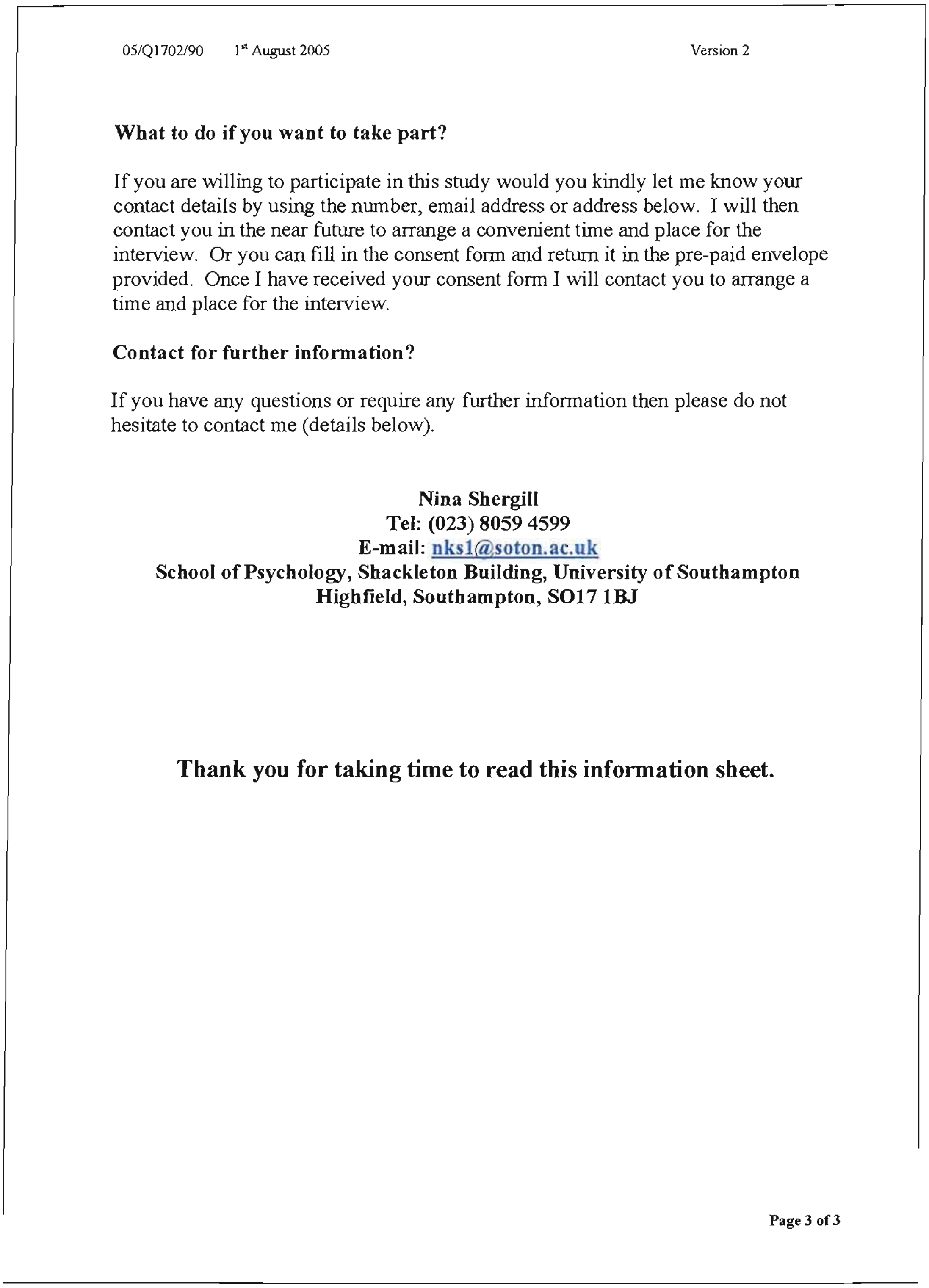
The research is part of a PhD and is partly funded by the ESRC (Economic and Social Research Council) and partly funded by the Clinical Effectiveness department at Southampton Hospital University NHS Trust.

Who has reviewed the study?

The study has been reviewed by the ESRC (Economic and Social Research Council) and by Southampton and South West Hampshire Local Research Ethics Committee.

Page 2 of 3

Appendix L



What to do if you want to take part?

If you are willing to participate in this study would you kindly let me know your contact details by using the number, email address or address below. I will then contact you in the near future to arrange a convenient time and place for the interview. Or you can fill in the consent form and return it in the pre-paid envelope provided. Once I have received your consent form I will contact you to arrange a time and place for the interview.

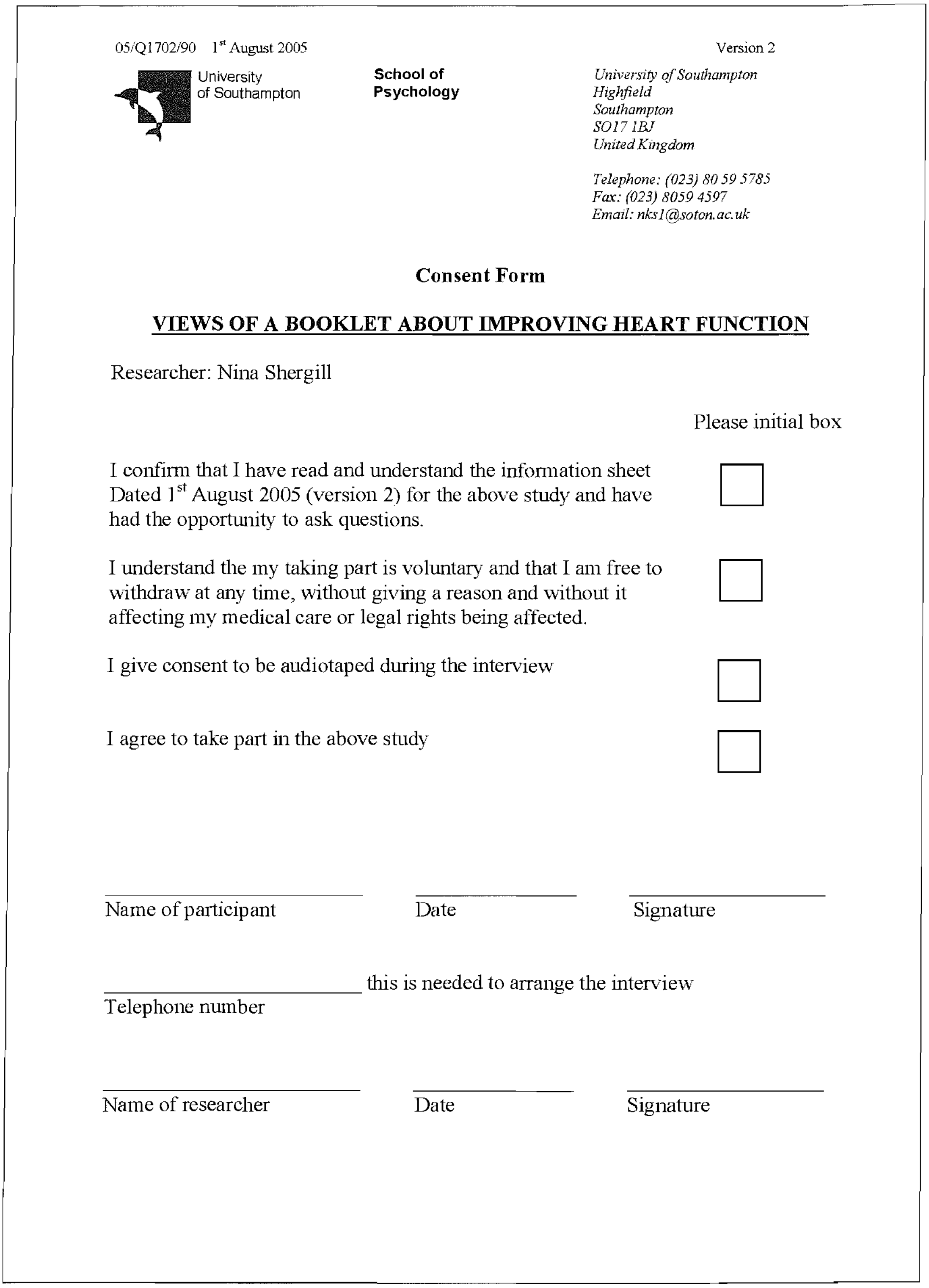
Contact for further information?

If you have any questions or require any further information then please do not hesitate to contact me (details below).

Nina Shergill
Tel: (023) 8059 4599
E-mail: nks1@soton.ac.uk
School of Psychology, Shackleton Building, University of Southampton
Highfield, Southampton, SO17 1BJ

Thank you for taking time to read this information sheet.

Appendix M: Consent form used for study in chapter 7



05/Q1702/90 1st August 2005

Version 2

University
of Southampton

**School of
Psychology**

*University of Southampton
Highfield
Southampton
SO17 1BJ
United Kingdom*

*Telephone: (023) 80 59 5785
Fax: (023) 8059 4597
Email: nks1@soton.ac.uk*

Consent Form

VIEWS OF A BOOKLET ABOUT IMPROVING HEART FUNCTION

Researcher: Nina Shergill

Please initial box

I confirm that I have read and understand the information sheet Dated 1st August 2005 (version 2) for the above study and have had the opportunity to ask questions. ☐

I understand the my taking part is voluntary and that I am free to withdraw at any time, without giving a reason and without it affecting my medical care or legal rights being affected. ☐

I give consent to be audiotaped during the interview ☐

I agree to take part in the above study ☐

Name of participant	Date	Signature

____________________ this is needed to arrange the interview
Telephone number

Name of researcher	Date	Signature

Appendix N: Interview schedule for study in chapter 7

Stage 1: Elicitation of salient beliefs

Participants were asked the following questions for the following management behaviours: taking medications as prescribed, participating in regular physical activity, daily weighing and eating a low salt and healthy diet

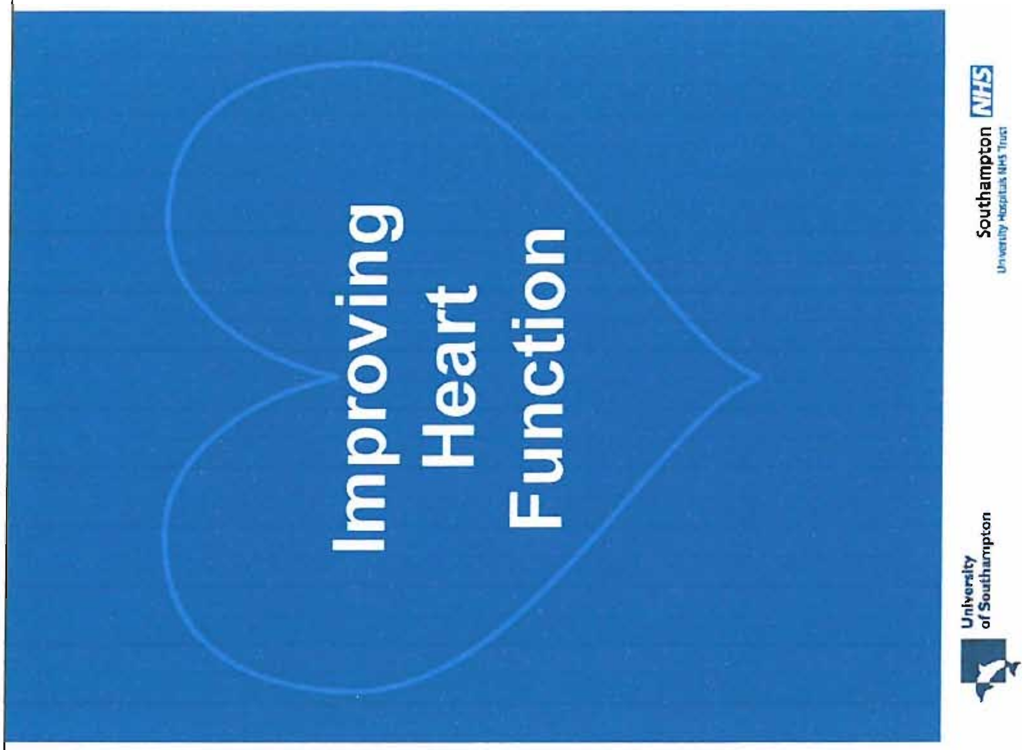
Behavioural beliefs:
(1) What are the advantages of performing the behaviour
(2) What are the disadvantages of performing the behaviour

Control beliefs:
(1) Are there any problems in performing the behaviour
(2) Is there anything that could help you to perform this behaviour

Stage 2: Participants' views about the booklet

1) What are your thoughts about what you have just read?
2) How did you find the information in this section?
3) Do you see any problems with doing what the booklet suggests?
4) Do you do any things that are different?
5) Do you think this would help you?
6) Are there any changes that could be made to help you more?

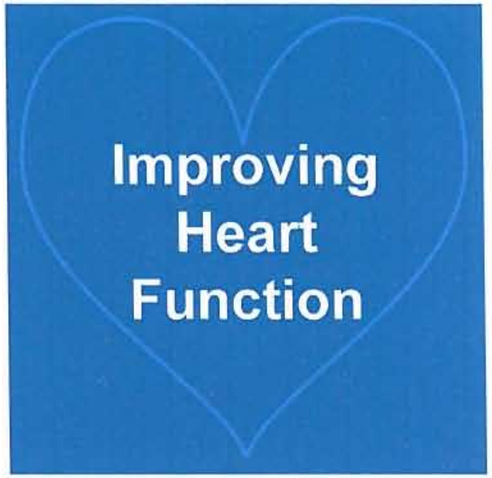
Appendix O: Improving heart function booklet



Improving
Heart
Function

Southampton
University Hospitals NHS Trust
NHS

University
of Southampton



January 2006

This booklet was developed by Nina Shergill and Professor Lucy Yardley (University of Southampton) from a booklet originally drafted by doctors and nurses at Southampton General Hospital and using material from a booklet developed by Margaret Martin (Heart Specialist Nurse, Portsmouth Hospitals NHS Trust).

This booklet has been approved by Dr Zaman (Consultant in Medicine for older People) and Dr Waller (Clinical Service Director and Consultant Cardiovascular Physician) from Southampton General Hospital.

Improving Heart Function

This booklet has been written to help you understand how to **improve your heart function** and what **you can do** to achieve this.

This booklet has been designed by working with your doctors and with other people who have your heart condition.

Your doctor or cardiologist (heart specialist) will give you the advice that is **right for you** based on their knowledge of your condition - it is very **important** that you follow this advice.

This booklet is in two sections, the first section is about **'Understanding your Heart Function'** and the second is about **'Improving your Heart Function'**.

Understanding your heart function

How does my heart work?

Your heart is a muscle that beats. Your heart sends blood to the lungs to get oxygen. It then pumps this blood around the body to give it the oxygen and nutrients it needs to keep working.

What is wrong with my heart?

Your heart is having some problems pumping enough blood around your body, so your body is not getting as much oxygen as it needs. This is why you may experience symptoms such as shortness of breath and tiredness. We will look at these in more detail later. By following a few simple guidelines and understanding your condition, you can improve the quality of your life and feel better.

What has caused it?

Things that can decrease the function of your heart include high blood pressure, narrow or leaking heart valves, heart attacks in the past, excessive alcohol intake, viral heart infections. Sometimes it is not easy to know, or find out, what has caused your heart condition.

BUT.....

Whatever the cause, **heart function can be improved** by:

- Taking a range of medications to reduce the work the heart has to do and help it pump better.
- Monitoring your condition to control your symptoms.
- Making changes to your lifestyle to reduce symptoms and improve your heart function.

How will you feel?

Here is a list of some of the symptoms that may affect you. These symptoms are due to your heart not pumping properly, not taking your medications properly and not eating properly (e.g. eating too much salt). Remember **not everyone has the same symptoms and not everyone will have all of them.**

- Breathlessness: at rest or when you are doing normal every day activities such as washing and dressing, walking short distances or when you are lying flat in bed. The heart is not able to pump blood into the arteries as well as it should. This causes fluid to build up in the lungs, which causes breathlessness.
- Fluid retention: your legs, ankles and stomach may become swollen because the body is holding onto extra salt and water. This happens because the heart is not strong enough to pump all the fluid in your body back to the heart.
- Weight gain: this is the extra weight of the fluid that the body is holding.
- Tiredness or general lack of energy: this can happen with a small amount of activity, making it harder for you to carry out your normal tasks. This is because of the reduced blood flow to some parts of the body, especially the leg muscles when you walk.
- Other symptoms: include dizziness, coughing, poor memory, confusion and problems sleeping.

The onset of these symptoms may be gradual. If your symptoms get worse or you experience any new symptoms, **contact your doctor right away**, who can help you to reduce them. Remember untreated symptoms may get worse.

What type of care can you expect?

Specialist doctors, GPs and nurses will manage your care.

Your doctor/GP will

- provide you with information that is right for you
- answer any questions you have
- adjust your tablets to improve your symptoms and heart function
- listen to your feelings and views.

How often you see your doctor depends on what is right for you and your condition.

There may be times when you have to go to hospital. This can be for a variety of reasons, including:

- going to hospital for special tests
- going to the hospital to see a specialist doctor
- if your heart function becomes weaker, then you may have to go into hospital until you feel stable again.

How can you help your doctor to help you?

It is very important that you tell your doctor/nurse if you have any new symptoms, if your symptoms get worse or if you are experiencing any side effects from your medication. Your doctor will use this information to help manage your symptoms and heart function.

Please use this booklet to **share information** with your doctors. When you fill in the tables in this booklet you will be able to show this information to your doctors and help them to provide you with the best care for your heart.

Improving Heart Function

What can be done?

There is much that can be done to improve your heart function. The damage to the pump function of your heart cannot be cured. But careful monitoring of your condition, along with good treatment from your doctors, can allow you to have a good quality of life. **It makes good sense to do everything you can to improve the function of your heart.**

What can you do to help yourself?

You are the most important person in managing your heart condition. A little extra care and a few simple lifestyle changes can make a **big difference** to how well you feel. On the following pages are tips and guidelines you should follow to take good care of yourself.

Taking your medications

Taking your medications properly can have a **positive** effect on your life. Other people with your heart condition find that they **feel better** when they take their medications properly.

The medications you take will help to

- improve your heart's pumping action and keep it working properly
- help to control your symptoms
- make you feel better
- help you live longer

All your medications work in different ways. In this booklet on page 24 you will find some information about the medicines commonly used to improve heart function.

Taking your medications

Your medications will only work if you **take them as prescribed by your doctor**. Not taking your medications will result in your symptoms and heart condition getting worse. It is very important that you remember to take your medications and take them at the right times. **You must take your medicines even when you are feeling well.**

What should you do if you have side effects?

Most people take their medications without any problems but sometimes side effects can occur. If you start feeling unwell or get any new symptoms please contact your doctor right away. **DO NOT STOP** taking your tablets until you are told to by your doctor.

What other things do you need to know?

- You must make sure you never run out of tablets
- **Do not** take any medications or supplements bought from a chemist/health shop without telling your doctor or nurse. They may interfere with the tablets you are already taking.

If you have trouble remembering to take your tablets, what can you do?

Other people with your heart condition have found that writing down their tablets and which time to take them can be helpful. Enclosed with this booklet is a medication chart you can use to remind yourself.

- Put the chart somewhere you will see it everyday
- If you still have problems taking your medications then speak to your doctor, nurse or chemist. They can help you to organise your tablets to make them easier to take.
- There are also kits available from chemists to help organise your tablets.

The medication chart enclosed can also be used to keep up to date with changes in your medication. You just have to remember to change the chart every time your medication changes.

Now write down your medications and when to take them on the medication chart and put it somewhere you will see it often every day.

Be physically active

Doctors agree that **planned and controlled physical activity** is one of the best ways to **strengthen your heart** and **reduce your symptoms**. This will make it easier for you to continue doing all the things that you like to do. Being inactive will gradually make you feel weaker and less able to do things.

What types of physical activity are safe for me?

You can do many things to increase your activity levels, such as walking, swimming, gardening or housework. If you have been unwell and activity has been limited it is a good idea to set yourself **small goals**. Gentle exercising of the arms and legs whilst sat on a chair for short periods of time will improve your fitness. If you are unsure about the types of physical activity you can do safely then discuss this with your doctor.

How can you do physical activity safely?

- When doing physical activity you should feel as though your **heart rate has increased slightly** but you **can still talk while doing the activity**.
- Make sure you take time to rest after doing some physical activity.
- If your symptoms get **worse** while being physically active **you must stop right away**.

How much physical activity can you do?

It is normal to worry about starting physical activity especially if you get tired or breathless. How much physical activity you can do depends on your health and levels of fitness. You must avoid pushing yourself too much physically. This will strain your heart and increase your breathlessness and tiredness.

How can you start to be physically active?

A good way to start being physically active is to set yourself easy targets.

If you are not doing much physical activity at present then start slowly by doing physical activity for only 5 or 10 minutes a day.

If you can, then aim to gradually increase to an average of 15 minutes a day, but only if you are comfortable and not short of breath.

Monitoring your fluid retention

What is fluid retention?

- Fluid retention is when your heart is not strong enough to pump all the fluid in your body back to the heart.
- The extra fluid your body holds also has to be pumped by the heart and adds to the workload of your heart.
- When fluid builds up in the lungs it can increase breathlessness
- Fluid retention causes swelling in your legs, hands and stomach
- It is very important that you get help dealing with fluid retention as it will worsen your condition.

There are a few simple changes you can make to your lifestyle that can help you to monitor your fluid retention and help you to reduce the amount of fluid your body may retain.

How will weighing everyday help with my fluid retention?

- Fluid build-up **increases your weight**.
- Weighing yourself **regularly** will help you to find out if you are retaining fluid even before swelling begins.
- Even if your weight remains steady, you should still weigh yourself regularly, as fluid retention can happen at any time.
- **You should weigh yourself every morning after going to the toilet and before you eat.**
- Other people with your heart condition monitor weight changes by keeping a daily record. You can do this by using the weight recording chart that is enclosed with this booklet.
- If you gain 3-4 pounds or more in weight over two days this is probably caused by your body retaining water rather than any change in your diet.
- **Report any weight gain to your doctor** as changes to your medication can fix these problems early.
- Follow your doctor's advice about adjusting your water tablets according to weight gain or to limit the fluid you drink.

Reducing your fluid retention

How does eating salt effect fluid retention?

Salt causes the body to hold onto fluid. The more salt you have, the more likely your body will retain fluid and your symptoms will worsen.

How can you reduce salt in your diet?

- **Do not add** additional salt to your food during or after preparation
- Seek **advice** from a doctor before using a salt substitute
- Look at the **salt content** on canned, processed or packaged foods and only choose foods that contain less salt/sodium.
- You should aim to have less than 6 grams of salt a day (one level teaspoon contains 6 grams of salt).
- Use **other** seasonings to add flavour to food. Seasonings, such as pepper, herbs, garlic, lemon or onion are all safe.

How can you check for salt in processed foods?

- Salt appears as sodium on food packaging.
- The British Heart Foundations says that foods containing **0.25g of salt per 100g** or **0.1g of sodium per 100g** are low in salt; you should avoid foods with more salt.

Foods high in salt	Foods low in salt
Crisps, peanuts, salty snacks, bacon, sausages and tinned meats, processed and canned foods, cheese, smoked foods and tinned fish in brine.	Rice, pasta, potatoes, poultry, meat, eggs, fruit and vegetables

Healthy lifestyle

There are many different things that you can do to lead a healthy lifestyle. Follow the tips below to lead a healthier lifestyle:

- Eat a healthy diet: you should reduce the amount of saturated fats in your diet and eat at least five portions of vegetables and fruit a day. You can get more information on healthy eating from leaflets available from your GP surgery.
- If you smoke, stop smoking: if you feel that you would like help you can ring the NHS Smoking Helpline 0800 169 0 169
- Reduce alcohol: you should check with your doctor before drinking alcohol. Some medicines may react differently if alcohol is taken.
- Get immunised: you should have a flu jab every year. Flu can make you feel very unwell and puts an extra strain on your heart.

Getting support

- It is very important to talk about how you are feeling, whether this is with family, friends or carers. They can **support you to make changes** to your lifestyle to improve your heart function.
- You may also want to join a 'heart support group' and talk to people who are experiencing the same things as you. Details of support groups can be obtained from the British Heart Foundation on 02074877110.

You should remember these basic points to IMPROVE YOUR HEART FUNCTION:

- **Taking your medications**
  - Take your medication regularly and carefully
  - Do not stop taking your tablets unless your doctor has told you to
  - Make sure you do not run out of tablets
- **Being physically active**
  - Regular physical activity will strengthen your heart
  - Make sure you rest after physical activity
- **Monitor your fluid retention**
  - Monitor and record your fluid retention by weighing yourself everyday
  - Weigh yourself every morning after going to the toilet and before you eat
  - Report any sudden weight changes (over 2-3lbs/day) to your GP or nurse.

- **Reduce your fluid retention**
  - Reduce your salt intake to reduce fluid retention
- **Monitor your symptoms**
  - Report any increase in breathlessness to your GP/nurse
  - Report any increase in swelling to your GP/nurse.
  - Report any new or worsening symptoms to your GP/nurse

Medications used to improve your heart function

There are many medications used to improve heart function. Below you will find information about the medicines commonly used to improve heart function. You may be prescribed all of the drugs described in this booklet or you may need only some of them. Your doctor or nurse will explain why a particular drug is prescribed and how the doses of some will be increased over a period of time.

ACE inhibitors (Angiotensin Converting Enzyme)

ACE inhibitors (Perindopril, Ramipril or any name ending in 'pril') can help to improve your symptoms and heart function. They relax blood vessels, making it easier for blood to move around the body. They reduce the amount of work the heart has to do. ACE inhibitors also help to lower the amount of salt and water in your body. You may find that you are able to do much more when taking this medication properly. ACE inhibitors are started at a low dose and slowly increased to a level that is right for you.

Beta Blockers

Beta blockers (such as Bisoprolol, Carvedilol) help the heart to pump better and, like ACE inhibitors, reduce the work that your heart has to do. Beta blockers prevent the heart from beating too fast; this helps you to do more physical activity without stressing your heart. They are started at a low dose and slowly increased to the dose that is right for you. It may take weeks or months to reach the right level.

Diuretics (water tablets)

Diuretics (such as Frusemide or Bumetanide) work on the kidneys to remove water and salt from the body in urine. They reduce the amount of fluid that can build up in your body and relieve any ankle swelling and breathlessness. The dose of your diuretic may change over time. Weighing yourself regularly will help you to notice if you are holding extra fluid. If this happens contact your doctor.

Other drugs

Digoxin: slows and steadies the heart rate in some people and helps the heart to pump better.

Spironolactone: helps to reduce the salt and water retention in the body.

Warfarin or Aspirin: Warfarin or Aspirin prevent blood clots from forming.

Blood tests: As some of the drugs can interfere with the function of the kidneys, regular blood tests are taken to ensure that the kidneys remain healthy.

Write down any questions you want to ask your G.P. or your specialist doctor/nurse.

	Useful numbers
G.P	
Specialist nurse	
Hospital	

Further information

If you need any further information about your heart condition or its treatment then please ask your doctor or nurse. NHS Direct can also give you more information about your heart condition, contact them on 0845 46 47 or on the website www.nhsdirect.nhs.uk.

Medications Chart

- Remind yourself - write down what medications you are taking and at what times.
- Put the list somewhere you will see it everyday
- You can also use the table to keep up to date with changes in your medication.
- Photocopy this page or make copies of this chart so that you can use it over and over again.

Date started	Tablet	When / where to take them

Weight Recording Chart

I agree to weigh myself every morning, after going to the toilet and before I eat.

- Keep this chart by your weighing scales and fill in your weight everyday.
- Make a copy or photocopy this table so you can use it over and over again.

Date	Weight	Date	Weight

If you gain 3-4 pounds or more in weight over a few days please contact your doctor right away.

Appendix P

Appendix P: Overview of the theory-base, patient literature and patient feedback which informed the development of the IHF booklet

Section of booklet and content	Theory-based approaches, previous research and patient feedback	Sample of written information
Understanding your Heart Function		
How does my heart work? What is wrong with my heart? What has caused it? How will I feel? What type of care can you expect? How can you help your doctor to help you?	*Theory-based approaches:* Illness representations: Identity Cause Time-line Perceived consequences Curability/controllability *Existing literature* Patients have an acute model of heart failure *Patient feedback* Controllability needs to be further emphasised	*controllability dimension* "Whatever the cause, heart function can be improved by: - taking a range of medication to reduce the work the heart has to do and help it pump better - monitoring your condition to control your symptoms - making changes to your lifestyle to reduce symptoms and improve your heart function" *cause dimension* "These symptoms are due to your heart not pumping properly, not taking your medications properly and not eating properly (e.g. eating too much salt)"
Improving Heart Function		
Introduction to this section What can be done? What can be done to help yourself?	*Theory-based approaches* Illness representations: Curability/controllability *Patient feedback* Controllability needs to be further emphasised	"There is much that can be done to improve your heart function. The damage to the pump function of your heart cannot be cured. But carefully monitoring of your condition, along with good treatment form your doctors, can allow you to have a good quality of life. It makes good sense to do everything you can to improve the function of your heart"

Appendix P

Section of booklet and content	Theory-based approaches, previous research and patient feedback	Sample of written information
Taking medications as prescribed What should you do if you have side effects? What other things do you need to know? If you have trouble remembering to take your tablets, what can you do?	*Theory-based approaches* Behavioural beliefs - unpleasant side effects - keep heart working - feel better - live longer Control beliefs - difficulty managing medications - difficulty keeping up to date with changes in medicines - making lists - stacking kits from chemist help Mediation chart incorporating implementation intentions Modelling *Existing literature* Necessity and concerns of medication Side effects Forgetfulness in managing medication Continuation of medication until advised otherwise by health professionals	*Promoting positive attitude and modelling* “Taking your medications properly can have a positive effect on your life. Other people with your heart condition find that they feel better when they take their medications properly” *Modelling and increasing PBC* “Other people with your heart condition have found that writing down their tablets and which time to take them can be helpful. Enclosed with this booklet is a medication chart you can use to remind yourself”

Appendix P

Section of booklet and content	Theory-based approaches, previous research and patient feedback	Sample of written information
Physical activity What types of physical activity are safe for me? How can you do physical activity safely? How much physical activity can you do? How can you start to be physically active?	*Theory-based approaches* Behavioural beliefs - keep mobile/fitness - benefit to heart - benefit to symptoms - worsening of symptoms Control beliefs - breathlessness/tiredness - other physical problems - physical limitations - exercising safely Goal setting *Existing literature* Reduction of physical activity following diagnosis Questions about type and amount of activity *Patient feedback* Majority of patients did not identify positive benefits of exercise for their heart Difficulty identifying and setting goals	*Promoting a positive attitude* "Doctors agree that planned and controlled physical activity is one of the best ways to strengthen your heart and reduce your symptoms. This will make it easier for you to continue doing all the things that you like to do" *Increasing PBC and goal setting* "A good way to start being physically active is to set yourself easy targets. If you are not doing much physical activity at present then start slowly by doing physical activity for only 5 or 10 minutes a day"
Monitoring your fluid retention What is fluid retention?	*Patient feedback* Lack of knowledge about fluid retention	"The extra fluid your body holds also has to be pumped by the heart and adds to the workload of your heart" "It is very important that you get help dealing with fluid retention as it will worsen your condition"

Appendix P

Section of booklet and content	Theory-based approaches, previous research and patient feedback	Sample of written information
Weighing regularly How will weighing everyday help me with my fluid retention?	*Theory-based approaches* Behavioural beliefs - controlling fluid retention Control beliefs - stable weight Modelling Weighing chart incorporating an implementation intention to enable self monitoring *Existing literature* Patients consider weighing unimportant in self-management *Patient feedback* Majority of patients did not know that daily weighing was to detect early signs of fluid retention.	*Knowledge deficits targeted* "Weighing yourself regularly will help you to find out if you are retaining fluid even before swelling begins" *Increase PBC and modelling* "Other people with your heart condition monitor weight changes by keeping a daily record. You can do this by using the weight recording chart that is enclosed with this booklet"
Salt restriction How does eating salt affect fluid retention? How can you reduce salt in your diet? How can you check for salt in processed foods?	*Theory-based approaches* Behavioural beliefs - bland food Control beliefs - how to identify foods low in salt - knowing what to eat *Existing literature* Lack understanding about how to reduce salt intake Difficulty interpreting salt content in food *Patient feedback* Majority of patients did not know that salt promoted fluid retention.	*Increasing PBC* "Salt appears as sodium on food packaging. The British Heart Foundation says that food containing 0.25g of salt per 100g or 0.1g of sodium per 100g are low in salt; you should avoid foods with more salt" "Use other seasonings to add flavour to food. Seasonings such as pepper, herbs, garlic, lemon or onion are all safe"

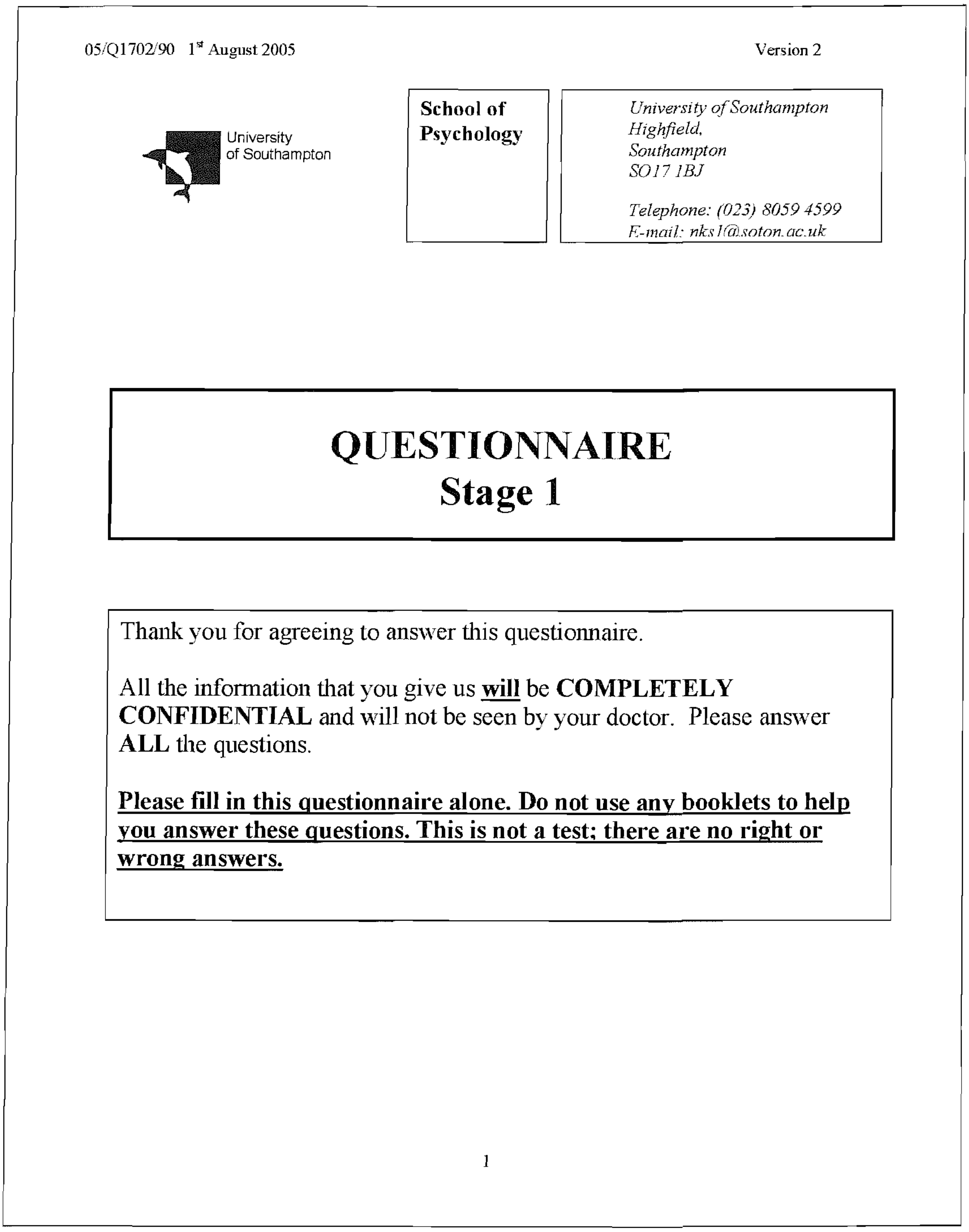
Section of booklet and content	Theory-based approaches, previous research and patient feedback	Sample of written information
Other information		
Information on eating a healthy diet, stopping smoking, immunisation against influenza, getting support, medications commonly prescribed for heart failure, section to write down questions for doctor, useful numbers and directing patients to further information.	*Patient feedback:* Sections on smoking and alcohol not as relevant Information about spironolactone Information about blood tests Setting small goals useful Difficulty identifying and setting goals	Social support "It is very important to talk about how you are feeling, whether this is with family, friends or carers. They can support you to make changes to your lifestyle to improve your heart function'.

Appendix Q: Recommendations for written information incorporated by the NICE and IHF booklet

Appropriateness of content	**IHF booklet**	**NICE booklet**
Information is written in clear and simple language that is understandable to the reader.	✓	x
Avoid technical words and acronyms. When using medical terminology provide an explanation and avoid frightening language.	✓	x
Make written information patient friendly by using personal pronouns to personalise messages.	✓	✓
Use positive language and avoid negative, patronising or alarmist language	✓	1/2 (uses term heart failure)
Provide balanced information, including an honest evaluation of potential risks and benefits.	✓	✓
Content of booklet		
Ensure that common concerns and misconceptions are addressed	✓	X
Provide specific instructions	✓	1/2
Include quantitative information where appropriate	n/a	n/a
Provide information about other available services or resources	✓	✓
Leaflets should be dated (determines whether the information contains recent information)	✓	✓
Use short sentences to convey information (approximately 15-20 words)	✓	✓
Emphasise important information by highlighting or reinforcement	✓	x
Use present and active tenses when possible	✓	1/2
Legibility		
Use diagrams and pictures to illustrate text	x	x
Use lower case letters with upper case letters where appropriate. This is easier to read than upper case alone.	✓	✓
Present information in small blocks of text	✓	✓
Use question and answer, bulleted or numbered points to divide text	✓ (bullet points and question and answer)	✓ (bullet points)
Use clear headings	✓	✓
An easy to read font size should be used and this should be point 12 or larger. When producing information for older adults the font size should be 14 or greater.	✓ Font size 14	X Font size 12
Use white space which makes information easier to read	✓	✓
Other		
Consider the information needs of minority groups, providing information in a range of languages	x	x
Produce a range of information materials on a particular topic to cater for differing patient requirements and information needs.	x	x

Key: ✓= yes, x = no, ½= sometimes

Appendix R: Pilot knowledge questionnaire



05/Q1702/90 1st August 2005

Version 2

University of Southampton

School of Psychology

University of Southampton
Highfield,
Southampton
SO17 1BJ

Telephone: (023) 8059 4599
E-mail: nks1@soton.ac.uk

QUESTIONNAIRE
Stage 1

Thank you for agreeing to answer this questionnaire.

All the information that you give us **will** be **COMPLETELY CONFIDENTIAL** and will not be seen by your doctor. Please answer **ALL** the questions.

Please fill in this questionnaire alone. Do not use any booklets to help you answer these questions. This is not a test; there are no right or wrong answers.

1

QUESTIONS ABOUT YOUR HEART CONDITION

The following questions are about your heart condition. **Tick the box next to the answer that you think is right.** Please tick just **ONE** answer for each question.

Do not use any written information to help you or ask anyone to help you with the answers. Fill in these questions alone. **THIS IS NOT A TEST**. If you are not sure what the answer is, tick the one that you think would be the most likely answer.

Patients who want to improve their heart function should:

☐ Avoid all physical activity
☐ Do regular light exercise but not enough to make symptoms worse
☐ Do hard and strenuous exercise to help strengthen the heart
☐ Do exercise to make you very out of breath and tired

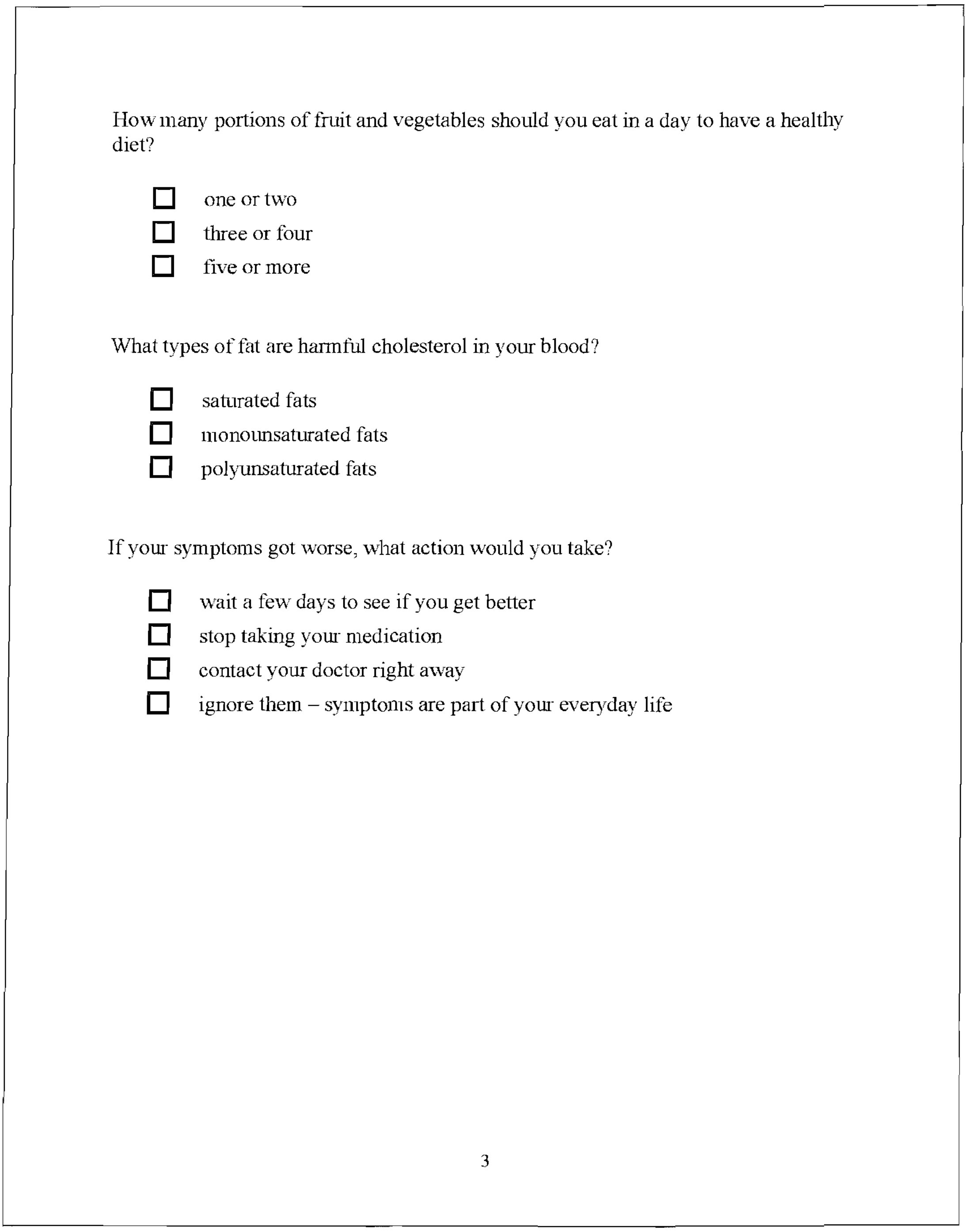
To monitor you heart function, you should weigh yourself:

☐ After breakfast, after going to the toilet
☐ Before breakfast, before going to the toilet
☐ After breakfast, before going to the toilet
☐ Before breakfast, after going to the toilet

If you have a lot of salt in your diet, which of the following is true:

☐ salt helps you to retain water and increases your weight
☐ salt helps you to retain water and decreases your weight
☐ salt helps you to lose water and increase your weight
☐ salt helps you to lose water and decrease your weight

Appendix R



How many portions of fruit and vegetables should you eat in a day to have a healthy diet?

☐ one or two
☐ three or four
☐ five or more

What types of fat are harmful cholesterol in your blood?

☐ saturated fats
☐ monounsaturated fats
☐ polyunsaturated fats

If your symptoms got worse, what action would you take?

☐ wait a few days to see if you get better
☐ stop taking your medication
☐ contact your doctor right away
☐ ignore them – symptoms are part of your everyday life

3

For the following questions, there is more than one correct answer; please tick all that you think are right.

What are the common symptoms of your heart condition?

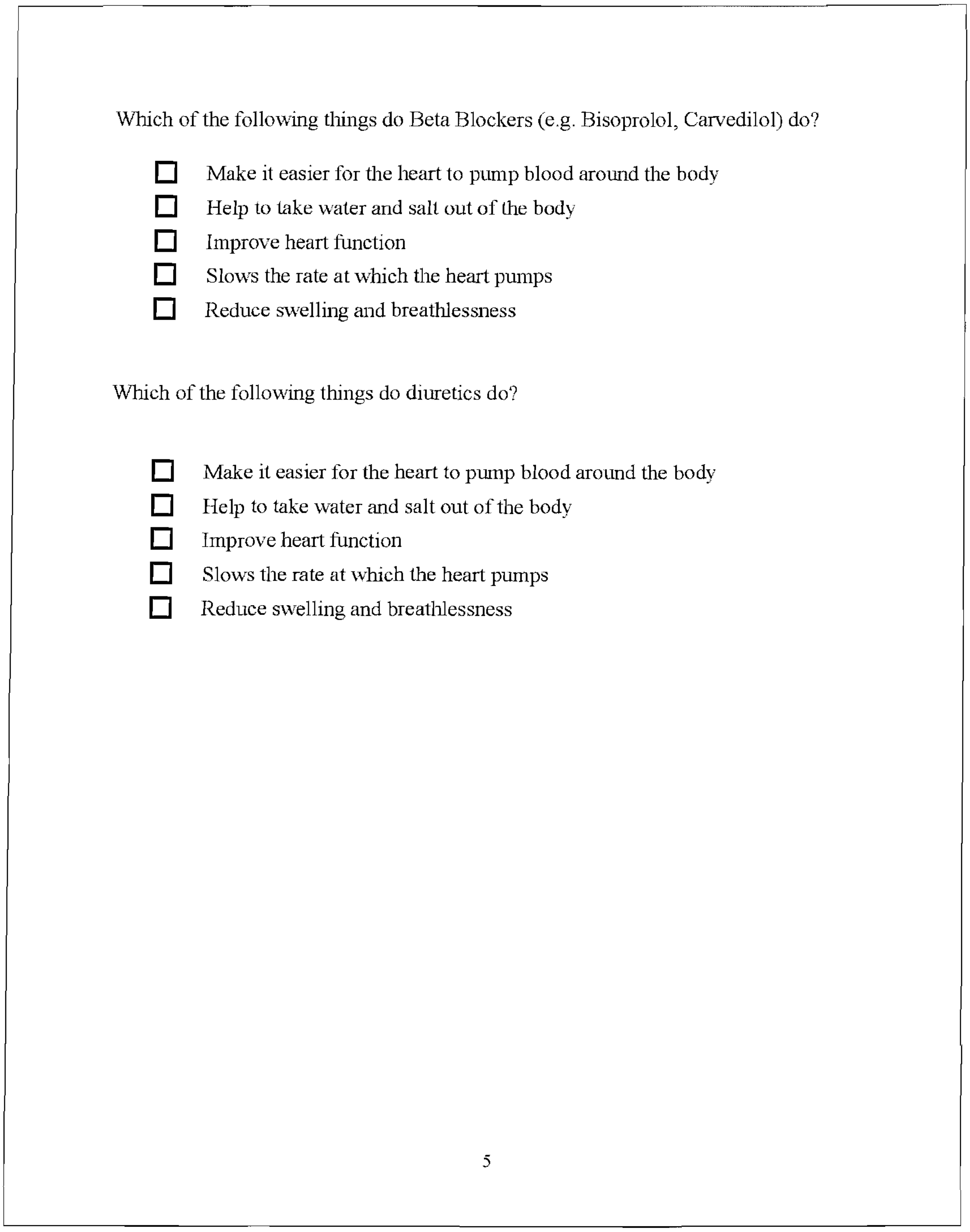
☐ Shortness of breath
☐ Blurred vision
☐ Skin rash
☐ Swelling of the ankles or legs
☐ Tiredness
☐ Retaining fluid
☐ Difficulty swallowing
☐ High temperature

The following three questions are about your medication.

Which of the following things do ACE inhibitors (e.g. Perindopril, Ramipril, or any name ending in pril) do?

☐ Make is easier for your heart to pump blood around the body
☐ Help to take water and salt out of the body
☐ Improve heart function
☐ Slow the rate at which the heart pumps
☐ Reduce swelling and breathlessness

Appendix R



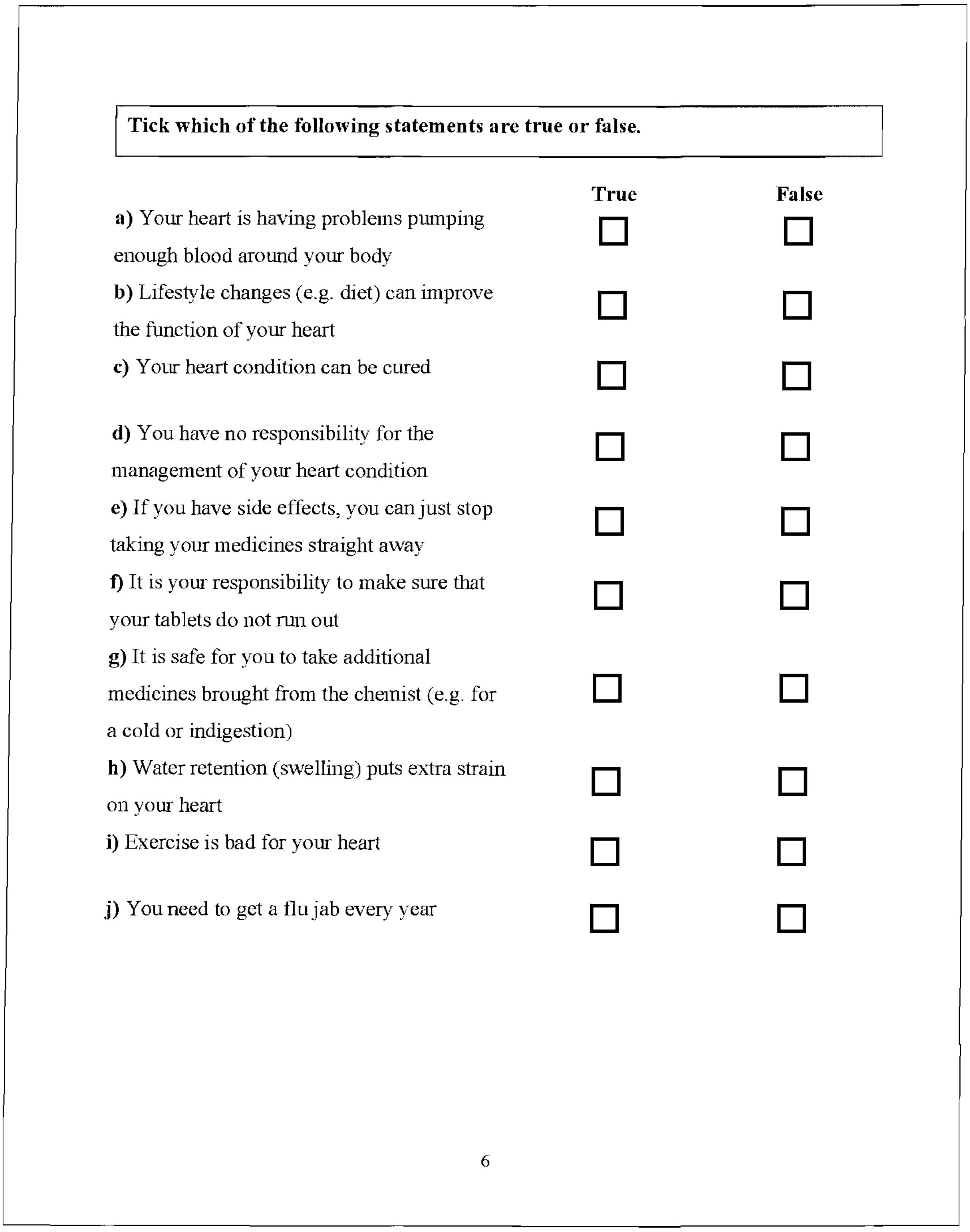
Which of the following things do Beta Blockers (e.g. Bisoprolol, Carvedilol) do?

- ☐ Make it easier for the heart to pump blood around the body
- ☐ Help to take water and salt out of the body
- ☐ Improve heart function
- ☐ Slows the rate at which the heart pumps
- ☐ Reduce swelling and breathlessness

Which of the following things do diuretics do?

- ☐ Make it easier for the heart to pump blood around the body
- ☐ Help to take water and salt out of the body
- ☐ Improve heart function
- ☐ Slows the rate at which the heart pumps
- ☐ Reduce swelling and breathlessness

Appendix R



Tick which of the following statements are true or false.

	True	False
a) Your heart is having problems pumping enough blood around your body	☐	☐
b) Lifestyle changes (e.g. diet) can improve the function of your heart	☐	☐
c) Your heart condition can be cured	☐	☐
d) You have no responsibility for the management of your heart condition	☐	☐
e) If you have side effects, you can just stop taking your medicines straight away	☐	☐
f) It is your responsibility to make sure that your tablets do not run out	☐	☐
g) It is safe for you to take additional medicines brought from the chemist (e.g. for a cold or indigestion)	☐	☐
h) Water retention (swelling) puts extra strain on your heart	☐	☐
i) Exercise is bad for your heart	☐	☐
j) You need to get a flu jab every year	☐	☐

Appendix S

Appendix S: Translated Dutch Heart Failure Knowledge Scale

(van der Wal, Jaarsma, Moser, & van Veldhuisen, 2005)

How often should patients with severe heart failure weigh themselves?
- ☐ Every week
- ☐ Now and then
- ☐ Every day

Why is it important that patients with heart failure should weigh themselves regularly?
- ☐ Because many patients with heart failure have a poor appetite
- ☐ To check whether the body is retaining fluid
- ☐ To assess the right dose of medicines

How much fluid are you allowed to take at home each day?
- ☐ 1.5 to 2.5 litres at the most
- ☐ As little fluid as possible
- ☐ As much fluid as possible

Which of these statements is true?
- ☐ When I cough a lot, it is better not take my heart failure medication
- ☐ When I am feeling better, I can stop taking my medication for heart failure
- ☐ It is important that I take my heart failure medication regularly

What is the best thing to do in case of increased shortness of breath or swollen of legs?
- ☐ Call the doctor or nurse
- ☐ Wait until the next check up
- ☐ Take less medication

What can cause a rapid worsening of heart failure symptoms?
- ☐ A high-fat diet
- ☐ A cold or flu
- ☐ Lack of exercise

What does heart failure mean?
- ☐ That the heart is unable to pump enough blood around the body
- ☐ That someone is not getting enough exercise and is in poor condition
- ☐ That there is a blood clot in the blood vessels of the heart

Why can the legs swell up when you have heart failure?
- ☐ Because the values in the blood vessels in the legs do not function properly
- ☐ Because the muscles in the legs are not getting enough oxygen
- ☐ Because of accumulation of fluid in the legs

What is the function of the heart?
- ☐ To absorb nutrients from the blood
- ☐ To pump blood around the body
- ☐ To provide the blood with Oxygen

Appendix S

Why should someone with heart failure follow a low salt diet?
- ☐ Salt promotes fluid retention
- ☐ Salt causes construction of the blood vessels
- ☐ Salt increases the heart rate

What are the main causes of heart failure?
- ☐ A myocardial infarction and high blood pressure
- ☐ Lung problems and allergy
- ☐ Obesity and diabetes

Which statement about exercise for people with heart failure is true?
- ☐ It is important to exercise as little as possible at home in order to relieve the heart
- ☐ It is important to exercise at home and to rest regularly in between
- ☐ It is important to exercise as much as possible at home

Why are water pills prescribed to someone with heart failure?
- ☐ To lower the blood pressure
- ☐ To prevent fluid retention in the body
- ☐ Because then they can drink more

Which statement about weight increase and heart failure is true?
- ☐ An increase of over 2 kilograms in 2 or 3 days should be reported to the doctor at the next check-up
- ☐ In case of an increase of over 2 kilograms in 2 or 3 days, you should contact your doctor or nurse
- ☐ In case of an increase of over 2 kilograms in 2 or 3 days, you should eat less

What is the best thing to do when you are thirsty?
- ☐ Suck an ice cube
- ☐ Such a lozenge
- ☐ Drink a lot

Appendix T

Appendix T: Doctor's invitation letter for study in chapter 8

05/Q1702/90 1st August 2005 Version 2

Southampton NHS
University Hospitals NHS Trust

Directorate of Medicine and Elderly Care
Mailpoint 47
Southampton General Hospital
Tremona Road
Southampton SO16 6YD

AN EVALUATION OF TWO DIFFERENT BOOKLETS FOR PROVIDING INFORMATION TO PATIENTS ABOUT IMPROVING THEIR HEART FUNCTION.

Dear

I am writing to invite you to take part in a research study, which is looking at whether written information is a good way to provide information about your heart condition. This is a joint research project between Southampton General Hospital and the University of Southampton.

If you decide to take part you will receive a booklet about your heart condition and be asked to fill in some questionnaires. You will find some more information about the study in the information sheet which has also been sent with this letter.

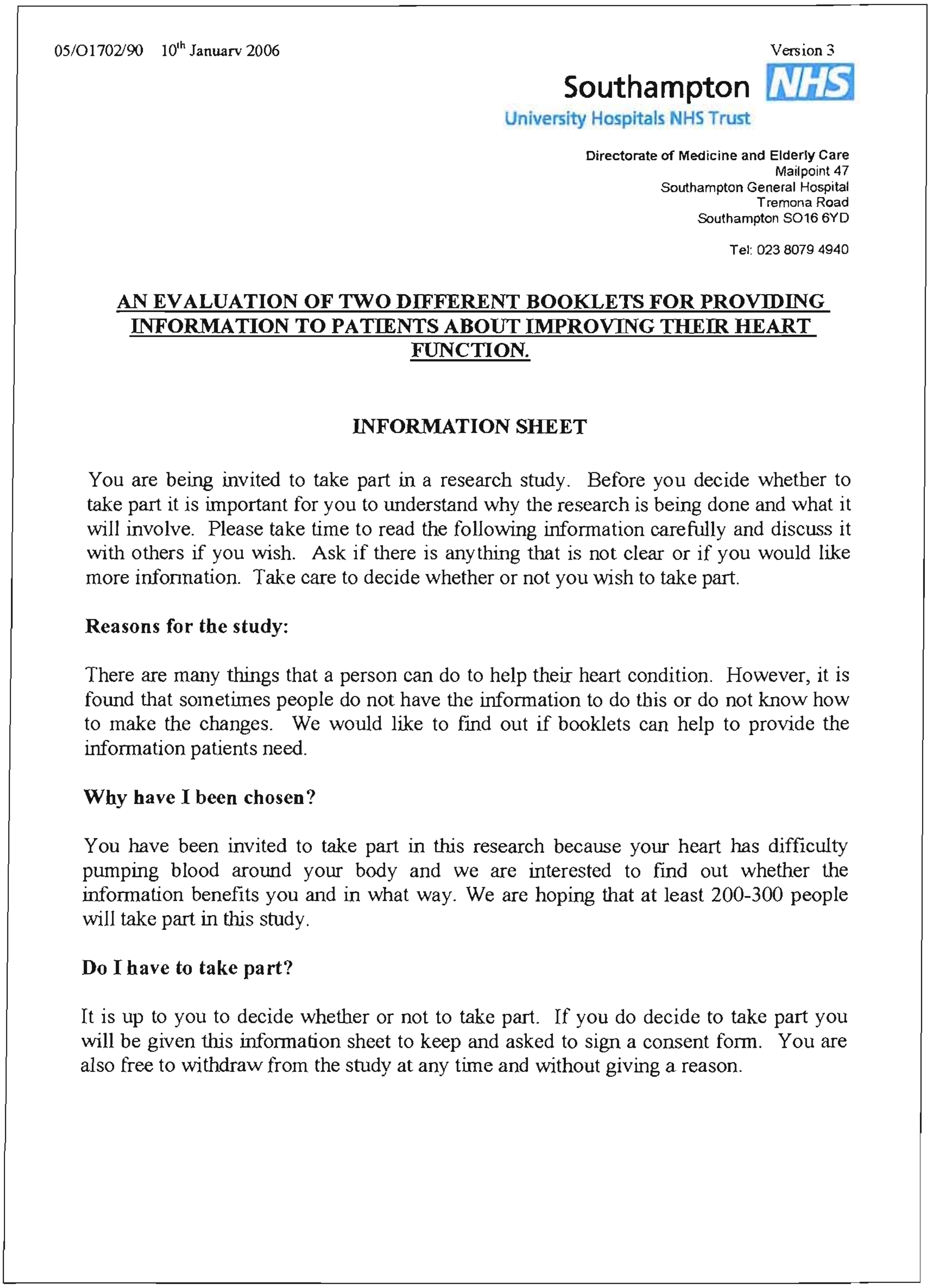
If you are interested in taking part, then please fill in the consent form and questionnaire and return them to Nina Shergill in the pre-paid envelope. If you have any questions then please contact Nina Shergill on 023-8059-4599.

Yours Sincerely

Consultant or Clinical Service Director
With contact details

Appendix U

Appendix U: Information sheet for study in chapter 8



05/O1702/90 10th January 2006

Version 3

Southampton NHS
University Hospitals NHS Trust

Directorate of Medicine and Elderly Care
Mailpoint 47
Southampton General Hospital
Tremona Road
Southampton SO16 6YD

Tel: 023 8079 4940

AN EVALUATION OF TWO DIFFERENT BOOKLETS FOR PROVIDING INFORMATION TO PATIENTS ABOUT IMPROVING THEIR HEART FUNCTION.

INFORMATION SHEET

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

Reasons for the study:

There are many things that a person can do to help their heart condition. However, it is found that sometimes people do not have the information to do this or do not know how to make the changes. We would like to find out if booklets can help to provide the information patients need.

Why have I been chosen?

You have been invited to take part in this research because your heart has difficulty pumping blood around your body and we are interested to find out whether the information benefits you and in what way. We are hoping that at least 200-300 people will take part in this study.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and asked to sign a consent form. You are also free to withdraw from the study at any time and without giving a reason.

Appendix U

What will happen to me if I take part?

1) Fill in consent form and questionnaire

If you decide to participate in this study, please fill in the consent form and questionnaire enclosed in this letter and return them in the pre-paid envelope provided. You will then be put into a group and contacted over the following weeks.

2) What groups can I be put in?

There will be four groups in this study. The first group will receive the 'improving heart function' booklet. The second group will receive an information booklet about your heart condition. The third group (a control group) will receive the 'improving heart function' booklet 2 weeks after filling in a follow-up questionnaire. The fourth group (a control group) will receive an information booklet about your heart condition 2 weeks after filling in a follow-up questionnaire.

3) Booklets and Follow-up questionnaire

<u>Group 1 and 2</u>: You will receive a booklet within two weeks of sending your consent form and first questionnaire. Two weeks after receiving the booklet, you will be sent a follow-up questionnaire to fill in and return.

<u>Group 3 and Group 4(control)</u>: A follow-up questionnaire will be sent to you two weeks after receiving your consent form and first questionnaire. Once we have received your follow-up questionnaire, we will send you a booklet within two weeks. Two weeks after receiving the booklet, you will be sent a further follow-up questionnaire to fill in and return.

<u>All groups</u>: If any follow-up questionnaire is not returned within two weeks, then you will be contacted by phone and have the opportunity to complete the questions over the phone

4) End of the trial

At the end of the trial, everybody in the groups will receive a copy of the booklet they have not had.

What are the possible benefits of taking part?

This research will enable you to obtain copies of informational booklets for your heart condition that are evidence-based and up to date. Both will provide information that will help you to understand how you can manage your heart condition.

Will my taking part in this study be kept confidential?

All information which is collected, about you during the course of the research will be kept strictly confidential. Personal information will not be released or viewed by anyone other than my supervisors of myself. Only investigators in the study will have access to the raw data. Any information about you will have your name and address removed so that you cannot be recognised from it. However, if you agree, your GP will be told that you are taking part.

What will happen to the results of the research study?

The findings from this study will be published in a journal and be part of a report for the Clinical Effectiveness at Southampton University Hospitals NHS Trust. It is hoped that this research will show how useful each booklet is. Results of this study will not include your name or any other identifiable characteristics and you will not be identified in any of the reports/publications. A general copy of the study findings can be sent to you if you wish.

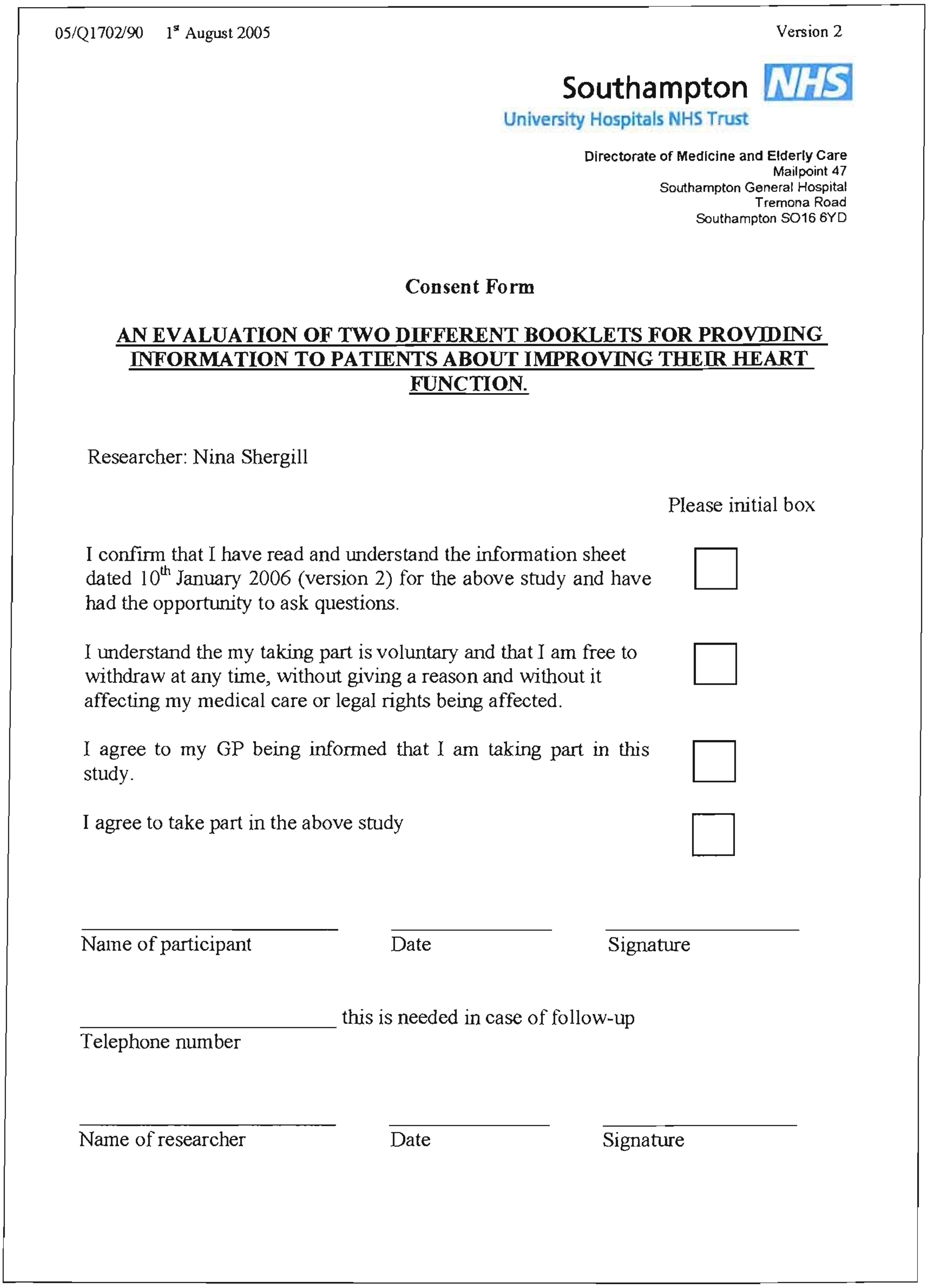
Funding of the research: The research is part of a PhD and is partly funded by the ESRC (Economic and Social Research Council) and partly funded by the Clinical Effectiveness department at Southampton Hospital University NHS Trust.
Study Review: The study has been reviewed by the ESRC (Economic and Social Research Council) and by Southampton and South West Hampshire Local Research Ethics Committee.

If you would like to take part in the research or if you have any questions or require any further information then please do not hesitate to contact me.

Nina Shergill
Tel: (023) 8059 4599
E-mail: nks1@soton.ac.uk
School of Psychology, Shackleton Building, University of Southampton,
Highfield, Southampton SO17 1BJ

Thank you for taking time to read this information sheet.

Appendix V: Consent form for study in chapter 8



05/Q1702/90 1st August 2005 Version 2

Southampton NHS
University Hospitals NHS Trust

Directorate of Medicine and Elderly Care
Mailpoint 47
Southampton General Hospital
Tremona Road
Southampton SO16 6YD

Consent Form

AN EVALUATION OF TWO DIFFERENT BOOKLETS FOR PROVIDING INFORMATION TO PATIENTS ABOUT IMPROVING THEIR HEART FUNCTION.

Researcher: Nina Shergill

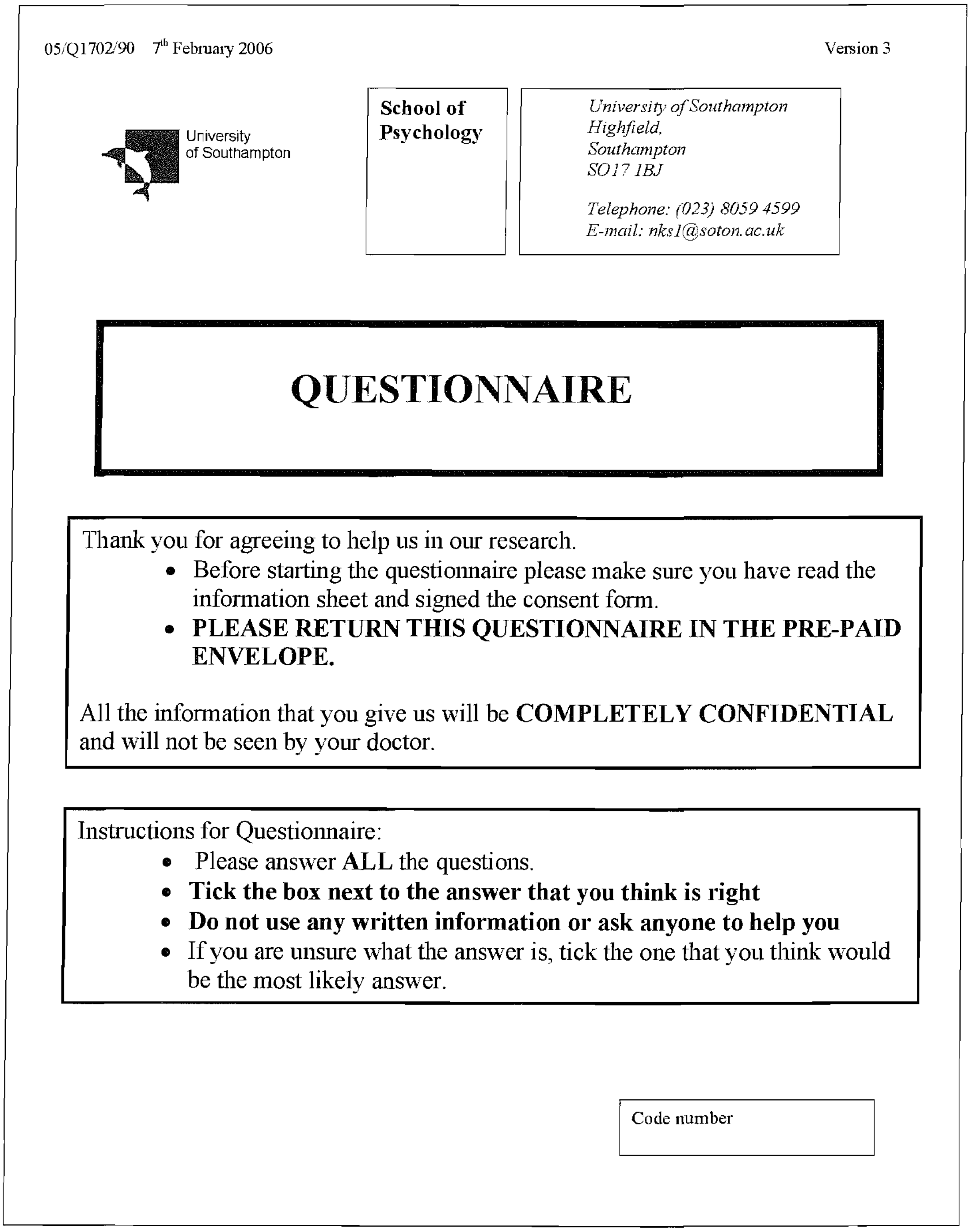
	Please initial box
I confirm that I have read and understand the information sheet dated 10th January 2006 (version 2) for the above study and have had the opportunity to ask questions.	☐
I understand the my taking part is voluntary and that I am free to withdraw at any time, without giving a reason and without it affecting my medical care or legal rights being affected.	☐
I agree to my GP being informed that I am taking part in this study.	☐
I agree to take part in the above study	☐

____________________	____________	____________
Name of participant	Date	Signature

____________________ this is needed in case of follow-up
Telephone number

____________________	____________	____________
Name of researcher	Date	Signature

Appendix W: Baseline questionnaire used for study in chapter 8



05/Q1702/90 7th February 2006 Version 3

University
of Southampton

School of Psychology

University of Southampton
Highfield,
Southampton
SO17 1BJ

Telephone: (023) 8059 4599
E-mail: nks1@soton.ac.uk

QUESTIONNAIRE

Thank you for agreeing to help us in our research.

- Before starting the questionnaire please make sure you have read the information sheet and signed the consent form.
- **PLEASE RETURN THIS QUESTIONNAIRE IN THE PRE-PAID ENVELOPE.**

All the information that you give us will be **COMPLETELY CONFIDENTIAL** and will not be seen by your doctor.

Instructions for Questionnaire:

- Please answer **ALL** the questions.
- **Tick the box next to the answer that you think is right**
- **Do not use any written information or ask anyone to help you**
- If you are unsure what the answer is, tick the one that you think would be the most likely answer.

Code number

Appendix W

OUESTIONS ABOUT YOUR HEART CONDITION

Please tick just ONE answer for each question.

1) Which of the following is true about your heart condition?

☐ That the heart is unable to pump enough blood around the body
☐ That you are not getting enough exercise and are in poor condition
☐ That there is a blood clot in the blood vessels of the heart

2) Someone with your heart condition should weigh himself or herself:

☐ Every day
☐ Once a week
☐ Now and then
☐ When you feel unwell

3) Which of these statements is true?

☐ When I cough a lot, it is better not to take the medications for my heart
☐ When I am feeling better, I can stop taking the medications for my heart
☐ It is important that I take my medications for my heart regularly

4) What is the best thing to do in case of increased shortness of breath or swollen legs?

☐ Call the doctor or nurse
☐ Wait until your next appointment with your doctor
☐ Take less medication
☐ Wait a few days to see if you get better

5) What can cause a rapid worsening of your heart symptoms?

☐ A high fat diet
☐ A cold or flu
☐ Lack of exercise

6) Why can the legs swell up in people who have your heart condition?

☐ Because the valves in the blood vessels in your legs do not work properly
☐ Because the muscles in the legs are not getting enough oxygen
☐ Because there is fluid retention in the legs

7) What is the function of the heart?

☐ To absorb nutrients from the blood
☐ To pump blood around the body
☐ To provide the blood with oxygen

Appendix W

8) Why should someone with your heart condition follow a low salt diet?

☐ Salt promotes fluid retention
☐ Salt causes blood vessels to narrow
☐ Salt increases the heart rate

9) Which statement about exercise for people with your heart condition is true?

☐ It is important to exercise as little as possible at home in order to not put pressure on the heart
☐ It is important to exercise at home and to rest regularly in between
☐ It is important to exercise as much as possible at home

10) Why are water pills prescribed to someone with your heart condition?

☐ To lower blood pressure
☐ To prevent fluid retention in the body
☐ Because then you can drink more

11) Which statement about weight increase and your heart condition true?

☐ An increase of over 3-4 pounds in 2 or 3 days should be reported to the doctor at the next check up
☐ In case of an increase of over 3-4 pounds in 2 or 3 days, you should contact your doctor/nurse
☐ In case of an increase of over 3-4 pounds in 2 or 3 days, you should eat less

12) Why is it important that people with your heart condition should weigh themselves regularly?

☐ Because many people with your heart condition have a poor appetite
☐ To check whether the body is retaining fluid
☐ To assess the right dose of medicines

13) To monitor your heart function, you should weigh yourself:

☐ After breakfast, after going to the toilet
☐ Before breakfast, before going to the toilet
☐ After breakfast, before going to the toilet
☐ Before breakfast, after going to the toilet

14) If you have a lot of salt in your diet, which of the following is true:

☐ Salt helps you to retain water and increases your weight
☐ Salt helps you to retain water and decreases your weight
☐ Salt helps you to lose water and increase your weight
☐ Salt helps you to lose water and decrease your weight

15) How many portions of fruit and vegetables should you eat in a day to have a healthy diet?

☐ One or two
☐ Three or four
☐ Five or more

16) Which of the following lets you spot fluid retention early?

☐ Increase in weight of a few pounds
☐ Swelling of ankles
☐ Increased breathlessness

For the following questions, there is MORE THAN ONE correct answer; please tick all that you think are right.

17) What are the common symptoms of your heart condition? (tick all that you think are right)

☐ Shortness of breath
☐ Blurred vision
☐ Skin rash
☐ Swelling of the ankles or legs
☐ Tiredness
☐ Retaining fluid
☐ Difficulty swallowing
☐ High temperature

18) Which of the following things do ACE inhibitors (e.g. Perindopril, Ramipril, or any name ending in pril) do? (tick all that you think are right)

☐ Relax blood vessels
☐ Help to take water and salt out of the body
☐ Improve heart function
☐ Prevent the heart from beating too fast
☐ Reduce swelling and breathlessness

19) Which of the following things do Beta Blockers (e.g. Bisoprolol, Carvedilol) do? (tick all that you think are right)

☐ Relax blood vessels
☐ Help to take water and salt out of the body
☐ Improve heart function
☐ Prevent the heart from beating too fast
☐ Reduce swelling and breathlessness

20) Which of the following things do diuretics do? (tick all that you think are right)

☐ Relax blood vessels
☐ Help to take water and salt out of the body
☐ Improve heart function
☐ Prevent the heart from beating too fast
☐ Reduce swelling and breathlessness

21) **Tick only one box for every question**

		TRUE	FALSE
a)	Pain in your joints is a sign that your heart condition is getting worse	☐	☐
b)	Rapid weight gain is a sign that your heart condition is getting worse	☐	☐
c)	Your heart condition can be cured	☐	☐
d)	You have no responsibility for the management of your heart condition	☐	☐
e)	If you have side effects, you should stop taking your medicines straight away	☐	☐
f)	It is safe for you to take additional medicines brought from the chemist (e.g. for a cold or indigestion)	☐	☐
g)	You need to get a flu jab every year	☐	☐

QUESTIONS ABOUT HOW YOU FEEL

22) Taking my medications for my heart condition, as prescribed by the doctor (the right tablets at the right time) would be: (please tick one box for a, one box for b and one box for c)

	extremely	slightly	neither	slightly	extremely	
a) Harmful	☐	☐	☐	☐	☐	Beneficial
b) Unimportant	☐	☐	☐	☐	☐	Important
c) Hard	☐	☐	☐	☐	☐	Easy

23) Doing planned physical activity at least 3-4 times a week would be: (please tick one box for a, one box for b and one box for c)

	extremely	slightly	neither	slightly	extremely	
a) Harmful	☐	☐	☐	☐	☐	Beneficial
b) Unimportant	☐	☐	☐	☐	☐	Important
c) Hard	☐	☐	☐	☐	☐	Easy

24) Limiting my salt intake (having less than 6 grams a day) would be: (please tick one box for a, one box for b and one box for c)

	extremely	slightly	neither	slightly	extremely	
a) Harmful	☐	☐	☐	☐	☐	Beneficial
b) Unimportant	☐	☐	☐	☐	☐	Important
c) Hard	☐	☐	☐	☐	☐	Easy

Appendix W

25) Weighing myself before breakfast every day would be: (please tick one box for a, one box for b and one box for c)

	extremely	slightly	neither	slightly	extremely	
a) Harmful	☐	☐	☐	☐	☐	Beneficial
b) Unimportant	☐	☐	☐	☐	☐	Important
c) Hard	☐	☐	☐	☐	☐	Easy

26) During the next week how stronger do you agree or disagree that you intend to do the following: (please tick one for every question)

	Strongly disagree	Disagree	Uncertain	Agree	Strongly agree
a) Take your medications as prescribed by the doctor	☐	☐	☐	☐	☐
b) Do physical activity, at least 3-4 times a week	☐	☐	☐	☐	☐
c) Limit your salt intake to less than 6 grams a day	☐	☐	☐	☐	☐
d) Weigh yourself every day before breakfast	☐	☐	☐	☐	☐

27) During the past week, how often have you done the following behaviours: (please tick one for every question)

	Everyday	Almost Everyday	Sometimes	Rarely	Not at all
a) Take your medications as prescribed by the doctor	☐	☐	☐	☐	☐
b) Do physical activity, at least 3-4 times a week	☐	☐	☐	☐	☐
c) Limit your salt intake to less than 6 grams a day	☐	☐	☐	☐	☐
d) Weigh yourself every day before breakfast	☐	☐	☐	☐	☐

28) How would you rate your understanding of your heart condition?

Very poor	Poor	Neither	Good	Very good
☐	☐	☐	☐	☐

29) How well do you understand the management of your heart condition?

Very poor	Poor	Neither	Good	Very good
☐	☐	☐	☐	☐

30) How strongly do you agree or disagree that you need more information about your heart condition?

Strongly Disagree	Disagree	Uncertain	Agree	Strongly Agree
☐	☐	☐	☐	☐

31) Is there anything you would like more information about? (please write below)

....

....

32) How much do you agree that you are: (please tick one for every question)

	Strongly disagree	**Disagree**	**Uncertain**	**Agree**	**Strongly agree**
a) Able to cope with life	☐	☐	☐	☐	☐
b) Able to understand your illness	☐	☐	☐	☐	☐
c) Able to cope with your illness	☐	☐	☐	☐	☐
d) Able to keep yourself healthy	☐	☐	☐	☐	☐
e) Confident about your health	☐	☐	☐	☐	☐
f) Able to help yourself	☐	☐	☐	☐	☐

BACKGROUND INFORMATION

a) How often do you see your GP?

☐ Every 2 weeks
☐ Every month
☐ Every 2-3 months
☐ Twice a year
☐ Once a year
☐ Other. Please state ____________________________

b) When was your last appointment with the doctor at the hospital?

☐ Past week
☐ 2-3 weeks ago
☐ 1 month ago
☐ 2- 3 month ago
☐ More than 3 months ago

c) When was the last time you spent a night(s) in hospital?

☐ Past week
☐ 2-3 weeks ago
☐ 1 month ago
☐ 2- 3 month ago
☐ 4-6 months ago
☐ Over 6 months ago

Appendix W

d) Do you have a specialist nurse for your heart condition that comes to visit you at home?

☐ Yes

☐ No (Go to question f)

e) How often do you see your specialist nurse?

☐ Every month

☐ Every 2-3 months

☐ Twice a year

☐ Once a year

☐ Other. Please state______________________

f) Have you ever been given information about your heart condition before?

☐ Yes

☐ No (Go to question j)

g) If yes, when did you get this information?

☐ Last 2 weeks

☐ 1 month ago

☐ 2- 3 month ago

☐ More than 3 months ago

h) Who provided this information?

☐ Hospital doctor

☐ GP

☐ Nurse

☐ Family member/friend

☐ Organisation

☐ Other please state__________________________

i) How was the information given to you?

☐ Verbal information (said to you)

☐ Magazine

☐ Book

☐ Booklet/leaflet

☐ Video

☐ Other please state______________

j) How long have you known about your heart condition?

…………………………………………………………………………………………………

k) Have you any other health problems?

…………………………………………………………………………………………………

…………………………………………………………………………………………………

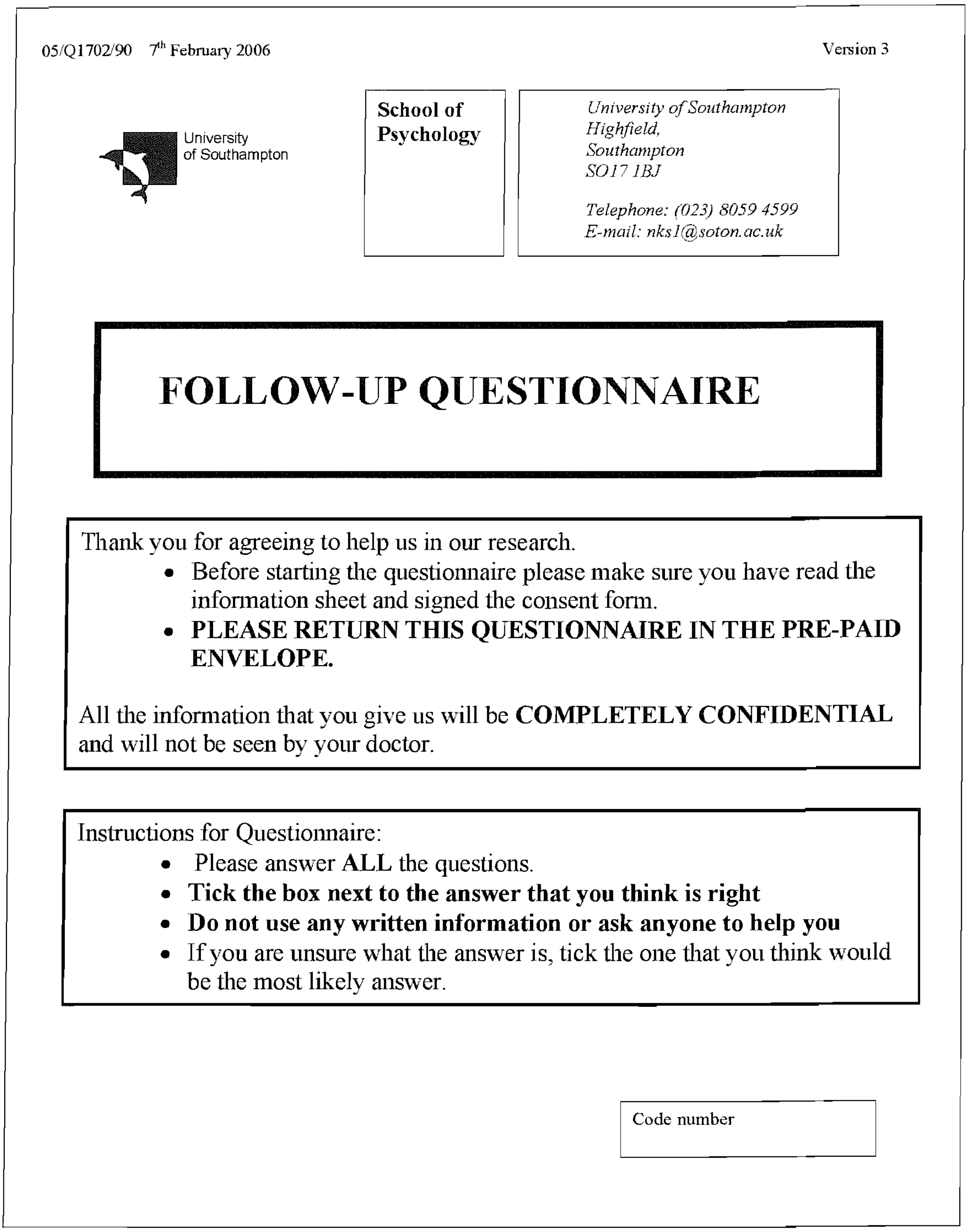
l) Have you had any full or part time further or higher education since you left school?

☐ Yes

☐ No

Thank you for filling in this questionnaire
Please return it in the pre-paid envelope with your consent form

Appendix X: Control follow up questionnaire pack for study in chapter 8



05/Q1702/90 7th February 2006

Version 3

University
of Southampton

School of Psychology

University of Southampton
Highfield,
Southampton
SO17 1BJ

Telephone: (023) 8059 4599
E-mail: nks1@soton.ac.uk

FOLLOW-UP QUESTIONNAIRE

Thank you for agreeing to help us in our research.

- Before starting the questionnaire please make sure you have read the information sheet and signed the consent form.
- **PLEASE RETURN THIS QUESTIONNAIRE IN THE PRE-PAID ENVELOPE.**

All the information that you give us will be **COMPLETELY CONFIDENTIAL** and will not be seen by your doctor.

Instructions for Questionnaire:

- Please answer ALL the questions.
- **Tick the box next to the answer that you think is right**
- **Do not use any written information or ask anyone to help you**
- If you are unsure what the answer is, tick the one that you think would be the most likely answer.

Code number

Appendix X

QUESTIONS ABOUT YOUR HEART CONDITION

Please tick just ONE answer for each question.

1) Which of the following is true about your heart condition?

☐ That the heart is unable to pump enough blood around the body
☐ That you are not getting enough exercise and are in poor condition
☐ That there is a blood clot in the blood vessels of the heart

2) Someone with your heart condition should weigh himself or herself:

☐ Every day
☐ Once a week
☐ Now and then
☐ When you feel unwell

3) Which of these statements is true?

☐ When I cough a lot, it is better not to take the medications for my heart
☐ When I am feeling better, I can stop taking the medications for my heart
☐ It is important that I take my medications for my heart regularly

4) What is the best thing to do in case of increased shortness of breath or swollen legs?

☐ Call the doctor or nurse
☐ Wait until your next appointment with your doctor
☐ Take less medication
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5) What can cause a rapid worsening of your heart symptoms?

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☐ Lack of exercise

6) Why can the legs swell up in people who have your heart condition?

☐ Because the valves in the blood vessels in your legs do not work properly
☐ Because the muscles in the legs are not getting enough oxygen
☐ Because there is fluid retention in the legs

7) What is the function of the heart?

☐ To absorb nutrients from the blood
☐ To pump blood around the body
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8) Why should someone with your heart condition follow a low salt diet?

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9) Which statement about exercise for people with your heart condition is true?

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☐ In case of an increase of over 3-4 pounds in 2 or 3 days, you should eat less

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13) To monitor your heart function, you should weigh yourself:

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☐ Before breakfast, after going to the toilet

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☐ Three or four
☐ Five or more

16) Which of the following lets you spot fluid retention early?

☐ Increase in weight of a few pounds
☐ Swelling of ankles
☐ Increased breathlessness

For the following questions, there is MORE THAN ONE correct answer; please tick all that you think are right.

17) What are the common symptoms of your heart condition? (tick all that you think are right)

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☐ Blurred vision
☐ Skin rash
☐ Swelling of the ankles or legs
☐ Tiredness
☐ Retaining fluid
☐ Difficulty swallowing
☐ High temperature

18) Which of the following things do ACE inhibitors (e.g. Perindopril, Ramipril, or any name ending in pril) do? (tick all that you think are right)

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☐ Relax blood vessels
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☐ Improve heart function
☐ Prevent the heart from beating too fast
☐ Reduce swelling and breathlessness

20) Which of the following things do diuretics do? (tick all that you think are right)

☐ Relax blood vessels
☐ Help to take water and salt out of the body
☐ Improve heart function
☐ Prevent the heart from beating too fast
☐ Reduce swelling and breathlessness

21) Tick only one box for every question

		TRUE	FALSE
a)	Pain in your joints is a sign that your heart condition is getting worse	☐	☐
b)	Rapid weight gain is a sign that your heart condition is getting worse	☐	☐
c)	Your heart condition can be cured	☐	☐
d)	You have no responsibility for the management of your heart condition	☐	☐
e)	If you have side effects, you should stop taking your medicines straight away	☐	☐
f)	It is safe for you to take additional medicines brought from the chemist (e.g. for a cold or indigestion)	☐	☐
g)	You need to get a flu jab every year	☐	☐

QUESTIONS ABOUT HOW YOU FEEL

22) Taking my medications for my heart condition, as prescribed by the doctor (the right tablets at the right time) would be: (please tick one box for a, one box for b and one box for c)

	extremely	slightly	neither	slightly	extremely	
a) Harmful	☐	☐	☐	☐	☐	Beneficial
b) Unimportant	☐	☐	☐	☐	☐	Important
c) Hard	☐	☐	☐	☐	☐	Easy

23) Doing planned physical activity at least 3-4 times a week would be: (please tick one box for a, one box for b and one box for c)

	extremely	slightly	neither	slightly	extremely	
a) Harmful	☐	☐	☐	☐	☐	Beneficial
b) Unimportant	☐	☐	☐	☐	☐	Important
c) Hard	☐	☐	☐	☐	☐	Easy

24) Limiting my salt intake (having less than 6 grams a day) would be: (please tick one box for a, one box for b and one box for c)

	extremely	**slightly**	**neither**	**slightly**	**extremely**	
a) Harmful	☐	☐	☐	☐	☐	Beneficial
b) Unimportant	☐	☐	☐	☐	☐	Important
c) Hard	☐	☐	☐	☐	☐	Easy

25) Weighing myself before breakfast every day would be: (please tick one box for a,one box for b and one box for c)

	extremely	**slightly**	**neither**	**slightly**	**extremely**	
a) Harmful	☐	☐	☐	☐	☐	Beneficial
b) Unimportant	☐	☐	☐	☐	☐	Important
c) Hard	☐	☐	☐	☐	☐	Easy

26) During the next week how stronger do you agree or disagree that you intend to do the following: (please tick one for every question)

	Strongly disagree	**Disagree**	**Uncertain**	**Agree**	**Strongly agree**
a) Take your medications as prescribed by the doctor	☐	☐	☐	☐	☐
b) Do physical activity, at least 3-4 times a week	☐	☐	☐	☐	☐
c) Limit your salt intake to less than 6 grams a day	☐	☐	☐	☐	☐
d) Weigh yourself every day before breakfast	☐	☐	☐	☐	☐

27) During the past week, how often have you done the following behaviours: (please tick one for every question)

	Everyday	**Almost Everyday**	**Sometimes**	**Rarely**	**Not at all**
a) Take your medications as prescribed by the doctor	☐	☐	☐	☐	☐
b) Do physical activity, at least 3-4 times a week	☐	☐	☐	☐	☐
c) Limit your salt intake to less than 6 grams a day	☐	☐	☐	☐	☐
d) Weigh yourself every day before breakfast	☐	☐	☐	☐	☐

28) How would you rate your understanding of your heart condition?

Very poor	Poor	Neither	Good	Very good
☐	☐	☐	☐	☐

29) How well do you understand the management of your heart condition?

Very poor	Poor	Neither	Good	Very good
☐	☐	☐	☐	☐

30) How strongly do you agree or disagree that you need more information about your heart condition?

Strongly Disagree	Disagree	Uncertain	Agree	Strongly Agree
☐	☐	☐	☐	☐

31) Is there anything you would like more information about? (please write below)

....

....

32) How much do you agree that you are: (please tick one for every question)

	Strongly disagree	**Disagree**	**Uncertain**	**Agree**	**Strongly agree**
a) Able to cope with life	☐	☐	☐	☐	☐
b) Able to understand your illness	☐	☐	☐	☐	☐
c) Able to cope with your illness	☐	☐	☐	☐	☐
d) Able to keep yourself healthy	☐	☐	☐	☐	☐
e) Confident about your health	☐	☐	☐	☐	☐
f) Able to help yourself	☐	☐	☐	☐	☐

Thank you for filling in this questionnaire
Please return it in the pre-paid envelope

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