

**An exploratory study of patient distress and
participation in treatment decision-making for
cancer**

Frances M. Scrutton

Submitted for the degree of

Doctorate of Clinical Psychology
The University of Edinburgh
2009



I, **Frances Scrutton**, declare that this thesis, submitted in August 2009, is my own work and has not been submitted for any other academic degree or professional qualification.

D. Clin. Psychol. Declaration of own work

This sheet must be filled in (each box ticked to show that the condition has been met), signed and dated, and included with all assessments - work will not be marked unless this is done

Name: **Frances Scrutton**

Assessed work Case Study SSR Essay Question Paper **Thesis**

Title of work: An exploratory study of patient distress and participation in treatment decision-making for cancer

I confirm that all this work is my own except where indicated, and that I have:

- Composed and undertaken the work myself
- Clearly referenced/listed all sources as appropriate
- Referenced and put in inverted commas any quoted text of more than three words (from books, web, etc)

- Given the sources of all pictures, data etc. that are not my own
- Not made undue use of essay(s) of any other student(s) either past or present (or where used, this has been referenced appropriately)
- Not sought or used the help of any external professional agencies for the work (or where used, this has been referenced appropriately)
- Not submitted the work for any other degree or professional qualification except as specified
- Acknowledged in appropriate places any help that I have received from others (e.g. fellow students, technicians, statisticians, external sources)

I understand that any false claim for this work will be penalised in accordance with the University regulations

Signature

Date

Please note: a) If you need further guidance on plagiarism, you can:

i/ Speak to your director of studies or supervisor

ii/ View university regulations at

<http://www.aaps.ed.ac.uk/regulations/Plagiarism/Intro.htm>

b) Referencing for all assessed work should be in the format of the BPS style guide, which is freely available from the BPS web site

Acknowledgements

With many thanks to all the people who took the time to complete my study at a difficult time in their lives. Your generosity in the face of adversity is inspiring.

Thanks also to my truly multi-disciplinary clinical and academic support network for advice in designing the research and feedback on drafts: Professor Mick Power, Ms. Liz Wilkinson, Dr Lesley Dawson, Dr Sara Erridge, Dr Tamasin Evans, Dr. Belinda Hacking and Dr. Gwen Baxter. Also a particular note of thanks to the specialist nursing team Cathy Brown, Anne Callander, John Samuels, and Isabel Williams.

Finally, thanks to Leon, my family, and friends who have supported me throughout.

i.	<i>List of figures</i>	7
ii.	<i>List of tables</i>	8
iii.	<i>Abstract</i>	9
1.	CHAPTER ONE: INTRODUCTION	10
1.1.	<i>Introduction</i>	10
1.2.	<i>Putting cancer in context</i>	12
1.3.	<i>Understanding the context of patient participation in treatment decision-making</i>	19
1.4.	<i>Patient participation in treatment decision-making</i>	24
1.5.	<i>Psychosocial outcomes related to patient participation in treatment decision-making</i> ..	30
1.6.	<i>Understanding the process of participating in treatment decision-making</i>	37
1.7.	<i>Factors influencing patient participation in treatment decision-making: A review of the literature</i>	46
1.8.	<i>Patient distress and decision-making</i>	61
1.9.	<i>Current study</i>	69
2.	CHAPTER TWO: METHODOLOGY	73
2.1.	<i>Study design</i>	73
2.2.	<i>Description of measures</i>	73
2.3.	<i>Participants</i>	81
2.4.	<i>Study procedure</i>	86
2.5.	<i>Statistical analysis</i>	89
2.6.	<i>Ethical considerations</i>	90
3.	CHAPTER THREE: RESULTS	93
3.1.	<i>Participants</i>	93
3.2.	<i>Descriptive statistics for the main variables</i>	95
3.3.	<i>Exploration of assumptions for parametric tests</i>	96
3.4.	<i>Patient distress and preference for participation in treatment decision-making</i>	98
3.5.	<i>Patient distress and participation in treatment decision-making</i>	99
3.6.	<i>Distress and attainment of preferred level of participation in treatment decision-making</i> 101	
3.7.	<i>Emotion regulation and attainment of preferred level of participation in treatment decision-making</i>	103
3.8.	<i>Exploratory analysis of Difficulties with Emotion Regulation Scale sub-scales</i>	106
3.9.	<i>Attainment of preferred role in treatment decision-making and psycho-social outcomes</i> 107	

4. CHAPTER FOUR: DISCUSSION	110
4.1. <i>Overview of findings.....</i>	<i>110</i>
4.2. <i>Evaluation of study design</i>	<i>122</i>
4.3. <i>Reconsidering the study of patient decision-making.....</i>	<i>130</i>
4.4. <i>Clinical implications</i>	<i>132</i>
4.5. <i>Areas of further study</i>	<i>134</i>
5. CHAPTER FIVE: CONCLUSION	137
6. CHAPTER SIX: REFERENCES	139
7. CHAPTER SEVEN: APPENDICES	157
<i>Appendix One: Correspondence from ethics committee</i>	<i>158</i>
<i>Appendix Two: Tables for literature review</i>	<i>168</i>
<i>Appendix Three: Patient pathways for each cancer type with oncology consultation highlighted</i>	<i>181</i>
<i>Appendix Four: Participant information (reformatted).....</i>	<i>186</i>
<i>Appendix Five: P-P plots and histograms for main variables and homogeneity of variance statistics</i>	<i>191</i>

i. List of figures

Figure 1: Summary of studies of percentage of patients preferring active, shared or passive role in treatment decision-making)..... 25

Figure 2 Siminoff and Stepp (2005) The Communication Model of Decision-making.. 44

Figure 3: A process model of emotion regulation, adapted from Gross (2002) 66

Figure 4: Summary of Research Questions and Hypotheses..... 72

Figure 5: Decision-making preference statements (Sutherland *et al.*, 1989) 76

Figure 6: Flowchart of procedure88

Figure 7: Box plot showing median distress by role preferred in treatment decision-making..... 98

Figure 8: Box plot showing distress by role taken in treatment decision-making..... 99

Figure 9: Calculation of post-hoc Mann-Whitney test effect size 100

Figure 10: Box plot graph showing distress and attainment of preferred role in treatment decision-making. Central tendency shown is the median. 102

Figure 11: Box plot graph showing emotion regulation and attainment of preferred role in treatment decision-making. Central tendency shown is the median. 104

Figure 12: P-P plot and histogram for distress measured by GHQ-12.....192

Figure 13: P-P plot and histogram for emotion regulation measured by DERS.....193

Figure 14: P-P plot and histogram for psychological adjustment measured by Fighting Spirit/ Helpless-hopeless Subscale.....194

Figure 15: P-P plot and histogram for psychological adjustment measured by FS/H-H subscale at three month follow up.....195

Figure 16: P-P plot and histogram for satisfaction with decision measured by Satisfaction with Decision Scale..... 196

Figure 17: P-P plot and histogram for satisfaction with decision measured by Satisfaction with Decision Scale at three month follow-up..... 197

ii. List of tables

Table 1: Models of treatment decision-making from Charles <i>et al.</i> (1999, p. 693)	21
Table 2: Summary of studies investigating concordance between patients' preferred and actual roles in treatment decision-making.....	28
Table 3: Search terms for review of literature.....	47
Table 4: Cronbach's alpha for Mental Adjustment to Cancer sub-scales	78
Table 5: Measures used for individual variables	80
Table 6: A priori sample size calculation using G*power 3 (Faul <i>et al.</i> , 2007).....	83
Table 7: Demographic characteristics of participants in study.....	93
Table 8: Patient preferred and actual roles in treatment decision-making	94
Table 9: Descriptive statistics for main variables.....	96
Table 10: Descriptive statistics for participants who attained and did not attain preferred role in decision-making	101
Table 11: Point biserial correlation for DERS subscales and patient attainment of role.....	106
Table 12: Descriptive statistics of psychosocial outcome measures	108
Table 13: Independent sample t-tests to compare psychosocial outcomes.....	109
Table 14: Summary of quantitative studies looking at factors associated with patient preferences for participation; *only descriptive statistics reported.....	169
Table 15: Summary of qualitative studies exploring factors affecting patient preferences for participation.....	175
Table 16: Summary of quantitative studies investigating factors affecting patients' actual participation in decision-making	178
Table 17: Summary of qualitative studies investigating factors affecting patients' actual participation in decision-making	180
Table 18: Table showing Levene's test for homogeneity of variance between groups of participants based on matched or unmatched roles. Continued overleaf.	198

Word count (including abstract): 27 831

iii. Abstract

Background: There is a growing expectation that medical patients should be more involved in decisions about their health and treatment. However, often decisions about treatments are required at times of stress, such as following a diagnosis of cancer.

Objectives: The purpose of this study was to investigate the relationship between distress, emotion regulation and patient participation in treatment decision-making for cancer, and whether patient participation affects psychosocial outcomes

Method: The study was an observational, longitudinal design. Participants were 26 patients with cancer, recruited at their initial oncology appointment, who completed a questionnaire at the time of their consultation, a second questionnaire following their consultation and a third at three months follow up. Univariate analyses were used for confirmatory data analysis.

Results: Participants who took a passive or active role in treatment decision-making had significantly higher levels of distress, compared to those who reported shared decision-making. Higher levels of distress and greater difficulties with emotion regulation were also significantly associated with participants not attaining their preferred role. No significant relationship was found between participation in treatment decision-making and psychological adjustment or satisfaction with the decision made.

Conclusions: Greater awareness of patients' emotional well-being, at key points in their care pathway, would be valuable, to ensure patients' psychological needs are met and to avoid detrimental consequences for their health care.

1. CHAPTER ONE: INTRODUCTION

1.1. Introduction

The paradigm of health care delivery in the National Health Service is changing. Shifting away from a model of paternalism, there is a growing expectation that patients should be more involved in, and take greater responsibility for, their health and treatment (Scottish Executive, 2003). In a policy briefing for the World Health Organisation, Coulter *et al.* (2008) highlight that, alongside improving patients' health literacy and self-management skills, promoting participation in treatment decision-making is key to achieving greater patient involvement. Models of health behaviour have long theorised that greater patient involvement can lead to improved medical and psychosocial outcomes (Bennett, 2000).

The process of making decisions about medical treatments, however, is becoming increasingly complex. With increasing treatment options for many health conditions, there is sometimes no single best treatment, rather manifold alternatives with differing risks and benefits. Choosing cancer treatments is a case in point. Often described as the most feared of modern diseases (Clarke & Everest, 2006), decisions about treatments for cancer are often required immediately following diagnosis, when the patient may be in the initial stages of psychological adjustment, that is experiencing their early emotional, cognitive and behavioural response to the changed circumstances. The rhetoric used in treatment decision-making consultations can be inhibiting, and, for the most part, patients lack expert knowledge on the subject about which they are being asked to make an informed choice. Research from the cancer literature has shown that not all patients

wish to be active participants in the process (Degner & Sloan, 1992). Furthermore, there is also a growing understanding that normative, or rational models of decision-making are insufficient to account for human behaviour, especially at times of stress (Tversky & Kahneman, 1981).

When woven together, these different strands of research pose questions about how we can negotiate the facilitation of greater patient participation in treatment decision-making for cancer care. Coulter *et al.* (2008, p.3) recommend that strategies to promote patient participation should be a “plank of health policy”. In order to develop such strategies, it is necessary to understand the challenges faced by patients at the time of making treatment decisions, and factors that may assist or hinder their participation. This exploratory study focuses on decision-making following a diagnosis of cancer and specifically investigates the association of a patient’s distress with their participation in treatment decision-making.

1.2. Putting cancer in context

Cancer is the third most common type of disease in the western world. Approximately 30 thousand people are diagnosed with cancer every year in Scotland, and this figure is expected to increase over the next five years, partly due to the ageing population (Scottish Government, 2008). Cancer is a complex group of diseases, with over 200 different types already identified. It is caused by the reproduction of damaged cells within a specific organ or type of tissue, to form an accumulation or mass of damaged cells. The most common types of cancers, for men, are cancers of the lung, prostate and large bowel, accounting for 53% of cases. For women, the most common types of cancer are breast, lung and large bowel, accounting for 55% of cases.

Improved detection rates and increasing options for treatment are leading to an improvement in the five year survival rate for the majority of cancer types. As medical care advances, recent policy has highlighted new challenges for health care providers. Firstly, to improve the psychological and social care for people affected by the disease. Secondly, in line with the changing paradigm of health care, there is a pressure to make care more patient-centred and encourage greater patient participation; for example, a consultation respondent for the recent Better Cancer Care document called for patients to “be an ‘active participant’ and not a ‘passive pyjama’ patient” (Scottish Government, 2008, p72). This section outlines these challenges in more detail, by describing the psychological needs of people diagnosed with cancer, and the current guidelines for treatment decision-making.

1.2.1. The psychological impact of cancer

Being diagnosed with cancer is not a discrete event; from the first detection of a concerning symptom, a catalogue of physical, emotional and social stresses is set in motion. Investigations, diagnosis, treatment, recovery and relapse each present challenges to the patient. Psychological adjustment to cancer can be prolonged: there are high levels of distress and an increased prevalence of psychopathology (Brennan, 2001). Successful psychological adjustment can be defined as enabling “the successful performance of adaptive tasks... the absence of psychological disorders, the presence of low negative affect and high positive affect, adequate functional (e.g. work) status, and the satisfaction and well-being in various life domains” (de Ridder *et al.*, 2008, p. 246). Research has consistently shown, however, that between 28 and 47% of people diagnosed with cancer experience clinically significant levels of psychological distress (e.g. Carlson *et al.*, 2004; Zabora *et al.*, 2001). The National Comprehensive Cancer Network (2008, DIS-3) define distress as “a multifactorial unpleasant emotional experience of a psychological (cognitive, behavioural, emotional), social and/ or spiritual nature that may interfere with the ability to cope effectively... Distress extends along a continuum, ranging from common normal feelings of vulnerability, sadness and fears to problems that can become disabling, such as depression, anxiety, panic...”. A large survey of 4496 cancer patients, at various stages of their treatment, found that 35% of patients were suffering from clinical levels of distress, with the most common difficulties reported including adjustment disorder, depression, and anxiety (Zabora *et al.*, 2001). Studies that have used a longitudinal methodology have found that distress levels for cancer patients can remain elevated from diagnosis through to the end of treatment (Northouse *et al.*, 1991).

Elevated levels of distress through the care pathway, is consistent with a diagnosis of cancer initiating a series of adverse events for the patient. Monitoring patient distress through the care pathway is now advocated in current guidance for the supportive care of adults with cancer. The National Institute of Health and Clinical Excellence (2002) states that assessment and discussion of patients' psychological needs should be undertaken at key times in the care pathway. However, although psychological research has produced evidence of the efficacy of formal psychological interventions, in addressing specific psychological problems, there is less research addressing how to best meet psychological needs within the usual system of medical care.

One approach to understanding how to meet psychological needs is to investigate the impact of physical and situational stressors, associated with different stages of the cancer treatment pathway, on a person's emotional well-being. Armitage *et al.* (1999) point out that, in turn, a person's emotional well-being can influence how they cope with further stressors, thereby potentially creating a spiraling negative trajectory, and having a compounding influence on a person's health and psychosocial outcomes. There may be a relatively complex interplay between stressors, a patient's distress and coping and their consequent physical and emotional well-being. The current study focuses on this interplay at the time of making treatment decisions following a recent diagnosis of cancer.

Being delivered a diagnosis of cancer has been likened to suffering a trauma: "a sudden unexpected life threatening event over which there is little personal control" (Brennan & Moynihan, 2005, p.17). In their seminal paper, Weisman and Worden (1976) described

the significance of the first 100 days in 'the existential plight' that follows a diagnosis of cancer. Their study found that the first 100 days following diagnosis were characterised by high distress, and specific concerns about survival and physical well-being, but crucially that well-being at this time was predictive of a person's long-term psychological adjustment. Although Weisman and Worden's time frame may have been somewhat arbitrary, their study suggests that psychologically sensitive care, in the period immediately following diagnosis, may be able to contribute to successfully guiding a person's long-term psychological adjustment to their illness.

During the initial period of adjustment, a patient faces several challenges, including key decisions about medical treatments. The successful negotiation of treatment decision-making is vital, in order that the patients can provide informed consent and commence the treatment quickly. However, research has shown that not all patients are successfully negotiating this challenge. Montgomery *et al.* (1999) interviewed 100 patients attending a radiotherapy clinic. One fifth of their participants did not recall having signed a consent form, even though all of them had, and almost a quarter could not recall any side effects of the treatment they had started. Participants who scored above the clinical cut-off for anxiety and depression were significantly more likely to report that they were less happy with the information they received, and wanted more information about both cancer and their treatment.

In keeping with the earlier point about the interdependence of illness related stressors and patients' emotional well-being, the authors suggest that patients who were psychologically distressed were perhaps less able to take on available information, and therefore more likely to report dissatisfaction as a result. As such, understanding the

potential effect that a person's distress can have during treatment decision-making will be important so that health care professionals can best support patients to negotiate these challenges successfully, and guide them towards a trajectory of positive psychological adjustment.

1.2.2. Current practice for treatment decisions for cancer

The majority of people with cancer will be treated using one, or a combination, of surgical intervention; radiotherapy; chemotherapy and hormone therapy. The treatment options will depend on the type and stage of the cancer; whether it has affected the lymphatic system; and whether the cancer has metastasised or spread.

The current government target in Scotland is that all primary cancers will be treated within 62 days of the patient's first presentation or referral to the cancer services. Within this time period a person must undergo investigations to diagnose and stage their illness and commence treatment. Even if the first 100 days, described by Weisman and Worden (1976) are an arbitrary time frame, this highlights that these first 62 days are a time of heightened distress and a person's experience at this time may have a substantial influence on their long-term psychological adjustment.

Prior to an oncology treatment decision-making consultation, the majority of decisions about a patient's treatment are discussed at a multi-disciplinary meeting, as advised by the Scottish Intercollegiate Guidelines Network (SIGN, 2003, 2005a, 2005b 2006). Patients do not ordinarily attend these meetings, however, all the guidelines advocate that patients are fully informed about decisions that are made. Some, although not all, of the specific cancer site guidelines explicitly state that patients should be involved in the decision-making process, if they so wish (NICE, 2002; SIGN 2003, 2005a). However, contrary to the recommendation made by Coulter *et al.* (2008), that strategies to support patient participation should be a "plank of health policy", the guidelines do not expound

on the practicalities of how to promote participation or how to address any potential impediments.

As previously discussed, it is likely that patients diagnosed with cancer will be suffering high rates of distress at the time of the treatment decision, which is the focus of this study. All the guidelines do advise that clinicians should be aware of patients' emotional well-being at all stages, with the guideline for the management of colorectal cancer specifically citing a research paper that found patients describe particular distress while waiting to see the Oncologist (Knowles *et al.*, 1999). However, none of the guidelines presents evidence on how high levels of distress may affect patients' interactions with the health care system, or provide specific guidance on the best management of this; in fact, many guidelines comment on the lack of evidence of how to best manage this.

1.2.3. Section summary

Cancer is one of the most common modern diseases. Improvements in medical outcomes have led to a greater awareness of the psychological impact of being diagnosed with cancer, and attention is turning towards the interplay between patients' emotional well-being, their engagement with health care services, and their longer-term psychological adjustment. While the extent of the psychological need in people diagnosed with cancer is well established, the impact and management of distress at key stages of the diagnosis and treatment process, such as treatment decision-making, remains under researched.

1.3. Understanding the context of patient participation in treatment decision-making

As recently as the 1960s, patients were not routinely informed that they had been diagnosed with cancer. This has dramatically changed, with patients increasingly being seen as active participants in their health care. This section outlines the development of the current theoretical ideal for patient participation in treatment decision-making.

1.3.1. Factors leading to increased patient participation in their health care

The shift in attitude, toward considering patients as active partners in their health care, can be understood as a product of medical, social and political changes. From a political perspective, there is an increasing focus on the ethical concern that people have the right to be considered as autonomous beings (Weinfurt, 2003). Giving informed consent is now recognised as a universal right for patients; this process in itself inherently requires active participation.

From a medical perspective, scientific advances have created a greater number of options for treatments and, simultaneously, patients are becoming progressively more informed about their own health due to the exponential growth in media technology. The correct choice for treatment is often not clear-cut, and becomes a matter of preference by the medical team or patient. There is also a changing pattern of physical health problems, with people facing less acute disease, but a greater number living with longer-term conditions. As such, increasing value is now being placed by patients on psycho-social

outcomes, such as quality of life, in addition to, or sometimes even at the expense of, more traditional medical outcomes, such as survival rates (Weinfurt, 2003).

The increasing prevalence of the view that patients should be involved in their health care is illustrated by the change in the dominant, or favoured, model of treatment decision-making. While acknowledging that different decision-making styles may be suitable in different settings, recent work attempting to clarify best practice in involving patients in decision-making has focused on the model of shared decision-making, described by Cathy Charles and colleagues (Charles *et al.*, 1997; Charles *et al.*, 1999)

1.3.2. From the paternalistic to the shared treatment decision model

Previously, the dominant model of delivering health care was one of paternalism, with doctors assuming the dominant role (Table 1). Underlying this model were four basic tenets: first, that the majority of illnesses had a definite best treatment; second, that doctors knew the best treatment for the patient; third, that doctors were best placed to evaluate any decisions if there was a choice in treatment; and fourth, that doctors were professionally bound to act in the best interest of the patient (Charles *et al.*, 1999). Patients adopted a passive role in any decision-making process, akin to Parsons' (1951) depiction of a 'sick role', in which he describes that the sick have an obligation to seek help, and comply with medical treatment. It is evident that this autocratic style of health care delivery, for the majority of treatment contexts, is becoming increasingly less credible in the current social climate. In reaction to the prevalent paternalistic model therefore, the informed decision-making model was developed.

The informed decision-making model (Table 1) recognises that the patient participation in making decisions, within the paternalistic model, is inhibited by the patients' lack of knowledge. Embracing the concept, that patients should now be held as active participants in their health care, the model focuses on the doctor communicating all the technical and scientific knowledge to the patient, in order to allow the patient to deliberate and make the decision (Emanuel & Emanuel, 1992). However, this model has also been heavily criticised.

	Paternalistic model	Shared decision making model	Informed model
Information transfer	Flow	One way	Two way
	Direction	Doctor to patient	Doctor to patient Patient to doctor
	Type	Medical	Medical and personal
	Amount	Minimum legally required	All relevant for decision-making
Deliberation	Doctor alone, or with other doctors	Doctor and patient (possibly with others)	Patient (possibly with others)
Decision about implementing treatment	Doctor	Doctor and patient	Patient

Table 1: Models of treatment decision-making from Charles *et al.* (1999, p. 693)

The model effectively reduces the doctor's role to providing information and disregards their technical expertise. Research has found that a patient reporting a desire for information is not equivalent to their wanting to participate in the decision-making process (Cassileth *et al.*, 1980). In addition, research has found that simply imparting knowledge about a treatment may not be sufficient to enable the patient to make an informed decision. For example, Chapman *et al.* (2003) evaluated the level of understanding, in lay people, of key terms used in an oncology consultation. The level of

understanding was very poor, with just over half of the participants understanding euphemisms for the progression of the cancer. At a more basic level, 94% of the sample were able to identify the location of the lungs in the body correctly, but only 46% were able to identify the liver accurately. Hurley *et al.* (1992) explain that, in fact, the asymmetry of knowledge in treatment decision-making affects both the doctor and the patient. While the doctor possesses better knowledge of the effectiveness of certain treatments, the patient possesses better knowledge about their well-being and quality of life: both sets of knowledge need to be combined for an effective treatment decision to be made.

This led to Charles *et al.* (1997) outlining the model of shared decision-making (Table 1). At a minimum this model requires that both doctor and patient are involved in the treatment decision-making process, both share information with each other, both express treatment preferences and, in due course, a treatment decision is made by both the doctor and the patient. Shared decision-making ultimately balances doctors' expertise with patients' preferences, to achieve informed and high quality decisions. The model now dominates the rhetoric of research and policy in decision-making. Its description of the ideal characteristics of the doctor-patient relationship clarifies the concept of shared decision-making, and therefore provides guidance for ideal clinical practice.

The model does not, however, address some of the more specific processes that may impact on achieving shared decision-making. In order to participate in the decision-making process patients have to appreciate complex information; understand and interpret information about probabilities; and form and express their own preferences (Entwhistle & Watt, 2006). Treatment decisions often occur at times of stress, which is

known to affect the quality of a person's information processing. Therefore, in order to facilitate not just greater patient participation, but valid patient participation, it is necessary to begin to understand the processes of patients participating in treatment decision-making, what facilitates it and what hinders it. These specific processes are discussed further in section 1.6.

1.3.3. Section summary

Patient participation in treatment decision-making is increasingly being regarded as preferred practice. Previously doctors adopted a paternalistic role, making, and taking responsibility for, all health care decisions; however, changes in social, ethical and legal views, have led to this style of health care delivery being overturned. Debate has ensued about the best model of practice, with some authors theorising that patients could potentially take the active role in treatment decision-making, if provided with sufficient information. However, research has shown that in practice this may not be possible, or preferable to patients, and the majority of recent research has promoted a model of shared decision-making as best practice (Charles *et al.*, 1997).

1.4. Patient participation in treatment decision-making

The Shared Decision-making Model is recommended as the best theoretical model of practice, however, research in a naturalistic clinical setting has not found that it is either unilaterally preferred by patients, or the prevalent style of decision-making used in consultations. This section describes research looking at patient preferences for, and actual, participation in treatment decision-making for cancer.

1.4.1. Patient preferences for participation in treatment decision-making

Patterns of patient preferences for participating in treatment decisions for cancer vary widely in published studies. The majority of studies have used the Control Preference Card Sort (Degner & Sloan, 1992), or the statements by Sutherland *et al.* (1989), to categorise patients into preferring one of three roles in the process of treatment decision-making: passive, active or shared. The three roles mirror the different paradigms of health care delivery described early, the paternalistic, informed and shared decision-making models. In order to summarise the available research, the results of 28 studies which used the Control Preferences Card Sort, decision preference statements or similar classifications are summarised in Figure 1.

It is immediately apparent that patients vary in the degree that they want to be involved in decisions about their treatment; however, trends are evident. The majority of studies (24/28) report that less than 30% of patients prefer an active role in decision-making. Almost all the studies (27/28) show that over 20% of patients prefer a collaborative or shared role in decision-making. However, the proportion of patients preferring a passive

role varies from less than 10% to over 60%. This is in stark contrast to the shift towards encouraging patients to be included in their health care decisions.

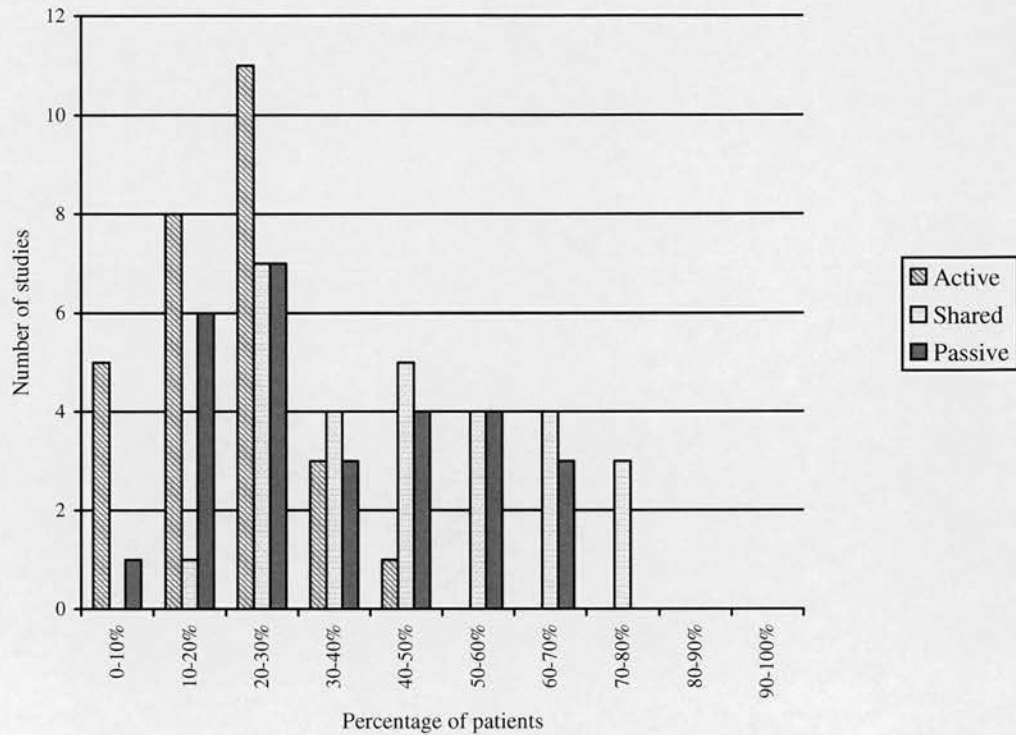


Figure 1: Summary of studies of percentage of patients preferring active, shared or passive role in treatment decision-making (Included studies: Beaver & Booth, 2007; Beaver *et al.*, 1996; Bilodeau & Degner, 1996; Bruera *et al.*, 2002; Butow *et al.* 1997; Davison & Degner, 1997; Davison *et al.*, 2004; Degner & Sloan, 1992; Degner *et al.*, 1997; Elkin *et al.*, 2007; Hack & Degner, 1999; Hack *et al.*, 1994; Jansen *et al.*, 2006; Janz *et al.*, 2004; Kraetschmar *et al.*, 2004; Lam *et al.*, 2003; Lobb *et al.*, 2003; Ong *et al.*, 1999; Ramfelt *et al.*, 2000; Ramfelt *et al.*, 2005; Rothenbacher *et al.*, 1997; Salkeld *et al.*, 2004; Stewart *et al.*, 2000; Stiggelbout & Kiebert, 1997; Sutherland *et al.*, 1989; Vogel *et al.*, 2008; Wallberg *et al.*, 2000; Wong *et al.*, 2000)

The studies do differ in their quality and methodology; for example, the sample sizes of the studies vary widely. Ramfelt *et al.* (2005) found that 1.8% of their sample of 55 patients diagnosed with colorectal cancer would prefer an active role in the treatment decision-making process, which equates to only one participant, limiting any conclusions

that can be drawn; however, even studies with a greater number of participants have not provided consistent results (Degner & Sloan, 1992; Jansen *et al.*, 2006; Kraetschmar *et al.*, 2004). A survey of 436 cancer patients found 12% of people preferred an active role in decision-making; 29% a shared role and 59% a passive role (Degner & Sloan, 1992). However, another study of 446 cancer patients found that twice as many people preferred an active role in decision-making; and half as many a passive role (Jansen *et al.*, 2006).

1.4.2. Stability of patient preferences

The inconsistency of findings suggests that there are variables influencing patient preferences that differ between studies. One methodological inconsistency between studies is the point of a person's illness or treatment at which they were surveyed. For example, Davison *et al.* (2004) asked their participants their preferences for participation at the time of diagnosis, whereas some of the participants in the study by Degner *et al.* (1997) were over 30 years post-diagnosis. A study by Butow *et al.* (1997) found that the majority of their 80 participants changed their preferences for participation between their baseline and follow up measurement, with a trend toward wanting greater participation. This suggests that patients' preferences for participation in decision-making are changeable.

In a larger study, with 729 participants, Mallinger *et al.* (2006) also found changes in patients' preferences for participating, from before their treatment until its completion. While the majority of patients who initially preferred a passive role maintained this preference, overall, 37% of patients wanted to be less active and 22% wanted to be more

active. A multivariate analysis of factors associated with a patient's preference for participation in treatment decision-making following the end of their treatment found that only 16% of the variance was explained by previously expressed preferences and socio-demographic variables. Malingier *et al.* (2006) suggested that a patient's preferences for participation are not static, but rather influenced by dynamic factors, related to their clinical, psychological and social conditions. For example, from the point of diagnosis, the patient will learn more about the illness they must make decisions about; start to adjust psychologically; and build a relationship with the medical team caring for them. All of these factors may influence the role a patient wishes to take in treatment decision-making; unfortunately, key decisions about treatment are often made before these factors have had time to develop.

1.4.3. Actual participation in decision-making

Studies looking at patients' actual role in treatment decision-making for cancer again report varying trends. Estimates of the proportion of patients taking a passive role range from 8% to 77%, and similarly the proportion of patients taking an active role ranges from 7% to 62% (Janz *et al.*, 2004; Ramfelt *et al.*, 2000). The proportion of patients reporting a shared treatment decision ranges from 13% to 30% (Fischer *et al.*, 2006; Vogel *et al.*, 2008).

Table 2 summarises quantitative studies that have investigated whether patients have attained their preferred role. Again, findings vary widely, different studies report that patients take their preferred role in treatment decision-making in between 34% and 80%

of cases (Gatellari *et al.*, 2001; Wallberg *et al.*, 2000); no studies found complete concordance.

Study	Patient population	Attained preferred role (%)	More active than preferred (%)	More passive than preferred (%)
Gatellari <i>et al.</i> (2001)	233 heterogeneous cancer patients	34%	29%	37%
Beaver <i>et al.</i> (1999)	150 breast cancer patients	38%	22%	39%
Degner <i>et al.</i> (1997)	1012 breast cancer patients	42%	n/a	n/a
Janz <i>et al.</i> (2004)	99 breast cancer patients	42%	39%	18%
Ramfelt <i>et al.</i> (2000)	85 colorectal patients	44%	8%	48%
Keating <i>et al.</i> (2002)	1081 breast cancer patients	49%	26%	25%
Bilodeau & Degner (1996)	74 breast cancer patients	50%	n/a	n/a
Beaver <i>et al.</i> (1999)	48 colorectal cancer patients	60%	18%	22%
Vogel <i>et al.</i> (2008)	137 breast cancer patients	63%	15%	22%
Beaver & Booth (2007)	53 gynaecological cancer patients	66%	11%	23%
Hawley <i>et al.</i> (2007)	1038 breast cancer patients	66%	21%	13%
Davidson <i>et al.</i> (1999)	21 lung cancer patients	71%	0%	29%
Wallberg <i>et al.</i> (2000)	201 breast cancer patients	72%	8%	20%
Lam <i>et al.</i> (2003)	154 breast cancer patients	80%	13%	7%

Table 2: Summary of studies investigating concordance between patients' preferred and actual roles in treatment decision-making

For the majority of studies, patients were more likely to report taking a more passive role in decision-making than they would have preferred. For example, in their study with 85 colorectal patients, Ramfelt *et al.* (2000) found that nearly half of their participants were

more passive in decision-making than they would have preferred. Furthermore, Vogel *et al.* (2008) found that patients who preferred a distinct active or passive role were significantly more likely to achieve this, compared to those who preferred a shared role. As shared decision-making has been promoted as best practice within the evidence base (Charles *et al.*, 1997), the discrepancy between preferred and actual roles leads to the question of what factors are influencing patients' level of participation in treatment decision-making consultations. The studies which have investigated concordance shows that the studies all differed in the age and gender of participants included, and the type of cancer participants had been diagnosed with; however they do not reveal any immediate obvious stark demographic trends in rates of concordance.

1.4.4. Section summary

A synthesis of published studies highlights the variability in patient preferences for participation in treatment decision-making. A significant proportion of patients with cancer express that they would not wish to be involved in treatment decision, and studies report that less than a third of participants are sharing decisions with their doctors. This is an evident disparity with the dominant shared decision-making model.

Furthermore, studies have consistently found that patients do not always achieve their preferred level of participation in treatment decision-making, suggesting that a patient's preferences is only one variable that will influence their level of participation in treatment decisions. The evidence for other variables influencing patient participation in treatment decision-making is discussed further in sections 1.6 and 1.7.

1.5. Psychosocial outcomes related to patient participation in treatment decision-making

Despite the shift toward a shared decision-making model, less than one third of patients report sharing treatment decisions with their doctors. Further, a significant proportion of patients describe being more passive than they would have preferred. In order to understand the implication of this disparity, it is useful to consider the outcomes associated with patient participation in treatment decision-making.

There is a growing assumption that traditional clinical outcomes, such as survival rates, are enhanced by considering psycho-social outcomes as well, with patients placing an increasingly high value on outcomes such as social functioning (Weinfurt, 2003). This section considers the research into the impact of patient participation in treatment decisions on patients' social functioning and emotional well-being.

1.5.1. Knowledge about treatment options

Cancer treatment methods are often described using complex medical terminology, and choosing between treatments may involve weighing up potential risks and benefits. As previously discussed, many lay people find this level of medical knowledge hard to understand (Chapman *et al.*, 2003). However, in order for patients to give informed consent for their medical treatment, it is necessary that they are aware of the implications of any decisions. Greater patient participation in the decision-making process has been found to be associated with the patient having increased knowledge about the illness and

treatment, suggesting a more ethical decision-making process (Fagerlin *et al.*, 2006; Gatellari *et al.*, 1999)

Gatellari *et al.* (1999) investigated the recall of important information about treatment decisions in 118 patients with incurable disease two weeks after they had attended the oncology clinic for the first time. Greater encouragement of participation by the clinician was found to be associated with greater recall of information by the patients (Gatellari *et al.*, 1999). In a larger study, Fagerlin *et al.* (2006) surveyed 1844 breast cancer patients, who had either had breast conservation surgery or mastectomy, an average of 8 months after their diagnosis. Despite rating 'recurrence rates' and 'survival rates' as important factors in their treatment decision-making, less than half the women, accurately knew what these were, or the difference in these rates for the two treatment choices. Multivariate analysis, controlling for demographic and illness variables, showed that the women's level of understanding was positively associated with whether they reported surgeons had explained the different treatments to them. In keeping with Gatellari *et al.*'s (1999) finding, this illustrates the central importance of patient participation in consultations for increasing knowledge about treatment options.

Of note, and particular relevance to the current study, Fagerlin *et al.* (2006) suggests that low literacy; poor access to information; insufficient time to make a decision; and patient anxiety may all have detrimental effect on the level of a patient's understanding, with one in three of the study's participants reporting that fear inhibited their decision-making ability.

1.5.2. Psychological adjustment

The most widely researched outcome of patient participation in decision-making is short and long-term psychological adjustment. Morris and Royle (1988) studied 30 breast cancer patients to examine whether having a choice of type of surgery, between either mastectomy or breast conservation surgery, affected their levels of anxiety and depression. The patients who were not offered a choice were found to have higher levels of anxiety and depression before and after surgery, which remained elevated two months later. This preliminary study has been criticised however, as patients were not randomly assigned to one of the two comparison groups, rather the groups were dictated by whether a choice in type of surgery was feasible given the illness characteristics. This may have resulted in group specific variables, such as patients perceiving their illness as more serious when they were not offered a choice, which may have naturally led to heightened distress.

Deadman *et al.* (2001) compared the psychological adjustment of 114 patients divided into three groups: one group required compulsory mastectomy; one group's treatment was elected by the surgeon and one group elected the treatment themselves. In this study, patients were randomly assigned to one of the latter two groups where a choice of treatment was possible. Overall, patients who elected their own treatment had significantly better psychological adjustment, suggesting that increased participation in decision-making does lead to improved emotional well-being. While this study is a valuable contribution to the evidence base, studies using this methodology are increasingly difficult from an ethical perspective, as patient choice becomes increasingly recommended by policy.

Fallowfield *et al.* (1994) carried out a three year prospective study of the impact of participating in surgical decision-making for 269 cancer patients. The patients attended one of 22 surgeons who preferred mastectomy; preferred breast conservation surgery; or offered a choice where possible. The patients attending surgeons who offered a choice where possible had the lowest incidence of distress over a three year follow up period. However, further investigation found that, within this group, just over half genuinely had a choice to make, whereas the other patients' treatment was determined by clinical factors. There was no difference in the rate of distress between these groups, which led the researchers to conclude that, rather than the availability of treatment options, the doctor's consultation style was key in determining patients' psychological well-being.

There is consistent evidence that patients do not have a universal preference for their level of participation in decision-making (Degner & Sloan, 1992). This has led some researchers to investigate whether it is simply participating or participating the preferred amount in the decision-making process that leads to improved psychological adjustment. Hack *et al.* (1994) found that breast cancer patients who prefer a more passive role found pressure to be active in the decision-making process very anxiety provoking. Gatellari *et al.* (2001) assessed patients' preferences for participation in their treatment decisions prior to attending their initial oncology appointment, and then compared this to their actual experience. Only one third of their 233 participants attained the level of participation that they had wanted. A mismatch of roles was found to be significantly associated with higher anxiety levels immediately post-consultation, but the level of anxiety at two weeks follow up was not different between the two groups. Therefore, there is evidence that patient participation in treatment decision-making can lead to better psychological adjustment; however, this may be dependent on a patient's desire

for participation. Indeed, where patients feel forced to become involved there may be a deleterious impact on their psychological well-being.

1.5.3. Quality of life

Research has also investigated the impact of a person's participation in making treatment decisions on their functioning and quality of life. Street and Voigt (1997) followed up 51 breast cancer patients 12 months after their initial surgical consultation. The patients who had actively participated in their consultation reported a higher health related quality of life and a greater feeling of responsibility for their treatment decisions. Similarly, a larger scale study followed up 205 breast cancer patients, three years after their initial treatment decision, to assess their quality of life and functioning (Hack *et al.*, 2006). Patients who had actively participated reported a significantly higher quality of life, specifically for physical and social functioning compared to patients who had reported a shared or passive role in decision-making. Emotional, role and cognitive functioning were not significantly different between the groups.

Both the studies indicated that greater participation is associated with an improved quality of life. The findings of both studies, however, require caution as, despite Hack *et al.* (2006) finding that several socio-demographic characteristics were significantly associated with participants' quality of life, these were not considered in the analyses. This was similarly the case in Street and Voigt's (1997) study. In conclusion, therefore, further consolidating research is required about the relationship between patient participation in treatment decision-making and quality of life.

1.5.4. Satisfaction with decision

Finally, research has also studied the relationship between patient participation in treatment decision-making and their satisfaction with the decisions made. Fischer *et al.* (2006) found that prostate cancer patients involved in decisions about their medical care had higher satisfaction with their treatment decisions and that this level of satisfaction was not associated with their level of distress or quality of life.

However, in line with the argument that patients should be encouraged to take their preferred role, research has found that satisfaction with health care is highest for patients whose participation in their treatment decisions is in concordance with their preferences. A large study of 1081 women with early stage breast cancer showed that, approximately three months after surgery, those who attained their preferred role in decision-making were more likely to be satisfied with the decision-making process, when patient, surgeon and hospital characteristics were controlled for (Keating *et al.*, 2002).

Just as satisfaction has been associated with patient participation in decision-making, research has found that being unable to participate in decision-making can result in regret. A survey of 123 women approximately one year after diagnosis found that while over half experienced no regret over their treatment decisions, a sizeable minority (19.5%) experienced moderate to strong regret (Sheehan *et al.*, 2007). Lantz *et al.* (2005) found that, while patients whose preference for participation in decision-making is met are more satisfied with their care, patients who have more or less participation than preferred show more ambivalence about their decisions, or regret.

1.5.5. Section summary

Overall research has found that patient participation in treatment decision-making is associated with improved outcomes, including better psychological well-being, increased satisfaction, decreased regret, increased knowledge and improved quality of life. However, there is some evidence that this association is not simple, and in some instances, rather than absolute patient participation, a patient participating to the degree that they prefer, may be key in improving outcomes. This leaves a somewhat ambiguous picture. Given the paradigmatic shift toward increased patient participation, it will be important for the ongoing research to resolve the conundrum of whether universally promoting patient participation, or enabling patients to achieve their preferred level of participation, leads to improved outcomes, and indeed whether at times participation can be deleterious. In either instance, further understanding of factors that influence patient participation in treatment decision-making is necessary. Understanding what facilitates and hinders the process of a patient participating in decision-making will provide a guiding framework by which to improve patient care.

1.6. Understanding the process of participating in treatment decision-making

Research has shown that patients with cancer do not always attain their preferred level of participation in treatment decision-making. The massive variability in concordance between patients' preferences and actual role in treatment decision-making between studies (section 1.4) illustrates that static demographic factors, patient preferences and cancer type, may be insufficient to explain what influences patient participation. This section explores processes that may contribute to patient participation in treatment decision-making from a theoretical perspective.

1.6.1. Theory of Planned Behaviour

One of the dominant models used to understand human behaviour in a health context is the Theory of Planned Behaviour (Ajzen, 1988), an extension of the Theory of Reasoned Action (Ajzen & Fishbein, 1980). The Theory of Reasoned Action predicted that behaviour can be determined by a person's intention to carry it out. A person's intentions are shaped by their attitudes, that is their beliefs about the behaviour and its potential outcome; and subjective norms, that is the person's perceptions about other people's beliefs about the behaviour. The Theory of Reasoned Action, however, was criticised for being limited to explaining behaviours which were solely dependent on personal agency; it was argued that regardless of the strength of a person's intention to carry out a behaviour, inevitably behaviour is partially determined by personal and environmental barriers (Armitage & Connor, 2000). Therefore, the Theory of Planned Behaviour added an additional factor to the model of behaviour: perceived behavioural control. Perceived behavioural control indexes a person's perception of their ability to perform the

behaviour and has variously been described as indexing a person's internal resources, their self-efficacy and their locus of control (Armitage & Christian, 2003).

For the most part research into the Theory of Planned Behaviour has focused on volitional health promotion behaviour; however, it is useful to consider it here to understand the process of patient participation in treatment decision-making consultations for two reasons. Firstly, the research into patient participation shows that patient preferences for participation do not concord with their actual decision-making behaviour. In parallel, the Theory of Planned Behaviour has found that intention to perform behaviour does not always result in it being implemented. A recent meta-analysis of 185 studies found that the Theory of Planned Behaviour accounted for 27% of variance in subsequent behaviour (Armitage & Connor, 2001); while 27% is a substantial proportion, it leaves 73% unaccounted for, namely the intention to action gap.

The theory has been praised for its economy; it requires only a few factors to account for significant variance in behaviour (Abraham & Sheeran, 2003); however, the opposing view is that its parsimony leads to the exclusion of key factors. A criticism levelled at the Theory of Planned Behaviour is that it relies too heavily on rational decision-making processes by the individual (Armitage *et al.*, 1999; Ingham, 1994); one of the most significant variables that authors contend is absent from the Theory of Planned Behaviour is the influence of a person's emotion (Armitage *et al.*, 1999). Therefore the second reason that the Theory of Planned Behaviour is important to consider, when understanding the process of patient participation in treatment decision-making consultations, is that it is the main contention of the current study that emotion can

significantly impact on the implementation of the preferred role in treatment decision-making.

The addition of perceived behavioural control to the Theory of Planned Behaviour acknowledges that there are personal and environmental barriers which may directly affect whether a behaviour is carried out. Indeed, Armitage and Connor (2001) established that perceived behavioural control directly contributes to the variance in behaviour; however, it only adds 2% to the explained variance. Sheeran *et al.* (2003) argue that people are not accurate at judging the control they have over future behaviour; perceptions of control may be influenced by task familiarity; the implications of the task and, notably, mood. Loewenstein (2005) argues that we do not appreciate the extent to which our actual behaviour will be influenced or motivated by our emotional state, termed a 'cold-to-hot empathy gap'. At its extreme, Loewenstein (2005, p.S49) argues that "people often behave myopically under the influence of affect". In relation to the current study, the potential influence of emotion on people's behaviour is illustrated by theories of human decision-making, and the current understanding about how emotion can influence these processes.

1.6.2. Decision-making theory

Traditional models describing the process of decision-making, similarly to the Theory of Planned Behaviour, tend to assume that humans are rational actors. The Expected Utility Theory of decision-making, described by von Neumann and Morgensten (1947), proposed that a decision maker determines all the possible outcomes of a decision, and then ascertains the probability of each outcome and its usefulness, in order to calculate

the expected utility of a decision. However, the fundamental assumption of Expected Utility Theory, that a decision maker acts rationally when considering any decisions and has infinite time and unbiased cognitive processes, is inherently flawed.

Research has shown that people often display imperfections in their cognitive processes when making a decision; Simon (1957) described that people have a limited ability to consider differing options, termed 'bounded rationality', and therefore, instead of an exhaustive search, many people will make a decision when any satisfactory outcome is found, termed 'satisficing'. In cancer, key treatment decisions often involve highly complex information, which previous research has shown may be beyond many lay people's understanding (Chapman *et al.*, 2003). A study by Sutherland (1990) illustrated the complexities of making a decision about cancer treatments and how individual differences in cognitive processes may influence the decision made. The researchers asked 50 lay people to make a hypothetical decision on whether to enter a clinical trial based on information provided. Three quarters of their sample did not indicate that considering both risks and benefits was pertinent to their decision. Similarly between 26% and 54% of interpretations, by the participants, of statements about probability were incorrect. The decision-making process was neither robotic, nor exhaustive; rather it was based on another, unknown heuristic.

Subsequent theories of decision-making recognise that humans do not always act rationally when making decisions. In their Behavioural Decision-Making Theory, Tversky and Kahneman (1981) argued that a person's decision depends on the context in which the decision is made, and the differing values placed on the alternative outcomes. For example, Slevin *et al.* (1990) surveyed medical professionals, cancer patients and

healthy controls about whether they would accept a gruelling three month course of chemotherapy if it would extend their life expectancy. No Radiotherapists, 6% of Oncologists and 10% of healthy controls stated they would accept this, compared to 42% of people with cancer. The context and personal value of opting for the chemotherapy was central to a person's decision whether to accept the treatment.

Key decisions in cancer may arise only once and have a major impact for the patient; often there are high levels of distress at the time patients are asked to make serious decisions. Nearly 50% of doctors report patient anxiety as a barrier to involving them in treatment decision-making (Charles *et al.*, 2004). In fact, some researchers have argued that the lack of an absolute treatment and the increase in treatment choices can potentially exacerbate patients' distress (Kiesler & Auerbach, 2006). Decision-making theorists have speculated about several mechanisms by which emotion may impact on a decision-making process.

1.6.3. Emotion and decision-making

Winkleman *et al.* (2007) outline four main mechanisms by which emotion may have an effect on a person's decision-making. The first is by influencing cognitive processes such as recall; so, for example, a person who is anxious will be more likely to interpret information as threatening. For example, Shapiro *et al.* (1992) presented 40 women, at risk of breast cancer, with a simulated video of an oncologist presenting results. The oncologist and results were identical; however, the oncologist presented with either a worried or non worried affect. Women watching the 'worried' clinician remembered

significantly less information, viewed the situation as more severe, and experienced higher anxiety.

The second mechanism by which emotion may influence decision-making is by influencing a person's behaviour such as speeding up a search, or increasing avoidant behaviour, when exposed to negative information. The third is by being a direct component of a person's decision, when a person bases a judgement on how they 'feel' about the subject. The fourth mechanism is whereby people alter their behaviour or actions to regulate their emotional experience to either restore a previous emotional state; generate a preferred emotional state; or make their emotional state complicit with the demands of a situation.

The fourth mechanism is central to the Decision Conflict Theory described by Janis and Mann (1977). Janis and Mann (1977) argued that the actual process of making a decision is inherently stressful, and propose that when a person is under stress they adopt adaptive decision-making styles. Pinquart *et al.* (2004) suggested that four of these styles are directly relevant to patients making treatment decisions about cancer: unconflicted change, defensive avoidance, hypervigilant, and vigilant. Defensive avoidance and unconflicted change are indicative of a patient adopting a passive role in decision-making and seeking others to either make the decision or recommend the correct choice. Hypervigilant decision-making is defined by the person attending to as much information as possible, but seizing upon a solution to allow relief from their emotion, potentially at the expense of choosing the correct option. Vigilant decision-making is akin to shared or active decision-making, weighing up the benefits and disadvantages of a choice, and is seen as producing the highest quality decisions. The relationship of

patient distress and participation in treatment decision-making is discussed further in section 1.8.

1.6.4. Communication Model of Treatment Decision-making

To date there is no unifying theory or model that has been extensively used to account for patient participation in treatment decision-making. The Shared Decision-making Model describes the ideal end state, but not the processes that would predict a patient's participation. More general models predicting human behaviour, such as the Theory of Planned Behaviour, mostly focus on volitional behaviour and assume the person approaches their decisions rationally. More recent theories of decision-making, such as Decision Conflict Theory have recognised, however, that people do not act rationally when faced with decisions and that decision-making processes are affected by factors such as the context of the decision; personal values; and the person's emotional state.

Siminoff and Stepp (2005) described a series of factors that may contribute to the level of a patient's participation in treatment decision-making, in their Communication Model of Decision-making. There are three contributory elements in their model of the decision-making interaction: a) patient-physician antecedents; b) the communication climate and c) the treatment decision (Figure 2). Patient and physician antecedents include socio-demographic characteristics, personalities and competence in communication. The communication climate depends on the medical issue to be discussed, and is created by the participants. It can be dependent on the preference of the patient for participation, the emotional response of the patient as well as the physician's affective demeanour. Finally, the model describes that the treatment decision is the

starting point for future interactions, underscoring that intervention at this point may be valuable in improving patient outcomes. The model has not been tested empirically, however, it provides an overarching framework to further consider what factors may influence patient participation in treatment decision-making.

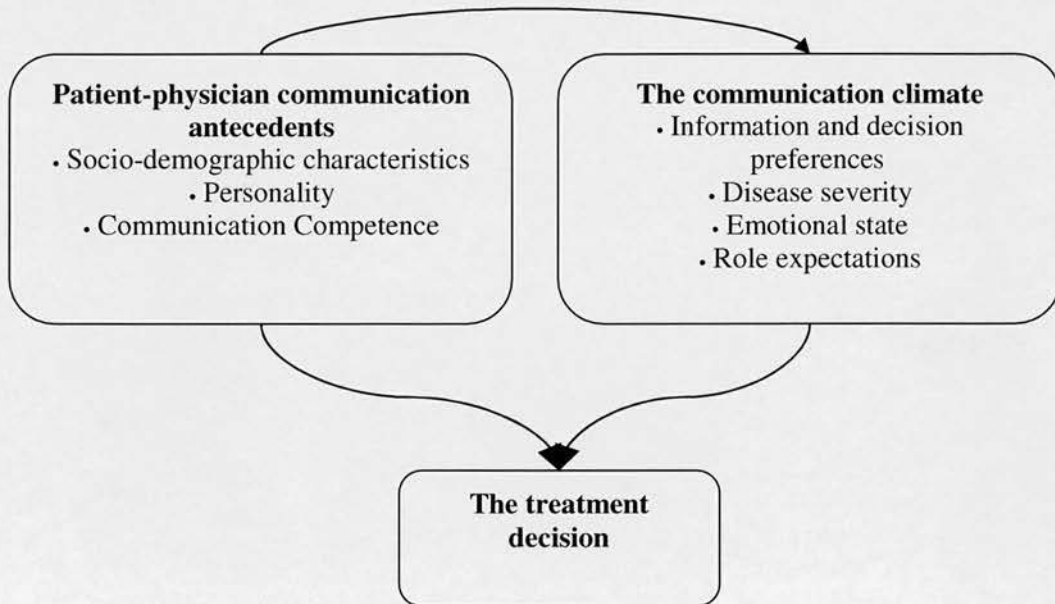


Figure 2 Siminoff and Stepp (2005) The Communication Model of Decision-making

1.6.5. Section summary

In the context of medical treatment decision-making, it is fundamental to ensure the quality of a person's decision-making, as all decisions require informed consent from the patient. The current dominant paradigm of health care delivery emphasises patient participation, with decisions about treatment being made collaboratively, between the health care provider and health care service user. However, in order to realise this ideal

premise of shared decision-making, it is vital to understand what may hinder or facilitate it.

One of the most prominent theories of human behaviour in a health setting, the Theory of Planned Behaviour, has been criticised for being unable to explain the intention to action gap. In the context of treatment decision-making, many patients do not perceive that they participate, to the extent they indicate they would prefer. Siminoff and Stepp's (2005) Communication Model of Decision-making provides an overarching view of the multitude of factors which may influence the treatment decision-making process, one of which is the patient's emotional state. Research into intrapersonal decision-making processes has shown that people do not always act rationally under stress, due to the influence emotion can have on cognition and behaviour. Many key decisions about cancer treatments occur in the early phase of adjustment. The current study sets out to understand further how patient distress at this time impacts on treatment decision-making processes, especially as Siminoff and Stepp (2005) highlight that this is often the starting point for future interactions with the health care provider.

1.7. Factors influencing patient participation in treatment decision-making: A review of the literature

Siminoff and Stepp (2005) have developed the Communication Model of Decision-making to describe factors which may influence patient participation in decision-making. As the model has yet to be empirically tested, in order to summarise the existing literature on factors affecting participation in medical decision-making, a critical review of the literature was carried out. As the focus of the current study is the influence of patient distress on their participation in treatment decision-making, studies investigating this variable are central to the discussion.

1.7.1. Literature review search strategy

The literature review search strategy included all peer-reviewed journal articles published between 1988 and 2008 in the English language. All studies, regardless of methodology, were included; however, all were critically appraised to identify methodological limitations and potential biases. Previous research has found that patients express differing preferences for participating in treatment decisions, depending on the illness concerned (Arora & McHorney, 2000); therefore, the search was limited to studies with an adult cancer population measuring naturalistic decision-making. All studies investigating decision aids were excluded.

Searches were carried out using Ovid databases: Medline, Psycinfo and The Cochrane Library and the EMBASE database: CINAHL. The search terms that were used are listed in Table 3; search terms were combined using Boolean operators. The Ovid database

search yielded 303 articles, and the EMBASE database search yielded 33 articles. The abstracts of these were then reviewed for relevance. In addition, cited and citing journal articles from key articles were followed up. Summary tables of the included articles are in Appendix 2.

	SEARCH TERMS USED
Identification of Population	Cancer; neoplasm; tumour; oncology
Area of study	Medical decision-making; treatment decision-making
Subject of study	Patient participation; patient involvement; shared decision-making; joint decision-making

Table 3: Search terms for review of literature

1.7.2. Previous reviews of the literature

Three previous reviews of the literature regarding influences on patient preference were found during the search (Benbasset *et al.*, 2001, Hubbard *et al.*, 2008; Say *et al.*, 2006). The two later reviews (Say *et al.*, 2006; Hubbard *et al.*, 2008) do not acknowledge the previous reviews, which perhaps reflect the heterogeneous and sprawling nature of the evidence base, conducted in the fields of nursing, psychology and medicine. Benbasset *et al.* (1998) and Say *et al.* (2006) reviewed papers about preferences for participating in decision-making by patients with different conditions including cancer. Given this, they are not included in the current review.

Hubbard *et al.* (2008) reviewed 31 quantitative papers published between 1994 and 2004 about cancer patients' preferences for participation in treatment decision-making as well as what influenced this. This review reported that there is a trend toward younger, female

and better educated patients preferring more participation; however, demographic characteristics cannot fully account for the variance in patient preferences. The review also highlights that patient preferences are not being met and asks the reason some patients attain their preferred role and others do not. Unfortunately, its focus on papers investigating patient preference, does not allow this question to be addressed. The current review extends Hubbard *et al.* (2008) by reviewing papers that explored factors associated with patients' actual participation in decision-making, as well as factors associated with their preferences. Furthermore, the current review includes qualitative literature.

1.7.3. Patient preferences for participation

Thirty relevant articles using quantitative methodology; eight articles using qualitative methodology; and one using mixed methodology (Hack *et al.*, 1994) were found to have investigated variables influencing patient preference for participation in treatment decision-making (Appendix 2, Table 14 & Table 15).

1.7.3.1. Socio-demographic variables

Twelve studies found that there was a significant association between age and patient preferences for participation in decision-making (Appendix 2, Table 14): all the studies found that younger patients prefer a more active role. However, where possible to calculate, the variance in preferred participation explained by age is less than 3% (Beaver *et al.*, 1996; Degner & Sloan, 1992). Equally, 12 studies found that there was no significant association between age and patient preferences. In general these were smaller studies, with 11 of the 12 having less than 150 participants. Therefore, it is possible that as age holds a weak association with patient preferences for participation, only larger studies have detected its effect.

Six studies found that there was a significant association between education and patient preference for participation in decision-making (Appendix 2, Table 14): all these studies found that patients with more education prefer a more active role. Nine studies found no significant association between education and patient preference for participation in decision-making.

Many of the studies only include one gender due to the study population, such as breast or prostate cancer patients. Eight studies investigated whether gender was associated with preference for participation in decision-making: six studies found a significant association and two found no significant association. Again, all the studies reporting a significant association found that women preferred a greater level of participation than men.

There is a general trend that women, people of a younger age and people who have received more education prefer a more active role in decision-making. However, this trend is not always found to be significant, and a large study by Degner and Sloan (1992), using multivariate analysis, found that socio-demographic variables only accounted for 15% of the variance in preferences for participation in decision-making, leaving 85% of the variance unaccounted for. Therefore, it is not possible to define patients' preferences for participation based on static socio-demographic variables.

1.7.3.2. Emotional well-being

Six quantitative studies have investigated whether a patient's emotional well-being or coping style affects their preference for participation in decision-making (Appendix 2; Table 15). Three studies found a significant association between emotional well-being or coping style and a patient preferring a more passive role in treatment decision-making (Hack & Degner, 1999; Ong *et al.*, 1999; Vogel *et al.*, 2008). Three studies found no significant association (Janz *et al.*, 2004; Sainio & Lauri, 2003; Wong *et al.*, 2000).

Hack and Degner (1999) studied coping responses in 70 women diagnosed with breast cancer. They used cluster analysis to examine the women's preference for participation in treatment decisions and psychological adjustment. Women whose coping response was classed as avoidant of their illness had significantly higher levels of anxiety, depression and confusion. Significantly more women who were moderately avoidant preferred a passive role, compared to women who were low avoiders, suggesting that patients who were not adjusting well to their diagnosis preferred less participation in treatment decisions.

Similarly, in a study of 137 breast cancer patients, Vogel *et al.* (2008) found that patients who preferred a passive role in decision-making were significantly more depressed, and there was a trend that patients who preferred an active role in decision-making reported the lowest level of anxiety. However, the majority of patients were below the clinical cut-off for depression and anxiety on the Hospital Anxiety and Depression Scale. In addition, the difference in the average depression scores for women preferring different roles was less than three points on the scale. Therefore, while this trend is statistically significant, it is unclear if it is clinically relevant.

Nevertheless, findings from six qualitative studies support the hypothesis that emotional well-being can affect a patient's preference for participation in decision-making (Charles *et al.*, 1998; Cohen & Britten, 2003; Elit *et al.*, 2003; Hack *et al.*, 1994; Sainio *et al.*, 2001; Sanders & Skevington, 2004). Cohen and Britten (2003) interviewed 19 male prostate cancer patients, who had been given their diagnosis in the same consultation as being asked to make a treatment decision. The participants had difficulty concentrating on the decision-making process, and described welcoming a directive approach.

Similarly, Elit *et al.* (2003) interviewed 21 female gynaecological cancer patients; the participants did not receive their diagnosis and make a treatment decision in the same consultation; nevertheless, they described feeling overwhelmed during the period in which their treatment decisions were made.

The other three quantitative studies failed to find a significant association between patients' mood and their preferences for participation in decision-making (Janz *et al.*, 2004; Sainio & Lauri, 2003; Wong *et al.*, 2000). Sainio and Lauri (2003) did not find a significant association between the importance patients place on participation in decision-making and their score on a ten point depression scale, in a group of 273 patients, diagnosed with various types of cancer, who were up to 15 years post-diagnosis. This retrospective method is flawed in two ways. Firstly, mood is not stable, and therefore investigating the association of current mood and preference for participation in decision-making may not be a valid measure of the patient mood at the time of the actual treatment decision-making consultation. Secondly, mood has been shown to bias recall; therefore, people may not have an accurate recall of their preference for participation. As well as the difficulties associated with a retrospective design, the use of an idiosyncratic measure of mood and lack of consideration of extraneous variables, result in the findings of this study lacking conviction.

In contrast to the methodology used by Sainio and Lauri (2003), Janz *et al.* (2004) surveyed 101 breast cancer patients prior to their treatment decision-making meeting to establish their preferences for participation in decision-making. This prospective methodology allows a more valid investigation of the relationship between mood and

patients' preference for participation; nevertheless, no significant association with the patients' level of anxiety or depression was found.

Therefore, there is mixed evidence about whether a patient's emotional well-being affects their preferences for participation in decision-making. Evidence from several qualitative studies has shown that patients identify that their emotional well-being at the time of the decision partly dictates the role they would prefer to take; however, this is not always borne out in the quantitative literature. The quantitative literature completed so far is minimal and has some methodological flaws. Therefore, further research is required to examine whether patients' emotional well-being influences their preferences for participation in decision-making.

1.7.3.3. Other variables

Other studies have investigated various contextual variables associated with patient preferences for participation in decision-making, including physical well-being or disease progression (Sainio & Lauri, 2003; Blanchard *et al.*, 1998; Stewart *et al.*, 2000; Barry & Henderson, 1996); perception of choice (Jansen *et al.*, 2004; Vogel *et al.*, 2008); perception of responsibility for treatment choice (Charles *et al.*, 1998; Cohen & Britten 2003; Kenney *et al.*, 1999); knowledge of treatments (Kraetschmar *et al.*, 2004; Charles *et al.*, 1998; Elit *et al.*, 2003; Henman *et al.*, 2002; Husain *et al.*, 2008; Kenney *et al.*, 1999; Sainio *et al.*, 2001); and trust in the doctor (Kraetschmar *et al.*; 2004; Kenny *et al.*, 1999; Henman *et al.*, 2002; Husain *et al.*, 2008; Hack *et al.*, 2004).

1.7.4. Patients' actual participation

Ten quantitative, and one qualitative, studies were found to have investigated patients' actual participation in treatment decision-making (Appendix 2; Table 16 & Table 17). One of these studies (Sainio & Lauri, 2003) was also included in the review looking at factors influencing patient preferences. Only one study has investigated factors which explain the level of concordance between patients' preferred and actual participation in decision-making (Hawley *et al.*, 2007). The published studies do not have the same uniformity of methodology apparent in those examining patient preferences, for example the studies use a range of measures, which makes drawing general conclusions more difficult.

1.7.4.1. Socio-demographic variables

Six quantitative studies investigated whether age is associated with a patient's actual level of participation in decision-making (Appendix 2; Table 16). Only two studies concluded that age significantly affected a person's actual participation in medical decision-making (Fischer *et al.* 2006; Pinquhart *et al.*, 2004). The other four studies found no significant association between age and participation in medical decision-making (Hawley *et al.*, 2007; Liang *et al.*, 2002; Maly *et al.*, 2004; Sainio & Lauri, 2003).

In their study of 126 prostate cancer patients, Fischer *et al.* (2006) found that younger men were significantly more likely to report more active participation in their medical decision-making. This seems to mirror the trend identified that younger patients prefer

more active participation. Pinquart *et al.* (2004) found the same trend in their study which used a questionnaire based on the decision-making styles described by Janis and Mann (1977). The study of 140 patients, with different cancer types, found that age was positively associated with unconflicted change, that is adopting a passive role in decision-making, and negatively associated with vigilant decision-making, that is adopting a rational shared or active role. Both studies relied on univariate analysis of the data however, which may not have accounted for compounding effects of other variables, such as severity of disease.

In a larger study of 1038 female breast cancer patients, Hawley *et al.* (2007) concluded that age was not significantly associated with a patient's actual participation in decision-making. By dividing their sample into three age bands, Hawley *et al.* (2007) investigated the odds of each age band experiencing different levels of participation, controlling for other socio-demographic and illness variables. Their only significant finding was that the middle age group, aged 45 to 64 years, was nearly two times more likely than the older age group to report that the surgeon made the decision, as opposed to a shared decision-making process. This would indicate that younger women had less participation in the decision-making process, than the older age group, which counters Fischer *et al.*'s (2006) finding.

Overall, 66% of Hawley *et al.*'s (2007) sample reported the right amount of participation in the decision-making process. Of note, however, the two younger age groups were significantly more likely to report too little participation compared to the oldest age group. This finding shows that younger women were less involved than they had wanted to be. As such, age is the only factor that has been found to be significantly associated

with whether patients attain their preferred role in treatment decision-making and raises the question as to what variables impacted on these participants' ability to attain their preferred level of participation.

Three studies investigated whether education or cognitive ability were associated with a person's actual level of participation in treatment decision-making. Siminoff and Fetting (1991) carried out a behavioural analysis of 100 consultations with female breast cancer patients, to investigate factors affecting a patient's acceptance or rejection of their doctor's treatment recommendation. Patients with less formal education were significantly more likely to accept their doctor's recommendation for treatment. Similarly, Pinquart *et al.* (2004) found higher cognitive abilities were associated with vigilant, or rational, decision-making, and lower cognitive abilities were associated with hypervigilant, or panicked, decision-making. In contrast, Sainio and Lauri (2003) found no significant association between the level of formal education and participation in medical decision-making, although again it is important to note the limitations of this study that have been previously discussed. This study also found no significant association between patients' level of participation in medical decision-making and their gender. Neither did Pinquart *et al.* (2004), the only other study to investigate this. In summary, there is some evidence that higher levels of education, but not gender, may be associated with greater participation in treatment decision-making, however, the paucity of studies investigating these variables does not allow firm conclusions to be drawn.

1.7.4.2. Emotional well-being

Four quantitative studies and one qualitative study investigated the impact of a patient's emotional well-being or coping style on their actual participation in medical decision-making (Appendix 2; Table 16 & Table 17). McVea *et al.* (2001) interviewed 25 low income women with breast cancer and conducted thematic analysis of the transcripts. The authors assumed that women would engage in rational style of decision-making, actively gathering information about treatment options and considering the advantages of each alternative. However, thematic analysis of their data revealed that women reported that this did not happen due to the stressful nature of the situation. The authors identified four patterns in the women's treatment decision-making styles, which depended on how they were affected by emotion: panicked, avoidant, passive and rational. The largest group of participants were rational, describing the ability to regulate their fear and engage fully in decision-making. The idea that patients employ decision-making styles to regulate their emotions during decision-making is in line with decision-making theory (e.g. Janis & Mann, 1977). Given the inductive methodology, conclusions cannot be drawn around the validity of the four identified patterns; nevertheless, McVea *et al.*'s (2001) study suggests that patients who are suffering greater distress have difficulties participating in decision-making.

In their study, Sainio and Lauri (2003) measured their participants' mood using a ten-item screening tool for depression. Using this tool, one third of their sample was classed as depressed. The study found no significant association between whether a person was depressed and whether they had participated in decision-making. The previous methodological concerns about this study, in particular, the method of comparing a

patient's present mood to retrospectively reported participation in treatment decisions when some participants were significantly past the initial diagnosis, mean that this finding is unconvincing.

Fischer *et al.* (2006) investigated whether patients' level of participation in treatment decision-making was associated with their coping style. It was hypothesised that patients classed as using an active coping style would be significantly more active in decision-making; however, univariate analysis again did not indicate any significant association. In addition, similarly to Sainio and Lauri (2003), Fischer *et al.* (2006) employed a retrospective methodology with participants ranging from zero to three years post diagnosis, again weakening the validity of the study's findings.

In a study of 79 patients diagnosed with various cancer types, Peterson *et al.* (2003) measured the relationship between anxiety and depression and a patient's reported decision-making style. Decision-making style was measured using a new tool, developed by the authors. Participants had recently had a treatment consultation with a doctor and were awaiting the start of their treatment. Previous research has shown that patients' anxiety decreases immediately following treatment decision-making (Morris & Royle, 1988); however, compared to the retrospective methodology employed by Fischer *et al.* (2006) and Sainio and Lauri (2003), Peterson *et al.*'s (2003) time frame of study provided a more valid measure of the association between patient's emotional well-being and their participation in treatment decision-making. However, despite this, no significant associations were found between the style of a person's decision-making and their current mood. Pinquart *et al.* (2004) also failed to find a significant association using a similar methodology.

The four quantitative studies which have investigated whether a patient's emotional wellbeing is associated with their actual level of participation in decision-making, have found no significant relationship. This is at odds with qualitative research (McVea *et al.*, 2001) as well as researchers' hypotheses (e.g. Fischer *et al.*, 2006). The studies have differing methodologies and have used dissimilar measures, which make drawing comparisons and conclusions difficult. In addition, similarly to research investigating whether emotional well-being affects patient preferences for participation, some of the existing studies have lacked temporal validity in their methodologies, interviewing patients years past their diagnosis. Therefore, there is a need to further investigate the impact of patient's emotional well-being on their actual participation in medical decision-making.

1.7.4.3. Other variables

Other variables have also been found to account for variance in patient's actual participation in medical decision-making including the stage of their disease (Fischer *et al.*, 2006), the availability of treatment options (Hawley *et al.*, 2007; Liang *et al.*, 2002), their level of social support (Maly *et al.*, 2004; Liang *et al.*, 2002; Sainio & Lauri, 2003), the level of patient knowledge (Siminoff & Fetting, 1991) and whether there was a direct invitation to participate (Street *et al.*, 1995; Maly *et al.* 2004; Liang *et al.* 2002).

1.7.5. Section summary: Conclusion of literature review

The majority of the research investigating variables associated with patient participation in decision-making has focussed on understanding patient preferences. However, despite continued research over two decades, discrete variables which consistently impact upon the role a patient wishes to take in decisions about their treatment for cancer have not been established. Further, the proportion of patients achieving their preferred role varies widely. Given this, and that it is a patient's actual participation in decision-making, or achieving their preferred role, which is associated with improved psycho-social outcomes, it seems that continuing to focus on patient preferences, and static determinants of these, may limit the relevance of this body of research to clinical work.

Less research has looked at factors influencing a patients' actual participation in treatment decision-making. The clinical utility of the research could be increased by examining contextual factors, which may influence a patient's actual role in treatment decision-making and their ability to attain the role that they prefer. Identifying these contextual factors may highlight areas of possible intervention. One of the most evident challenges is that treatment decisions for cancer often occur in the early stage of adjustment, when patients are distressed. The impact of patient distress on their participation in treatment decision-making is the focus of the current study and is further discussed in the next section 1.8

1.8. Patient distress and decision-making

Theoretical models speculate that emotion influences a person's decision-making process, either by affecting the cognitive processes used when making a decision, or by altering a person's behaviour to help regulate the stress caused by the situation. When treatment decisions for cancer are required, patients are often in the early stages of adjustment and experiencing high levels of distress. This section draws together some of the previously discussed research to understand how distress may affect patient participation in treatment decision-making, and to introduce the concept of emotion regulation.

1.8.1. The impact of distress on the treatment decision-making process

Qualitative accounts by patients with cancer describe how distress impacts on their desire to be involved in the decision-making process and on their ability to actually be involved, for example by affecting their concentration (McVea *et al.*, 2001) or by creating a feeling of pressure to be involved (Hack *et al.*, 1994). However, to date, preliminary quantitative research with cancer patients investigating the impact of distress on their decision-making process has not provided conclusive findings to support the theoretical models or qualitative findings. A patient's emotional well-being has not been found consistently to be associated with, or to predict, their preferred decision style or their actual level of participation with treatment decision-making. At present, the research remains limited and beset by methodological inconsistencies, such as retrospective data collection, diverse procedures and measures, and univariate analysis. Therefore, there is a need to re-assess whether distress does impact on patient

preferences and participation in treatment decision-making using common measures, and a prospective methodology.

Furthermore, however, the research into patient participation in treatment decision-making has left another fundamental question unanswered. Research has shown that for a significant proportion of people in treatment decision-making their role in the process is not what they had initially wished for (Gatellari *et al.*, 2001). Current policy explicitly states that patients should be allowed to be involved in decision-making if they so wish (NICE, 2002), and the importance of this is highlighted by research showing the benefit that it can have for patients' psychosocial outcomes (Gatellari *et al.*, 2001; Keating *et al.*, 2002). Yet little or no research has explored what factors account for patients achieving the level of participation that they would prefer. Hawley *et al.* (2007) provides the exception, establishing that younger women amongst her participants were less likely to take their preferred role in decision-making. This leads to the question of what it was about these participants, or their consultations, that led to the mismatch between their preferred and actual roles in decision-making.

Criticism of the Theory of Planned Behaviour has highlighted that there is often a gap between a person's expressed intention and ultimate action. The evidence from decision theory shows that high emotion can impact negatively on people's planned behaviour. It is possible therefore that distress influences whether a patient takes their preferred level of participation.

1.8.2. Emotion regulation

Responding optimally and adaptively to the demands of different situations requires a person to regulate their emotions: increasing emotional responses which promote useful behaviour and decreasing emotional responses which promote ineffectual behaviour. “Emotion regulation refers to the processes by which individuals influence which emotions they have, when they have them, and how they experience and express these emotions” (Gross, 1998, p. 275). Given the impact that emotion can have on processes during decision-making, a person’s ability to regulate their emotions at this time may be key to their participation in decision-making for two possible reasons.

Firstly, emotion regulation may moderate the relationship between distress and participation in treatment decision making. Greater difficulties with emotion regulation may result in a person experiencing higher levels of distress when attempting to respond to the demands of the situation; the higher distress could then affect decision making in a number of ways (Winkleman *et al.*, 2007). Alternatively, it has already been theorised that emotion regulation may mediate the relationship between distress and participation in treatment decision making (Janis & Mann, 1977; Luce, 2005). A mediator variable can be understood as explaining the relationship between two other variables (Baron & Kenny, 1986). In Decision Conflict Theory, for instance, Janis and Mann (1977) suggest that a person uses their decision making style to regulate their emotion; the decision making style mediates the way a person’s distress influences their levels of participation. In fact, emotion regulation strategies may both moderate and mediate distress in relation to treatment decision-making; however, the present study will focus on examining

whether emotion regulation moderates the impact of distress on treatment decision-making.

The concept of emotion regulation has developed from research into the human behaviour when under stress. Folkman and Lazarus (1985, p.152) describe stress as “a relationship between the person and the environment, that is appraised by the person as relevant to his or her well-being, and in which the person’s resources are taxed and exceeded”. They further described a person’s cognitive and behavioural efforts to manage the stress as coping responses. Coping responses can be either problem-focussed, with the goal of fixing the stressor, or emotion-focussed, with the goal of ameliorating negative emotional experience. Emotion-focussed coping strategies are at the foundation of the concept of emotion regulation.

Gross (1999) makes a strong distinction between coping and emotion regulation. He argues that coping encompasses a broad range of responses to a challenging situation including practical, non-emotional strategies, and often occurs over an extended period of time, such as the first year after being diagnosed with cancer. Emotion regulation focuses on the active co-ordination of a person’s positive and negative emotional response at a specific time point. For example, Oatley and Johnson-Laird (1987) described that all our experiences are appraised in terms of our goals and plans. Specific basic emotions: happiness, sadness, anger, fear or disgust, are elicited at certain key junctures toward our trying to achieve those goals or plans and consequently guide our reactions.

Fundamentally, emotion regulation strategies can be conscious or unconscious and modulate rather than eliminate both negative and positive emotional responses. There are potentially limitless numbers of emotion regulation strategies. One conceptualisation is that the generation of emotions unfolds along a timeline, beginning with the evaluation of a cue. This 'emotion-generative process' is multifaceted and involves our cognitive, behavioural and physiological systems. Different emotion regulation strategies may be more effective at regulating different systems at different stages of the process (Gross, 2002). Gross (1998) developed a model to differentiate which specific emotion regulation strategies may be more relevant at different stages of the emotional response (Figure 3). Responses may be categorised as antecedent-focused strategies, which are utilised before our full emotional response is activated, and response-focused strategies, which are utilised after an emotion has been generated. Antecedent-focused strategies include selecting or modifying situations to regulate emotions, concentrating on specific aspects of a situation or assigning meanings to a situation. Response-focused strategies focus on attempts to influence the experience or expression of an emotional response.

As an illustrative example, a cancer patient attending a medical consultation may not be able to utilise emotion regulation strategies classified as situation selection or modification, as the situation may be unavoidable, in order to obtain treatment. Employing attentional deployment strategies may be detrimental to the person's ability to consent to treatment, if they were to focus attention away from threatening, yet important, information. Some cognitive change or reappraisal strategies may contribute directly to their emotional well-being. However, the objective fact of facing a life-threatening illness may not be easily re-appraised, hypothetically leaving the person's

response modulation strategies as key in regulating their emotion during a medical consultation.

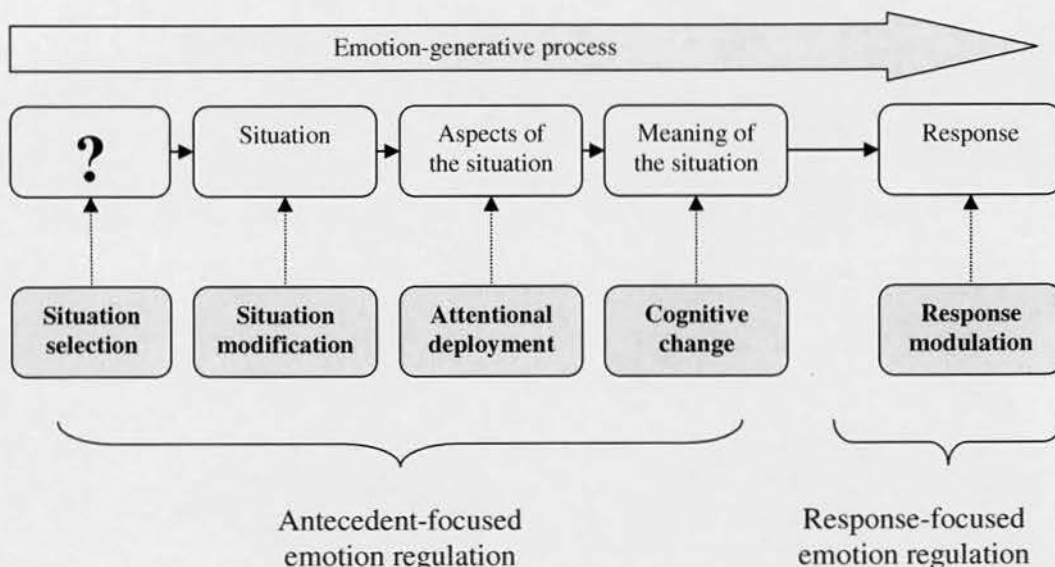


Figure 3: A process model of emotion regulation, adapted from Gross (2002)

The focus of James Gross' extensive work has been on two potential emotion regulation strategies: cognitive reappraisal, an antecedent-focussed strategy, and emotion suppression, a response-focussed strategy. In a study investigating the cognitive consequences of utilising each strategy, Richards and Gross (2000) found that experimental research participants asked to employ emotional suppression strategy when discussing distressing slides, had significantly poorer verbal recall than participants asked to employ cognitive reappraisal strategies or assigned to a control group. Much of Gross' research has focussed on experimental manipulation of participants' conscious emotion regulation style rather than naturalistic observation. It is possible that the act of asking participants to employ an unfamiliar emotion regulation strategy, artificially, may

impact on their cognitive functioning, as opposed to the strategy itself. However, a further individual differences study found participants who habitually used suppression, as opposed to cognitive reappraisal, had significantly poorer memory (Richards & Gross, 2000). Richards and Gross (2000) work shows the use of adaptive regulatory strategies may moderate a person's negative emotional experience and, thereby, the impact on cognitive processes and achievement of their goal. Therefore, it is also speculated, the impact of a person's distress on the treatment decision-making process will be moderated by their ability to regulate their emotions successfully.

Support for this speculation is found in a study by Collie *et al.* (2005). This study explored the relationship between self-efficacy, coping styles and difficulties interacting with health care professionals, in 89 women diagnosed with breast cancer. The study found that higher self-efficacy for emotion regulation was significantly associated with less problematic interactions with the health care team. This study not only suggests that a person's emotion regulation may influence their ability to achieve health care goals, but also highlights the interplay between patients' emotional well-being and their engagement with health care services.

Furthermore, Petersen *et al.* (2003) failed to find a significant association between a patient's decision-making style and their emotional well-being, discussed earlier in section 1.7.4. However, the study did show that the participants reported decision-making style was associated with coping strategies. In particular, participants describing themselves as more active in the decision-making process scored significantly higher on a 'focus on the positive' scale, whereas those describing themselves as passive in the decision-making process scored significantly higher on an 'avoidance' scale. These

studies provide rudimentary support that a persons' regulatory strategies may influence their level of participation in medical consultations.

1.8.3. Section summary

Research from the human decision-making tradition has found that stress can impact on the decision-making process. In the current climate, there is an increasing emphasis on the importance of offering patients the opportunity to participate in health care treatment decision-making. Often key decisions about cancer treatments occur early in a person's emotional adjustment to their illness; therefore it is reasonable to assume that the level of distress may impact on their ability to be involved in the decision-making process.

However, research so far has not conclusively established whether, or how, a patient's emotional well-being impacts on their participation in treatment decision-making. Theories of emotion regulation describe how people have differing abilities to moderate their emotions to allow them to achieve their desired goals. As such, it is possible that the impact of a person's emotional well-being on their participation in treatment decision-making is moderated by several factors, including their own and their doctor's ability to regulate their distress.

1.9. Current study

The current research is an exploratory study looking at the relationship between distress, emotion regulation and patient participation in treatment decision-making. It also aims to contribute to the body of research exploring whether achieving a preferred role in treatment decision-making affects longer-term psychological adjustment to illness and satisfaction with the decision made. This study sets out to expand on previous research in the area in two specific ways. Firstly, it will use a prospective methodology, approaching patients at the time of decision-making, to ensure the timely and judicious measurement of the variables. Secondly, although the study will explore the association of distress with patient preferences for and experiences of treatment decision-making, the main focus of study is on whether distress affects patients attainment of their preferred role.

Understanding the association between a patient's distress and their participation in decision-making is important. Resolving this interplay will help identify factors that may hinder a patient achieving their preferred role, and thereby ascertain opportunities for intervention which may produce benefits in their psychosocial outcomes. In this section, the reviewed literature is briefly summarised to explain each of the study hypotheses. A summary of the research questions and hypotheses is in Figure 4.

1.9.1. Study aims, research questions and hypotheses

The primary aim of the current study is to explore the impact of patient distress on participation in treatment decision-making. Specifically, it asks whether a patient's distress is associated with their preferred level of participation in treatment decision-

making, and their ability to attain this level of participation. It also asks whether a patient's ability to regulate their distress will moderate the relationship between patient distress and their attainment of their preferred role in treatment decision-making. Finally, it explores whether patient participation in treatment decision affects psychological adjustment to their illness and satisfaction with the decision made.

The first hypothesis is that patients preferring a passive role in decision-making will have a higher level of distress. Although there is mixed evidence about the association of mood with preferences for participation in decision-making, studies which have found a significant association report that depression and anxiety is associated with a passive or avoidant approach to treatment decision-making (Hack *et al.*, 1994; Vogel *et al.*, 2008). Similarly, the second hypothesis is that patients taking a passive role in decision-making will have a higher level of distress. Although previous quantitative studies have failed to find a significant association (Peterson *et al.*, 2003; Sainio & Lauri, 2003), qualitative accounts suggest distress can interfere with patient participation (McVea *et al.*, 2001).

The third, and main, hypothesis is that patients who do not attain their preferred level of participation in treatment decision-making will have higher levels of distress. Although no previous studies have examined this, it is well established that the concordance between patients' preferred and actual roles in decision-making is variable (Gatellari *et al.*, 2001). Furthermore, according to decision-making theory, distress interferes with decision-making processes, and it would therefore seem reasonable to hypothesise that higher distress will be associated with patients not achieving their preferred role. Following on from this the fourth hypothesis is that patients who do not attain their preferred level of participation in treatment decision-making have greater difficulty with

emotion regulation. In order to fulfill an intended behaviour, people must regulate their emotions to suit the demands of the situation. It is also therefore hypothesised, that a person's ability to regulate their emotions will moderate the association between their distress and their attainment of their preferred role in the treatment decision-making consultation. If there is a sufficient sample, the relationship between distress, emotion regulation and participation in treatment decision-making will be considered using multivariate statistics, also accounting for the socio-demographic variables, age and gender.

The final two hypotheses are that patients achieving their preferred role in treatment decision-making will have better psychological adjustment and higher satisfaction with the decision made. The trend towards encouraging participation in treatment decision-making is supported by evidence that participation leads to improved psychosocial outcomes; however, there is also some evidence that achieving a preferred role is key to improved psychological adjustment (Gatellari *et al.*, 2001) and satisfaction with the decision made (Keating *et al.*, 2002).

Research Questions:

- What is the relationship between distress and patient participation in treatment decision-making?
- Does a patient's ability to regulate their emotion affect the relationship between distress and participation in treatment decision-making?
- How does patient participation in treatment decision-making affect psychological adjustment to illness and satisfaction with treatment decision?

Hypotheses:

H₁: Patients who prefer passive roles in decision-making will have higher distress compared to those who prefer shared or active roles.

H₀: There will be no difference in the distress of patients preferring different roles.

H₂: Patients who are passive in decision-making will have higher distress compared to those who take a shared or active role.

H₀: There will be no difference in the distress of patients taking different roles.

H₃: Lower distress will be associated with patients attaining their preferred role in decision-making

H₀: There will be no association between distress and a patient attaining their preferred role in decision-making

H₄: Better emotion regulation will be associated with patients attaining their desired role in decision-making

H₀: There will be no association between emotion regulation and a patient attaining their preferred role in decision-making

H₅: Emotion regulation will moderate the relationship between distress and patients attaining their preferred role in decision-making

H₀: Emotion regulation will not moderate the relationship between distress and patients attaining their preferred role in decision-making

H₆: Patients attaining their preferred role in treatment decision-making will have better psychological adjustment to the diagnosis of cancer

H₀: There will be no difference in psychological adjustment between patients attaining, or not attaining their preferred role.

H₇: Patients attaining their preferred role in treatment decision-making will have higher levels of satisfaction with the decision made.

H₀: There will be no difference in satisfaction with the decision made between patients attaining, or not attaining their preferred role.

Figure 4: Summary of Research Questions and Hypotheses

2. CHAPTER TWO: METHODOLOGY

2.1. Study design

The study is a longitudinal observational design. Cross-sectional surveys were used at three points in a patient's care pathway to explore the relationships between distress, emotion regulation, participation in treatment decision-making, and psychosocial outcomes. Distress and preference for participation was measured before the patient's treatment decision-making consultation; emotion regulation, actual participation and psychosocial outcomes were measured after the treatment decision-making consultation; and psychosocial outcomes were measured again at three months follow up.

2.1.1. Setting

The study was carried out in a district general hospital's cancer out-patient department. The hospital serves a regional population of approximately 150 000 people.

2.2. Description of measures

The instruments selected to measure each of the study variables and reasons for selection are discussed below. Table 5 summarises the measures used in the study.

2.2.1. General Health Questionnaire 12 (Goldberg & Williams, 1989)

Patient distress was measured using the General Health Questionnaire 12 (GHQ-12). The GHQ-12 is a 12-item instrument used to screen for psychological distress, by asking respondents to rate, on a four-point scale, how frequently different problems have bothered them in the last week. Example items include: 'felt capable of making decisions about things'; 'been feeling unhappy and depressed' or 'been feeling reasonably happy, all things considered'.

The scale has good internal consistency (Cronbach's $\alpha = 0.87$) and was originally validated against clinician interview ($r = 0.80$) (Goldberg & Williams, 1989). There are several different scoring methods; for the current study, a Likert scoring scale was used, giving a score for each item between zero and three. The potential range of scores is from zero to 36. For this scoring method, a cut-off between 11 and 12 points is used to measure caseness (Goldberg *et al.*, 1997).

The GHQ-12 does not include somatic items, which can be confounded by poor physical health. The measure was chosen for the current study, therefore, due to its applicability in a physical health setting and its concision, as participants were asked to complete it at the time of their appointment with the Oncologist.

2.2.2. Difficulties in Emotion Regulation Scale (Gratz & Roemer, 2004)

The Difficulties in Emotion Regulation Scale (DERS) was used to measure participants' ability to regulate their emotions. The 36-item questionnaire provides an overall measure

of emotion regulation and has six subscales: 'non-acceptance of emotional responses'; 'difficulties in engaging in goal-directed behaviour'; 'impulse control'; 'awareness of emotions'; 'access to emotion regulation strategies' and 'emotional clarity'. 'Non acceptance of emotional responses' measures a person's secondary emotional response to their negative emotions. 'Difficulties in engaging in goal-directed behaviour' measures difficulties in accomplishing tasks when experiencing negative emotions. 'Impulse control' measures the ability to control behaviour when upset. 'Awareness' measures attentiveness to emotions. 'Strategies' measures self efficacy in regulating emotions, and 'clarity' measures the extent to which a person knows what they are feeling.

Respondents are asked to indicate how often each of the items applies to them on a five-point scale: almost never; sometimes; about half the time; most of the time, or almost always. Example items include: 'I experience my emotions as overwhelming or out of control'; 'when I am upset, I can still get things done'; and 'when I am upset, I have difficulty focussing on other things'. The potential range of scores is 36 to 180: a higher score on this scale means greater difficulty with emotion regulation.

The scale is relatively new; however, preliminary psychometric studies show that it has good construct validity with significant associations with the Generalized Expectancy for Negative Mood Regulation Scale (NMR) (Catanzaro & Mearns, 1990) ($r=0.69$, $p<0.01$), an established measure of emotion regulation, good internal consistency (Cronbach's $\alpha = 0.93$; >0.80 for each subscale) and good test-retest reliability over eight weeks ($r=0.88$, $p<0.01$). The population mean score is reported as 79.33 (s.d. 19.76) (Gratz & Roemer, 2004). The DERS was chosen for the current study as it provides a comprehensive

measure of emotion regulation, and includes items assessing access to emotion regulation strategies perceived as effective, which are not included in the NMR.

2.2.3. Decision-making preference statements (Sutherland *et al.*, 1989)

Patient preferences for participation in the decision-making consultation, and their perception of their actual participation, were measured by asking participants to choose which of five statements best described their opinion. The statements were then classified as representing active, shared or passive decision-making (Figure 5).

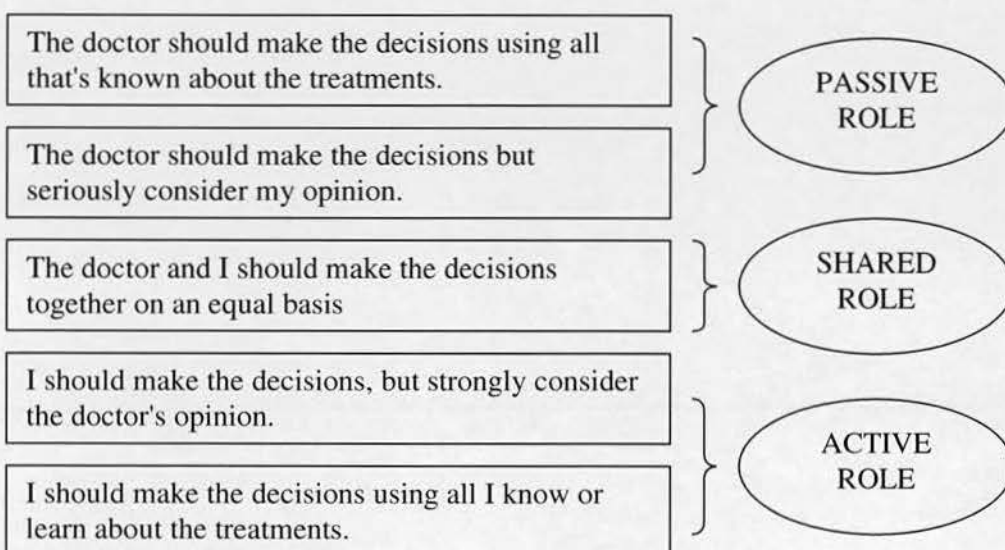


Figure 5: Decision-making preference statements (Sutherland *et al.*, 1989)

This technique was first described by Strull *et al.* (1984) and subsequently used by Sutherland *et al.* (1989). Since development, this tool has been used in further research into patient preferences in decision-making in cancer (Butow *et al.*, 1997; Jansen *et al.*, 2006; Ong *et al.*, 1999; Stiggelbout & Kiebert, 1997). It was also used in developing and validating the Autonomy Preference Index (API) (Ende *et al.*, 1989), a widely used

instrument, with good test-retest reliability (decision-making preference: $r=0.84$) and good internal consistency (Cronbach's $\alpha = 0.82$), for measuring patients' preference for autonomy in medical situations. Patient's responses correlated highly significantly with their score on the API ($r=0.54$, $p<0.01$). The tenses of the statements were modified and used to assess participants' perception of their actual role in treatment decision-making. This methodology has been used previously by Janz *et al.* (2004).

This method of measuring patients' preferences for participation, and their perception of their participation, was chosen for three reasons. Firstly, it is an established tool within relevant research about patient preferences, allowing the current study to be compared to previous findings. Secondly, the statements allow participants to be categorised into active, passive and shared roles, which is comparable to other widely used tools such as the Control Preferences Card-Sort (Degner *et al.*, 1997). Thirdly and finally, the tool was chosen for its brevity compared to other self-report tools, used to categorise preferences and perceptions of participation.

2.2.4. Mental Adjustment to Cancer Scale: Fighting spirit/ Helpless-hopeless subscales (Watson *et al.*, 1989)

Psychological adjustment was measured using two sub-scales from the Mental Adjustment to Cancer Scale, a well-established instrument designed to measure adjustment responses to a diagnosis of cancer. The original scale has 40 items, comprising five discrete sub-scales measuring different adjustment styles: fighting spirit, helpless/hopeless, anxious pre-occupation, fatalistic, avoidance. The scale has been found to have a satisfactory concordance with the independent ratings of a psychiatrist

(agreement obtained in 79% of cases, kappa=0.72). The different subscales have been shown to have varying internal consistency (see Table 4).

Respondents are asked to indicate how much each item on the scale applies to them on a four point scale: Definitely does not apply to me; does not apply to me; applies to me; definitely applies to me.

	Watson <i>et al.</i> (1988)	Schwartz <i>et al.</i> (1992)	Osborne <i>et al.</i> (1999)
Fighting Spirit	0.84	0.78	0.85
Anxious Preoccupation	0.65	0.43	0.65
Fatalism	0.65	0.67	0.64
Helpless-Hopeless	0.79	0.83	0.81
Avoidance	One item only	One item only	One item only

Table 4: Cronbach's alpha for Mental Adjustment to Cancer sub-scales

High levels of fighting spirit and low levels of helpless-hopeless are associated with positive adjustment. The fighting spirit and helpless/hopeless subscales have been found to form a bi-modal scale. In the original principal components analysis the Fighting Spirit and Helpless/Hopeless sub-scales contributed to the same dimension in the factor analysis; Fighting Spirit items loaded positively and Helpless/Hopeless items loaded negatively (Watson *et al.*, 1988). When measured separately, these scales have been found to be significantly inversely related ($r=-0.46$, $p<0.01$) (Watson *et al.* 1988). For the current study, analysis of the reliability of the combined subscale indicated good internal consistency (Cronbach's $\alpha = 0.93$).

The fighting spirit subscale has 16 items, including 'I try to keep a very positive attitude' and 'I try to keep a sense of humour about it'. The range of scores for the fighting spirit subscale is 16 to 64. The helpless-hopeless subscale has six items, including 'I feel like giving up' and 'I feel there is nothing I can do to help myself'. The range of scores for the helpless-hopeless subscale is 6 to 24. The scales can be amalgamated by subtracting the helpless/hopeless score from the fighting spirit score; a score of more than 12 on the helpless/hopeless subscale and less than 47 on the fighting spirit subscale can define caseness (Watson *et al.*, 1989). These two sub-scales will be amalgamated and used in the current study.

2.2.5. Satisfaction with Decision Scale (Holmes-Rovner *et al.*, 1996)

The Satisfaction with Decision Scale is a five-item scale designed to assess patients' satisfaction with general medical decision-making. The scale has been found to have good internal consistency (Cronbach's $\alpha = 0.86$) and be valid when compared to similar measures. The scale has also been found to be sensitive to interventions designed to aid patient decision-making. Respondents are asked to indicate on a five-point scale whether they agree with each item. Example items include: 'I am satisfied with my decision' and 'the decision I made was the best decision possible for me personally'. The potential range of scores is 5 to 30; the population mean response for each item is reported as 3.9 (s.d. 0.60) (Holmes-Rovner *et al.*, 1996).

Study Variable	Measure	Level of Measurement	Reference
Preference for participation in decision-making process	Decision-making preference statements	Nominal	Sutherland <i>et al.</i> (1989)
Psychological distress	General Health Questionnaire 12	Interval	Goldberg & Williams (1988)
Patient's ability to regulate their distress	Difficulties in Emotion Regulation Scale	Interval	Gratz & Roemer, 2004
Perception of participation in decision-making process	Modified decision-making preference statements	Nominal	Sutherland <i>et al.</i> (1989)
Psychological adjustment to cancer	Mental Adjustment to Cancer Scale: Fighting Spirit/ Helpless-Hopeless Subscale	Interval	Watson <i>et al.</i> (1998)
Patient's satisfaction about their decision-making	Satisfaction with Decision Scale	Interval	Holmes-Rovner <i>et al.</i> (1996)

Table 5: Measures used for individual variables

2.3. Participants

Potential participants for the study were patients attending their initial oncology outpatient appointment at a district general hospital between October 2008 and June 2009. This specific sampling time point was chosen, as it is the only consistent point of the treatment pathway at which patients are both aware of their diagnosis and expecting to make treatment decisions with the Oncologist. The care pathways for each cancer type, from which potential participants were recruited, are included in Appendix 3; attendance at the oncology outpatient clinic, where the study was conducted, is highlighted for each pathway. There are four outpatient oncology clinics per week at the hospital for haematological, breast, gastro-intestinal and colorectal, and lung cancer patients. The haematological team declined participation in the research for ethical reasons, as diagnosis and treatment decision-making is mostly completed within the same consultation for this cancer site. For all other clinics, patients were aware of their diagnosis prior to attendance.

The three participating clinics, for breast, gastro-intestinal and colorectal, and lung cancer patients, are each staffed by one oncologist. Approximately 1000 people in the region are diagnosed with cancer every year, with an estimated combined incidence of 576 breast, gastro-intestinal, colorectal and lung cancers. On average, each oncology clinic will see approximately 250 new and review patients every six months. Each clinic has three new patient appointments per week. Therefore, within the nine month data collection period, there was a maximum potential of 324 new patient appointments across all three clinics.

Care pathways within cancer services are heterogeneous. However, all potential participants attending the oncology clinic will have received their diagnosis and at this consultation been appraised of potential treatment pathways, for example surgery followed by chemotherapy, by the diagnosing clinician. They will also have been referred to a Clinical Nurse Specialist (C.N.S.), whose role is to provide information, support and advocacy. Specific information about treatment options, however, for example the type of chemotherapy, will not be available until all investigations are complete and reviewed by the Oncologist at the oncology clinic.

Some patients, although not all, may have had surgery prior to meeting with the Oncologist. Decisions about surgery are not the subject of the current study; these decisions are discussed with the Surgical team, as opposed to the Oncology team, most frequently during the diagnostic consultation. As such, this was not an appropriate sampling time-point.

The treatment decision-making at the oncology clinic may be about primary treatment of the cancer; adjuvant treatment of the cancer after surgery; or palliative treatment of the symptoms caused by the cancer. The treatment options could include one or more of radiotherapy; chemotherapy; hormone therapy; or best supportive care. Within each treatment choice, there may also be discussion and decision-making around the specific type of treatment; the mode of delivery of that treatment and the location where the treatment could be delivered. In any decision-making consultation, the patient also has the choice to refuse any intervention or treatment.

2.3.1. Number of participants required for study

The software G*Power 3 (Faul *et al.*, 2007) was used for *a priori* calculation of the number of participants required. The calculation was based on using logistic regression to analyse four predictors of patients achieving their preferred role, the predictors being demographic variables, emotion regulation and distress. The α level, that is the probability of incorrectly rejecting the null hypothesis, was set at 0.05. The β level, that is the probability of incorrectly accepting the null hypothesis, was set at 0.2. The corresponding level of power was 0.8 therefore, giving an 80% chance of detecting existing effects. Based on a medium predicted effect size, the required sample for the study was 95 participants (Table 6). Due primarily to poor recruitment, and an adverse event during recruitment, outlined in the recruitment of participants section (section 2.3.3), this sample size was not achieved.

Required power (1- β)	Alpha level	Effect size (f^2)	Required sample size
0.80	0.05	Small (0.02)	676
0.80	0.05	Medium (0.15)	95
0.80	0.05	Large (0.35)	44

Table 6: A priori sample size calculation using G*power 3 (Faul *et al.*, 2007)

2.3.2. Inclusion and exclusion criteria

Inclusion and exclusion criteria were applied to ensure the suitability of participants. The following inclusion criteria were used in the selection of potential participants:

1. Persons with a definite diagnosis of malignant cancer;
2. Persons attending a first oncology outpatient appointment for the current episode of care;
3. Persons aged over 18 years;
4. Persons with the ability to understand and write English, to the level of being able to complete study materials;
5. Permission to contact person granted by the medical team.

Similarly, the following exclusion criteria were used in the selection of potential participants:

1. Persons at end stage of illness (prognosis <6 months);
2. Persons under the age of 18 years;
3. Persons diagnosed with non-malignant tumour;
4. Persons who have previously attended an oncology outpatient appointment for the current episode of care;
5. Persons who have requested not to be approached for research purposes;
6. Permission to contact not gained or granted by the medical team.

2.3.3. Recruitment of participants

Potential participants for the study were identified from clinic lists. The suitability of potential participants for the study was discussed with the medical team and permission was sought to send study information. The researcher also attended three weekly multi-disciplinary meetings in order to be aware of any late changes to changes to clinic arrangements. Reasons for the medical team not granting permission to contact patients included the physical well-being of the patient and not knowing the individual patient's circumstances. Seventy two possible participants were identified of which, 26 agreed to participate.

During the study period, one oncology clinic was closed due to extraneous circumstances, reducing locally held clinics to two. Patients from the closed clinic were required to attend an oncology clinic at a cancer centre in different region and it was no longer possible to recruit this population to the current study. Other challenges to the recruitment process included the medical team being unavailable to grant permission to contact patients, and low numbers of patients meeting inclusion criteria. Given significant ethical concerns regarding approaching patients prior to their being aware treatment decisions may be required, the protocol could not be extended to include review patients, which may have increased recruitment. Therefore, due to the poor recruitment to the study, the statistical analysis was altered. This is discussed in the statistical analysis section (section 2.5).

2.4. Study procedure

The study procedure is illustrated in Figure 6. Following identification of potential participants, outlined in section 2.3.3, study information was sent by post. The study information, included in Appendix 4, outlined the purpose and procedure of the study. The researcher then approached potential participants while they waited for their oncology outpatient appointment, to enquire whether they would like to participate. Reasons for not participating were not requested following discussion with the ethics committee.

If wishing to participate, patients were asked to complete a consent form and given the first questionnaire to complete prior to their consultation. The first questionnaire included:

- Socio-demographic questionnaire including gender, age and occupation
- General Health Questionnaire 12 (Goldberg & Williams, 1988)
- Decision-making preference statements (Sutherland *et al.*, 1989)

Participants were also given the second questionnaire to be returned by post. Information about local support services was included with this questionnaire. The second questionnaire included:

- Modified Decision-making statements (Sutherland *et al.*, 1989)
- Difficulties in Emotion Regulation Questionnaire (Gratz & Roemer, 2004)
- Mental Adjustment to Cancer: Fighting Spirit/Helpless-Hopeless Sub-Scale (Watson *et al.*, 1988)
- Satisfaction with Decision Scale (Holmes-Rovner *et al.*, 1996)

Descriptions of the measures used and information about the psychometric properties are detailed in section 2.2. Three months after attending the oncology clinic, participants were posted a follow up questionnaire to be returned by post. The final questionnaires included:

- Mental Adjustment to Cancer: Fighting Spirit/Helpless-Hopeless Sub-Scale (Watson *et al.*, 1988)
- Satisfaction with Decision Scale (Holmes-Rovner *et al.*, 1996)

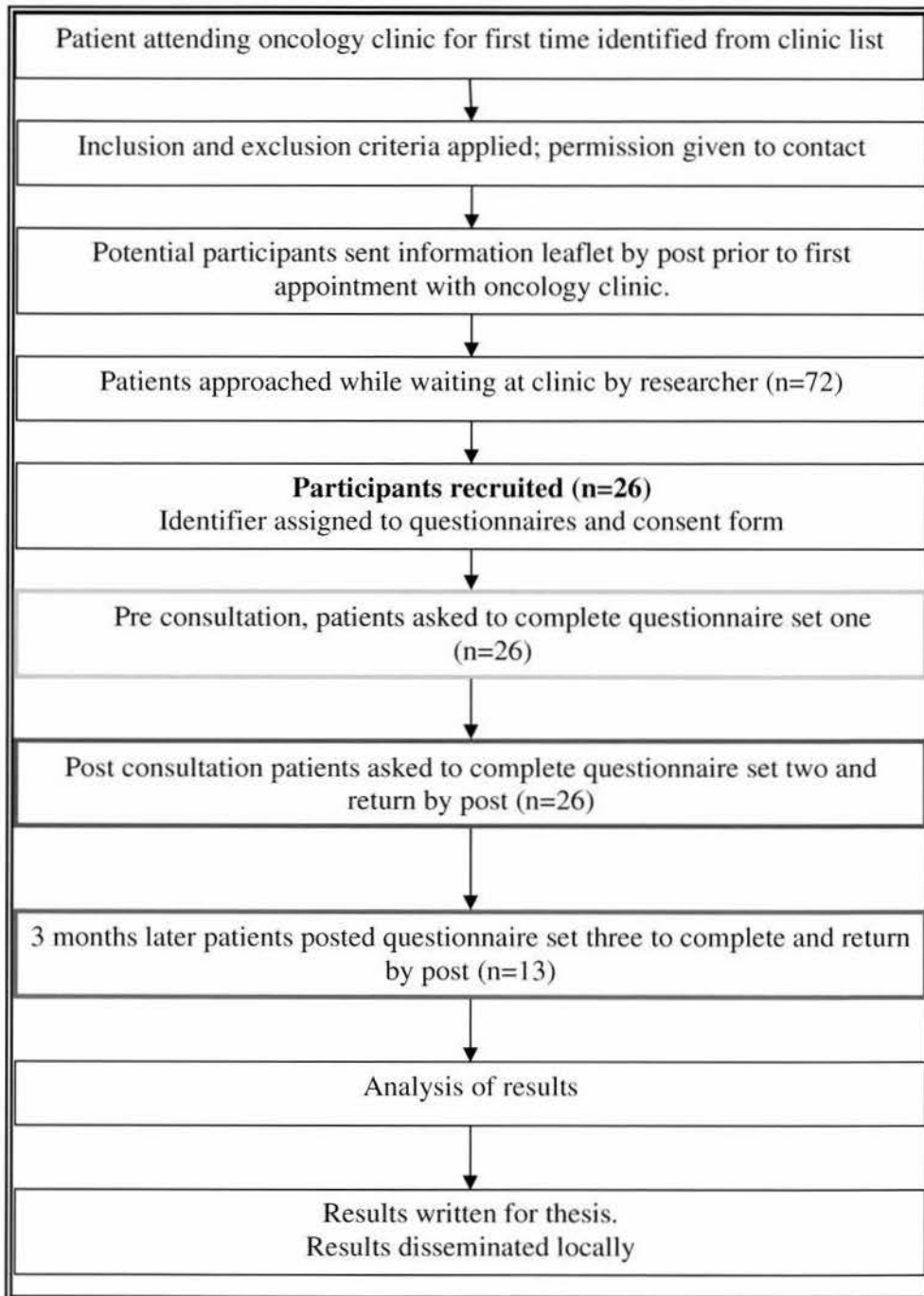


Figure 6: Flowchart of procedure

2.5. Statistical analysis

The collected data were entered anonymously into a SPSS™ 14.0 database for analysis. The measurement of the main variables was described using descriptive statistics. For the inferential statistics the significance level was set at $p < 0.05$. Although the alternative and null hypotheses were directional, where appropriate, two-tailed tests were used. The reason for this was to allow consideration of any results in an unexpected direction. The data were first tested, to establish whether they met assumptions for parametric testing. The planned analysis of the data in respect to the hypotheses is outlined below.

It was planned to explore the first two hypotheses, looking at distress and participants' preference for, and their perception of their actual, participation in treatment decision-making, using one-way ANOVA, and subsequent three post-hoc pair wise comparisons between groups. However, due to small sample size it was not possible to establish the data for each group were normally distributed or had homogeneity of variance. Therefore, a Kruskal-Wallis test was used to establish whether the groups differed. Using the Bonferroni correction, the α level for the post-hoc Mann-Whitney tests was set at $p < 0.02$.

For the main three hypotheses, looking at distress, emotion regulation and attainment of preferred role in treatment decision-making, it was planned to use a logistic regression model, with four predictors: age, gender, distress and emotion regulation. However, given the smaller sample size, simple correlation analysis was used to explore associations between the variables instead.

For the final two hypotheses looking at the attainment of preferred role in treatment decision-making and psychosocial outcomes, it was intended to use a repeated measures ANOVA to explore the effect of time and group. However, given attrition at three month follow up, independent sample t-tests were used to explore the differences between participants who had attained their preferred role and those who had not.

Outside the study hypotheses, some exploratory data analysis was also carried out. Weinberg & Abramowitz (2009, p.xiii) comment: "Seeing a three-dimensional sculpture in its entirety requires viewing that sculpture from many vantage points. Likewise, fully understanding the phenomenon under study often requires delving into data from more than one vantage point" Exploratory data analysis was used to look at sub-scales of the measures used, comparing sample means to the general population, and looking at the relationships between the repeated measure variables.

2.6. Ethical considerations

In line with British Psychological Society guidelines (2004, 2005) and government policy (Scottish Executive, 2006), ethical approval and advice for conducting the current study was sought and received from the NHS Research and Ethics Committee. In addition, approval from the local Research and Development Committee was sought and received. Specific ethical issues discussed with the ethics committee are outlined in section 2.6.1. Documents outlining ethical approval are included in Appendix 1.

2.6.1. Specific ethical issues

Several specific ethical issues were addressed in the ethical application or with the ethical committee. It was acknowledged that potential participants would be in the early stages of adjustment to a serious illness, and as such may be experienced elevated levels of distress. The fundamental nature of the study questioned the impact of patient distress levels on their ability to participate in decision-making. It was recognised that this issue may also be applicable to the process of potential participants giving informed consent for the study. In order to address this, specific permission was sought from the medical team prior to contacting potential participants, who were then all provided with study information the week prior to attending their clinic appointment. The information included the option for participants to inform staff if they did not wish to be approached for recruitment purposes. It was also agreed with the ethical committee not to enquire as to why potential participants may have refrained from the study or gather any information about them.

The research questionnaires directly questioned issues of emotional well-being and adjustment. Therefore, it was also acknowledged that the study a) had the potential to increase patient awareness of their emotional well-being and b) identify individuals suffering clinically significant levels of distress. In order to safeguard participant from unnecessary distress, information was provided about two local support services: the cancer information and support service and the psycho-oncology service. Further, the study information explicitly stated that if the researcher, an individual with training in identifying and managing distress, had concerns regarding the safety of participants or

that of another, information would be passed on. In this case, the participant would be contacted by the researcher to discuss, in more detail, the concern raised.

Associated with this, the study information emphasised that responses to the study were confidential, and that outwith exceptional circumstances the participant's medical team would not be informed of their response. All questionnaires and associated consent forms were assigned an identifier to allow anonymity. Questionnaires and consent forms will be stored separately and securely on NHS premises for four years, in accordance with research governance guidelines, and subsequently destroyed as confidential waste.

3. CHAPTER THREE: RESULTS

3.1. Participants

Of the 72 potential participants approached, 26 participants were recruited to the study (36.11% response rate). Demographic characteristics of the participants are described in Table 7. Participants were aged between 46 and 82 years, with a mean age of 63.02 years; the majority were female (84.62%); retired (73.08%) and the majority had a diagnosis of breast cancer (73.08%).

Demographic Characteristic		Frequency (n=26) N= (%)
Age	45-54	7 (26.92%)
	55-64	6 (23.08%)
	65-74	9 (34.62%)
	Over 75	4 (15.38%)
Gender	Female	22 (84.62%)
	Male	4 (15.38%)
Occupation	Retired	19 (73.08%)
	Unskilled work	1 (3.85%)
	Semi-skilled work	4 (15.38%)
	Skilled work	2 (7.69%)
Cancer Site	Breast	19 (73.08%)
	Gastro-intestinal/Colorectal	3 (11.54%)
	Lung	4 (15.38%)

Table 7: Demographic characteristics of participants in study

3.1.1. Reported preference for participation and actual participation in treatment decision-making

Participants reported varied preferences for participation in treatment decision-making (Table 8). Half of the sample (n=13) indicated that they would prefer shared decision-making; 34.62% (n=9) indicated they would prefer to be passive in decision-making and the smallest proportion, 15.38% (n=4), indicated they would prefer to be active in decision-making.

		Actual Level of Participation			Total (pref) N= (%)
		Passive N=	Shared N=	Active N=	
Preferred Level of Participation	Passive N=	8	0	1	9 (34.62%)
	Shared N=	4	7	2	13 (50%)
	Active N=	1	0	3	4 (15.38%)
Total (actual) N= (%)		13 (50%)	7 (26.92%)	6 (23.08%)	

Table 8: Patient preferred and actual roles in treatment decision-making

Half of the sample (n=13) reported that they took a passive role in decision-making, 26.92% (n=7) indicated that the decision-making was shared and 23.08% (n=6) indicated they were active in decision-making (Table 8). Overall, eight participants (30.77%) did not attain the role that they had preferred in treatment decision-making consultation (Table 8); 11.54% (n=3) were more active in the decision-making than preferred and 19.23% (n=5) were more passive than preferred.

3.2. Descriptive statistics for the main variables

The descriptive statistics for the main variables are shown in Table 9. Three participants did not complete the second set of questionnaires sufficiently, and were therefore excluded from certain analyses. On average participants scored 15.92 (s.d. 6.26) on the GHQ-12. 73.08% (n=19) of participants scored above the clinical cut-off for this measure of distress. For the Difficulties with Emotion Regulation Scale, the mean score was 63.42 (s.d.18.80); a one sample t-test found that this was a significantly lower score compared to the population mean (M=79.33, s.d.:19.76) reported by Gratz and Roemer (2004), indicating that the current study's participants had fewer difficulties with emotion regulation; $t(378)=3.75$, $p<0.01$, $r=0.19$.

On average, participants scores for the Fighting Spirit/Helpless-Hopeless scale increased from immediately after the time of the consultation (M=45.57, s.d. 7.34) to the three month follow up (M=50.18, s.d. 4.33). Similarly, participants scores for the Satisfaction with Decision Scale increased from immediately after the time of the consultation (M=25.52, s.d. 3.45) to the three month follow up (M=26.82, s.d.2.48). The mean score for an item on the Satisfaction with Decision Scale was 4.25 at the consultation and 4.47 at the three month follow up.

Measure	Range	Mean	S.D.	Z _{skewness}	Z _{kurtosis}
General Health Questionnaire – 12 (n=26)	7-27	15.92	6.26	0.58	-1.04
Difficulties with Emotion Regulation (n=23)	39-108	63.42	18.80	1.98	0.06
Fighting Spirit/ Helpless-Hopeless (n=23)	33-57	45.57	7.34	0.17	-0.99
Fighting Spirit/ Helpless-Hopeless – follow up (n=13)	45-58	50.18	4.33	0.62	-0.16
Satisfaction with Decision Scale (n=23)	19-30	25.52	3.45	0.19	-1.11
Satisfaction with Decision Scale – follow up (n=13)	23-30	26.82	2.48	0.09	-0.97

Table 9: Descriptive statistics for main variables

3.3. Exploration of assumptions for parametric tests

In order to use parametric statistical tests for analysis to answer the hypotheses, the study data were required to meet four assumptions (Field, 2009). The assumptions of parametric tests are a) the data are normally distributed; b) the data have homogeneity of variance; c) the data are at interval level and d) any between-subject data are independent.

To assess whether overall the data were normally distributed, the skewness (the symmetry of the distribution) and kurtosis (over or under population of the tails of the distribution) of the data were calculated. For considering the impact of data's skewness

and kurtosis, Miles and Shevlin (2001) recommend that z-scores greater than 2.0 indicate that there is cause for concern about the validity of any statistical tests. This recommendation is in line with other authors (Weinberg & Abramowitz, 2009). Overall, the z-scores for all the measures are less than 2.0 (Table 9). P-P plots and histograms for each variable are displayed in Appendix 5.

In order to answer each hypothesis, various groupings of participants were investigated; therefore, the data for each group was considered in relation to the assumptions required for parametric tests. For the first two hypotheses, the data was considered in groups based on patient preference and actual participation in decision-making. In smaller samples, the power of the tests used to assess whether the data meets parametric assumptions is reduced. For the most part, each group had less than ten participants, therefore, the data could not be adequately tested and accepted as meeting the assumptions required for parametric testing. Given this, non-parametric statistical analysis was used for these analyses.

For the remaining hypotheses, the data was considered in two groups, formed by a categorical variable: whether patients matched their preferred role in decision-making or not. The calculated z-scores for the skewness and kurtosis of the main variables are shown in Table 10 and Table 12. The distributions of the data for the groups were not significantly different to normal. An exploration of the data's homogeneity of variance is displayed in Appendix 5.

3.4. Patient distress and preference for participation in treatment decision-making

The role in decision-making that participants identified as preferring was compared to levels of distress. Figure 7 shows that participants reporting preferring a shared role in treatment decision-making had the lowest median score on the GHQ-12 ($Mdn = 16.00$), compared to participants reporting preferring a passive ($Mdn = 13.00$) or active role ($Mdn = 15.00$). A Kruskal-Wallis test, however, showed that there was no significant relationship between participants' distress and role preference, $H(2) = 1.35, p = 0.51, n.s.$

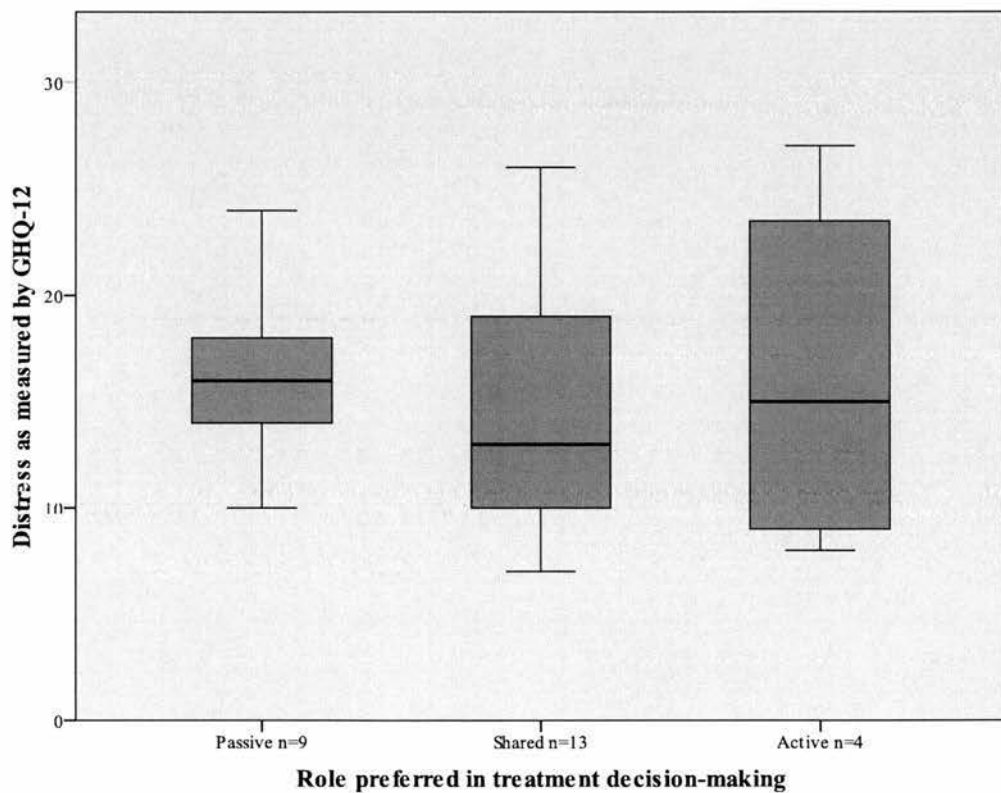


Figure 7: Box plot showing median distress by role preferred in treatment decision-making.

3.5. Patient distress and participation in treatment decision-making

The role participants perceived they had taken in treatment decision-making was compared to levels of distress. Figure 8 shows that participants reporting a passive role in treatment decision-making had the higher median score on the GHQ-12 ($Mdn = 17.00$), compared to participants reporting a shared role ($Mdn = 10.00$), but not compared to participants reporting an active role ($Mdn = 17.00$)

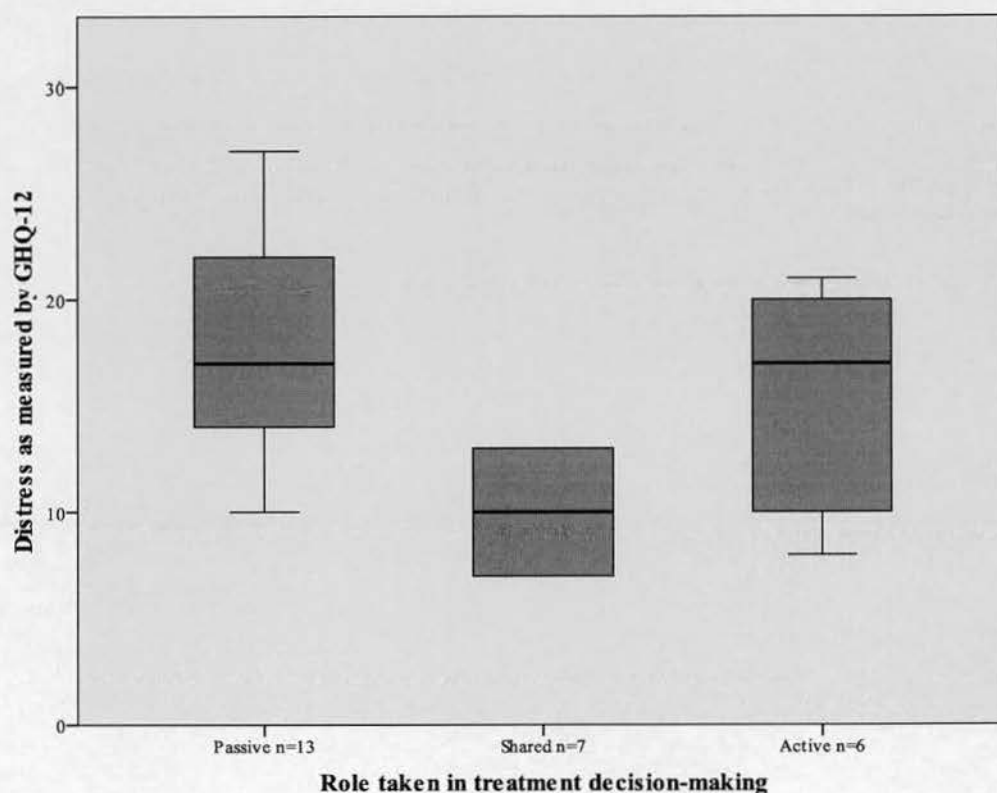


Figure 8: Box plot showing distress by role taken in treatment decision-making

A Kruskal-Wallis test showed that distress was significantly related to actual role in treatment decision-making, $H(2) = 9.97$, $p < 0.01$. Post-hoc Mann-Whitney test

comparisons showed that participants reporting a passive role had significantly higher distress ($Mdn = 17.00$) than those reporting a shared role ($Mdn=10.00$), $U = 6.50$, $z = 3.10$, $p < 0.01$, $r = 0.69$ (Figure 9), but not an active role ($Mdn = 17.00$), $U = 29.00$, $z = 0.89$, $n.s.$, $r = 0.20$. Participants taking an active role also had higher distress than those taking a shared role, but this was not significant, $U = 7.50$, $z = 1.95$, $n.s.$, $r = 0.54$.

$$r = \frac{z}{\sqrt{n}}$$
$$r = \frac{3.10}{\sqrt{20}}$$
$$r = 0.69$$

Figure 9: Calculation of post-hoc Mann-Whitney test effect size

3.6. Distress and attainment of preferred level of participation in treatment decision-making

Descriptive statistics, for participants who perceived that they took their preferred role in treatment decision-making and those who did not, are shown in Table 10.

		Role taken matched preference (n=18)	Role taken did not match preference (n=8)
Age		Mean: 63.56, <i>s.d.</i> = 11.01	Mean: 61.88, <i>s.d.</i> = 14.88
Gender	Male	2 (11.11%)	2 (25%)
	Female	16 (88.89%)	6 (75%)
Cancer Site	Breast	14 (77.78%)	5 (62.5 %)
	GI & Colorectal	2 (11.11%)	1 (12.5%)
	Lung	2 (11.11%)	2 (25%)
Distress	Mean	13.44	19.75
	S.D.	5.10	5.29
	Z _{skewness}	0.50	0.80
	Z _{kurtosis}	-0.78	0.03
Emotion Regulation	Mean	58.47	75.43
	S.D.	13.23	25.50
	Z _{skewness}	1.37	0.10
	Z _{kurtosis}	0.06	-0.41

Table 10: Descriptive statistics for participants who attained and did not attain preferred role in decision-making

There was no significant association between gender and whether a participant had attained their preferred role in decision-making, $r_{\phi}=-0.18$, $p=0.37$, *n.s.*. There was also no significant association between participants' age and attaining their preferred role in decision-making, $r_{pb}=-0.07$, $p=0.75$, *n.s.*.

The relationship between participant distress and matching of the preferred and actual role was investigated using point-biserial correlation. On average, participants who perceived that their actual role in treatment decision-making matched their preferred role had lower distress ($M = 13.44, s.d.= 5.10$), compared to participants whose actual role did not match their preferred role ($M = 19.75, s.d.= 5.29$) (Figure 10). There was a significant relationship between participant distress and whether they attained their preferred role in treatment decision-making, $r_{pb} = 0.51, p < 0.01$. This suggests that distress can account for 26.01% of the variance in participants achieving their preferred role.

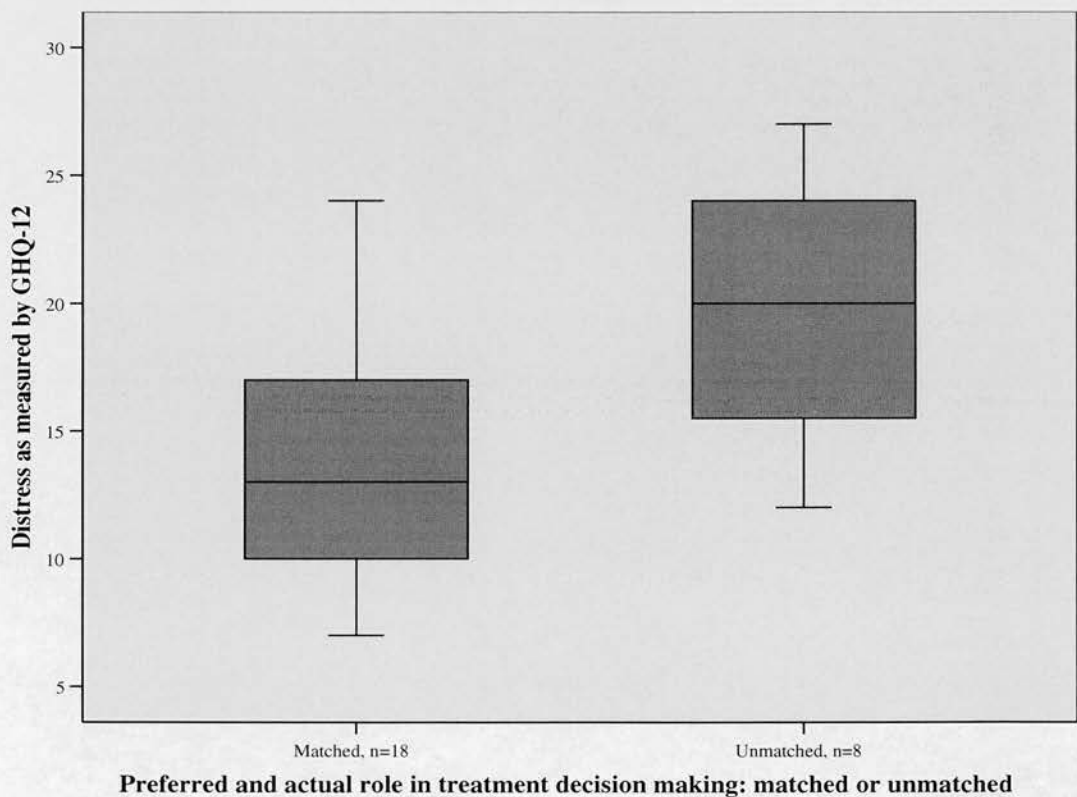


Figure 10: Box plot graph showing distress and attainment of preferred role in treatment decision-making. Central tendency shown is the median.

3.7. Emotion regulation and attainment of preferred level of participation in treatment decision-making

The relationship between difficulties with emotion regulation and reported attainment of preferred role was investigated using point-biserial correlation. On average, participants whose actual role in treatment decision-making matched their preferred role had lower ratings on the Difficulties with Emotion Regulation Scale ($M = 58.47$, $s.d. = 13.23$), compared to participants whose actual role did not match their preferred role ($M = 75.43$, $s.d. = 25.50$) (Figure 11). Higher scores on the scale indicate greater difficulty with emotion regulation. There was a significant relationship between emotion regulation and whether participants reported achieving their preferred role in treatment decision-making, $r_{pb} = 0.42$, $p < 0.05$. This suggests that emotion regulation can account for 17.64% of the variance in participants achieving their preferred role.

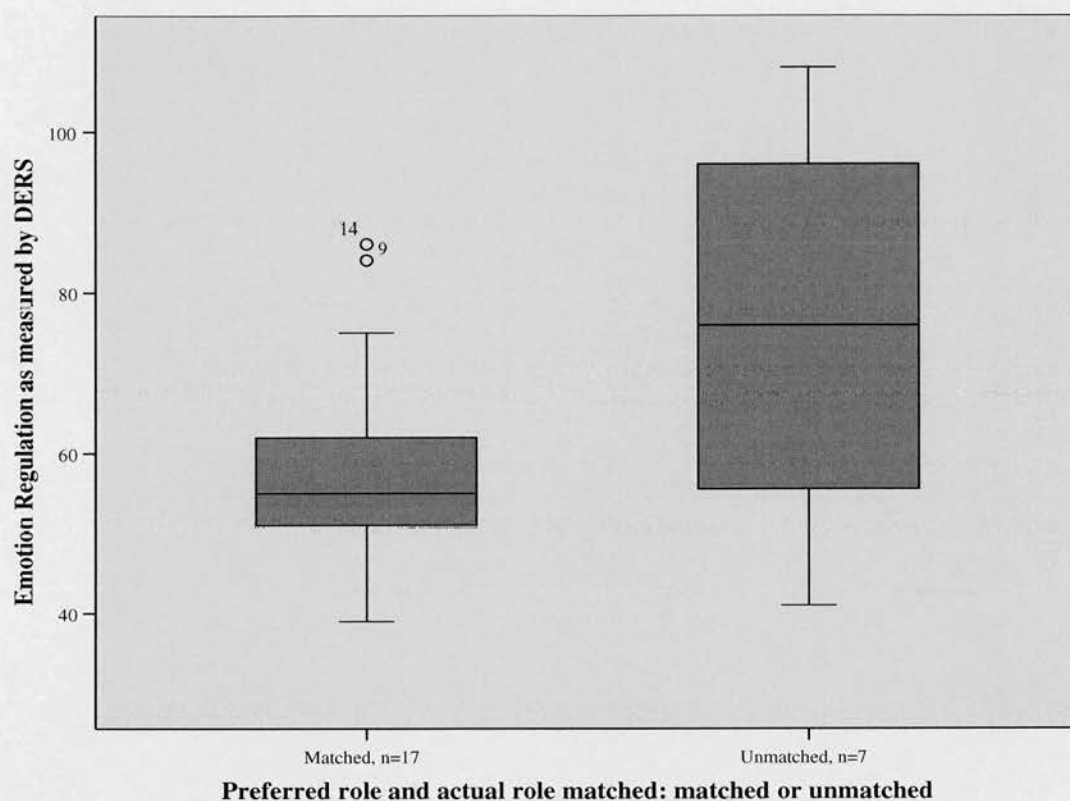


Figure 11: Box plot graph showing emotion regulation and attainment of preferred role in treatment decision-making. Central tendency shown is the median.

From a theoretical perspective, a person's emotion regulation ability moderates distress to allow a person to achieve goals. In the current sample, for participants who attained their preferred role in treatment decision-making, distress showed no association with emotion regulation, $r=0.05$, $p=0.86$, *n.s.*. However, for participants who did not attain their preferred role in treatment decision-making, higher distress showed a non-significant positive association with greater difficulty in emotion regulation, $r=0.62$, $p=0.13$, *n.s.*.

In order to test the hypothesis in the current setting, a partial zero-order correlation was carried out. Distress was not significantly related to whether a participant attained their

preferred role in treatment decision-making, when emotion regulation was controlled for, $r_{pb} = 0.33$, *ns*, now accounting for 10.89% of the variance. This suggests a more complex relationship between distress; emotion regulation; and whether a person takes their preferred role in treatment decision-making consultations.

3.8. Exploratory analysis of Difficulties with Emotion Regulation Scale subscales

The Difficulties with Emotion Regulation Scale has six sub-scales, each measuring different aspects of emotion regulation. To explore whether there were any significant differences between participants who did, and did not, attain their preferred role in decision-making, point-biserial correlations were carried out. No subscale significantly accounted for any variance in whether a participant attained their preferred role in decision-making, Table 11.

	Sub-scale					
	Non-acceptance	Goal-directed behaviour	Impulse control	Awareness	Strategies	Clarity
Correlation coefficient	$r_{pb}=0.13$, $p=0.58$, <i>n.s.</i>	$r_{pb}=0.23$, $p=0.23$, <i>n.s.</i>	$r_{pb}=0.37$, $p=0.09$, <i>n.s.</i>	$r_{pb}=0.25$, $p=0.27$, <i>n.s.</i>	$r_{pb}=0.18$, $p=0.44$, <i>n.s.</i>	$r_{pb}=0.30$, $p=0.17$, <i>n.s.</i>

Table 11: Point biserial correlation for DERS subscales and patient attainment of role

3.9. Attainment of preferred role in treatment decision-making and psychosocial outcomes

In order to investigate the effect of participants attaining their preferred role in treatment decision-making on their continued psychological adjustment and satisfaction with the decision, independent sample t-tests were carried out. The average scores for each group of participants on the psychological adjustment and satisfaction outcome measures is summarised in Table 12.

Measure		Actual role matched preferred role	Actual role DID NOT match preferred role
Fighting Spirit/ Helpless-Hopeless (n=23)	Mean	45.81	45.00
	S.D.	7.07	8.47
	Z _{skewness}	1.22	-0.66
	Z _{kurtosis}	-1.61	-0.32
Fighting Spirit/ Helpless-Hopeless – follow up (n=13)	Mean	46.44	51.50
	S.D.	8.95	4.43
	Z _{skewness}	-1.82	-1.72
	Z _{kurtosis}	1.97	1.58
Satisfaction with Decision Scale (n=23)	Mean	24.94	26.86
	S.D.	3.55	3.02
	Z _{skewness}	1.53	0.56
	Z _{kurtosis}	-0.60	-1.27
Satisfaction with Decision Scale – follow up (n=13)	Mean	26.22	26.75
	S.D.	2.95	2.75
	Z _{skewness}	-0.60	0.32
	Z _{kurtosis}	-0.71	-1.15

Table 12: Descriptive statistics of psychosocial outcome measures

There were no significant differences between those who had attained their preferred role and those who had not, for satisfaction with their decision or psychological adjustment, immediately following their consultation or three months subsequently (Table 13).

	Fighting Spirit/ Helpless- Hopeless (n=23)	Fighting Spirit/ Helpless- Hopeless – follow up (n=13)	Satisfaction with Decision Scale (n=23)	Satisfaction with Decision Scale – follow up (n=13)
Preferred and actual role: matched or unmatched	$t(21) = 0.24, p=0.23, ns, r = 0.05$	$t(11) = 1.06, p=0.31, ns, r = 0.30$	$t(21) = 1.24, ns, r = 0.26$	$t(11) = 0.30, p=0.77, ns, r = 0.09$

Table 13: Independent sample t-tests to compare psychosocial outcomes

Exploratory data analysis showed that, for all participants together, scores for positive psychological adjustment at follow up ($M=48.00, s.d.= 8.01$) were not significantly higher than at the time of consultation ($M=45.56, s.d.= 7.34$), $t(12)=2.04, p=0.06, n.s., r=0.50$. There was also no significant difference for overall scores for satisfaction with decision from consultation ($M=25.52, s.d.=3.45$) to follow up ($M=26.38, s.d.=2.79$), $t(12)=1.73, p=0.13, n.s., r=0.45$.

Exploratory Kruskal-Wallis tests found no significant association between participants' actual level of participation in treatment decision-making (active, shared or passive) and psychological adjustment immediately following the consultation, $H(2) = 0.20, p = 0.91, n.s.$ or at three month follow up, $H(2) = 1.46, p = 0.48, n.s.$ Nor any association between actual participation in treatment decision-making and satisfaction with decision made, at the time of consultation, $H(2) = 1.46, p = 0.48, n.s.$ or at three month follow up, $H(2) = 0.72, p = 0.70, n.s.$

4. CHAPTER FOUR: DISCUSSION

4.1. Overview of findings

The current study looked at patient participation in treatment decision-making for cancer. Its primary aims were to explore the how distress is associated with this process, and whether participating in treatment decision-making affects patients' psychosocial outcomes.

Patients preferred varying levels of participation in treatment decision-making consultations, with the majority preferring a shared role. Based on previous research, it was hypothesised that high levels of distress would be associated with a preference for a passive role in treatment decision-making, with the doctor making the treatment decision. In fact, no association was found between distress and patient preference for participation.

The most prevalent role assumed during treatment decision-making was passive. Again, it was hypothesised that high levels of distress would be associated with patients taking a passive role in treatment decision-making. The study findings showed partial support for this hypothesis. Significantly higher levels of distress were associated with patients taking a passive role, but distress was also elevated, albeit not significantly, in patients taking an active role, as the main decision maker. This suggests that patient distress does not always hinder participation in decision-making.

However, the hypothesis, that higher distress would be associated with patients not achieving the level of participation they preferred, was supported by the findings. Furthermore, greater difficulty with emotion regulation was also associated with this, and in line with the experimental hypothesis, emotion regulation moderated the association that distress had with patients achieving the level of participation they preferred.

The final hypotheses were that patients achieving their preferred role in treatment decision-making would have better psychosocial outcomes, that is psychological adjustment and satisfaction with the decision made. The study findings did not support this hypothesis: concordance with preferred role in treatment decision-making was not found to be significantly related to psychosocial outcomes.

This final chapter considers each of the research questions in turn, and details the study findings in answering each one, as well as, comparing the findings to the previous literature. Following this, the strengths and limitations of the study are discussed, and the potential clinical and policy implications of the findings are outlined.

4.1.1. Preference for participation in treatment decision-making

The participants in the study reported varying preferences for participating in treatment decision-making. Exactly half of the sample reported to prefer a shared role in treatment decision-making and just over one third preferred a passive role with less than one sixth an active role. In line with previous studies, summarized in section 1.4, the findings illustrate that the shift in health policy, toward encouraging patients to be more actively

involved in their health care, does not correspond to a universal patient preference for participating in oncology treatment decisions. Given this, it would be useful to understand further which patients want to be involved and why; how we can facilitate participation when it is desired and whether participating has an effect on patient outcomes.

Contrary to experimental hypothesis, the study found no significant relationship between distress and participants' preferred level of participation in treatment decision-making. Previous qualitative research has found that patients often cite emotional distress as affecting their desire to participate (Cohen & Britten, 2003; Kenny *et al.*, 1999). Vogel *et al.* (2008) found that people who had higher levels of depression were more likely to prefer a passive role in decision-making. In contrast, similarly to the current study Wong *et al.* (2000) and Janz *et al.* (2004) also did not find a significant association between present mood and preferences for participation.

On average, participants in the study by Vogel *et al.* (2008) were below the clinical cut off for anxiety and depression; in comparison, a significant proportion of the participants in the current study were above the clinical cut-off for distress. Of note, participants in the study by Vogel *et al.* (2008) had already started treatment at the time of completing the measure of mood, which may have reduced any distress associated with uncertainty around this time. Therefore, perhaps, the current study's finding indicates that, at times of heightened distress, there is no association between distress and patient preferences for participating in treatment decision-making.

In fact, despite the abundance of research, over the past 20 years, into patient preferences for participation in treatment decision-making, few variables have been consistently found to account for significant proportions of variance in individual preferences. Previous research has established a trend that younger, female patients prefer greater participation; however, these demographic characteristics account for only a small proportion of the variance in preferences for participation (Degner & Sloan, 1992). It is also possible, however, that demographic variables co-occur with other factors that may have a more substantial influence on patients' preferences, such as attitudes about health care professionals, or the prognosis of illness.

Themes emerging frequently in qualitative research centre upon practical concepts, such as expertise and knowledge; cultural concepts, such as attitude towards doctors; and intra and inter personal concepts, such as anxiety, trust and attribution of responsibility. The frequent replication of the finding that preferences for participation are not stable, and can change over the course of a person's treatment, strongly indicates that a preference is not a static characteristic but rather a product of a number of factors (Malingier *et al.*, 2006; Degner *et al.*, 1997). However, the evidence from quantitative studies so far, including the current study, provides little support that a patient's current emotional well-being is likely to be a central determining factor.

4.1.2. Actual participation in treatment decision-making

The participants in this study reported varying levels of participation in treatment decision-making; exactly half of the participants reported having a passive role; just over a quarter reported that the decision-making was shared; and just under a quarter reported

that they had made the decision. These findings are in line with the existing research body, which has found wide ranging reports of participation, indicating that shared decision-making happens in between 12% and 30% of cases (Fischer *et al.*, 2006; Vogel *et al.*, 2008). The discrepancy between the dominant model of shared decision-making and the finding that patients often taking a passive role in treatment decision-making begets a question about what factors influences the level of patient participation in treatment decision-making.

For the current study, a strong, significant effect was found for reported participation in relation to levels of distress; however, this was not a simple relationship. It was hypothesised that higher levels of distress would be associated with less participation in the consultation. A shared role in treatment decision-making was associated with the lowest level of distress. However, distress was significantly elevated in people reporting both a passive or active role. On average, the level of distress for people reporting a passive or active role was above the clinical cut-off, whereas on average those taking a shared role reported distress below the clinical cut-off.

This finding is in contrast to previous quantitative studies, which have not established a significant relationship between a patient's distress and their participation in treatment decision-making. Unlike the current study, the previous work has focused on depression as an index of distress, and all previous studies have relied on retrospective measurement (Hack *et al.*, 1994, Sainio & Lauri, 2001). The current study measured generic distress as opposed to a specific constellation of symptoms, and correlated mood at the time of the consultation with the role that participants took. From this perspective, the current study's findings can be considered credible. It is recognised, however, that this finding is

based on a small sample, using univariate analysis only, which may limit inferences that can be drawn at this stage. Therefore, the current finding does provide some modest evidence that a patient's distress is associated with their level of participation in decision-making.

Although a person's level of distress was not associated with their preference for participation in decision-making, it was found to be significantly associated with their actual participation in decision-making. This is congruent with the Communication Model of Decision-making, that emotion impacts upon the communication climate (Siminoff & Stepp, 2005). However, this leads to the question of how a person's distress affects the decision-making process, and whether being distressed is impeding patients' ability to be involved in treatment decision-making to the extent they would prefer.

4.1.3. Patient distress and attainment of preferred role in treatment decision-making

Nearly one third of the participants in the study did not attain the level of participation in treatment decision-making that they had indicated they would prefer. This was a relatively small proportion in comparison to previous research, which has found a lack of concordance in anything from 20% to 75% of cases (Gatellari *et al.*, 2001; Lam *et al.*, 2003). There was a strong relationship between the level of distress participants reported and whether they attained their preferred level of participation in treatment decision-making; participants who did not attain their preferred role in decision-making reported higher distress. No previous study in oncology has explored the association of distress with patients achieving a preferred role in treatment decision-making. Government

guidance specifically recommends that patient with cancer should be involved in treatment decisions to the extent they prefer (NICE, 2002). In line with this, outcome research is beginning to suggest that a person achieving their preferred level of participation, rather than their actual level of participation, may lead to improved psychosocial outcomes (Hack *et al.*, 2006; Lantz *et al.*, 2005 Keating *et al.*, 2006). Consideration of the mechanisms that influence a person's participation in decision-making, therefore, is key in establishing strategies to support patients. The current study's finding suggests that patient distress may be a major influence to consider, when understanding these mechanisms.

The discrepant findings that distress is associated with a person's actual role in treatment decision-making but not their preferred role reflect the arguments of Loewenstein (2005), who suggests that emotion can affect people's behaviour, often beyond their own prediction. The current study's findings are in keeping with theoretical understanding of emotion and decision-making, which suggests that emotion can interfere with normative decision-making (Winkleman *et al.*, 2007). As the current study used univariate analysis, we cannot predict causal direction from the statistical analysis; however, given that distress was measured at the time of the consultation, it would seem reasonable to conclude that distress could interfere with patients' interaction with their doctor. Consultations about treatment decision-making may include further test results, a choice between unattractive alternative courses of care, and the delivery of complex information, all of which may exacerbate negative emotion while simultaneously requiring the person's deliberation.

4.1.4. Emotion regulation and participation in treatment decision-making

Participants who did not attain their preferred role reported greater difficulties in emotion regulation; this was indicative of a moderate, statistically significant relationship. No previous studies have directly looked at the relationship between a person's ability to regulate their emotions and participation in medical decision-making. However, there are some previous studies, which can be considered alongside the current finding.

The current findings are in line with the study by Collie *et al.* (2005) which found that self-efficacy for affect regulation was associated with less problematic medical encounters for women with breast cancer; certainly achieving the level of participation preferred in a consultation may be akin to a less problematic consultation. Two studies have looked more specifically at patient participation in medical decision-making and its association with patient coping strategies. Fischer *et al.* (2006) failed to find an association between people who habitually used problem-focused coping and taking an active role in decision-making, however, Hack *et al.* (1994) found that people who were avoidant were more likely to prefer a passive role. The distinction that Gross (1999) makes between coping and emotion regulation, is that emotion regulation is an immediate and dynamic modulation of the emotional response, whereas coping includes habitual or dispositional behaviour strategies that may not solely be focused on emotion. Therefore, perhaps habitual coping strategies are associated with people's preferred or intended role in decision-making, such as shown by Hack *et al.* (1994) but are insufficient to account for their real time actions under stress, such as shown by Fischer *et al.* (2006).

Levels of distress are evidently raised at the time when oncology treatment decisions for cancer are made; the majority of the participants in the current study scored above the clinical cut-off on the measure of distress. However, in spite of this, the majority of the participants did attain their preferred role. It was proposed that emotion regulation moderates the relationship between distress and participation in treatment decision-making. The current results go some way to supporting this. A partial correlation showed that the unique contribution of a patient's distress in explaining variance in their achieving their preferred role in decision-making was reduced from 26% to 10%, when accounting for their emotion regulation ability. In order to explore this model further, these relationships need to be considered multivariately, which is beyond the scope of this study. Of course, other factors may also moderate the impact a patient's distress, such as the doctor's consultation style and social support, which would need to be considered in further research.

Theories of emotion regulation propose that emotion regulation strategies are used to guide our behaviour towards goals, increasing emotional responses that promote useful behaviour and decreasing emotional responses that promote ineffectual behaviour (Gross, 1998). For patients with cancer, when the goal is participating in treatment decision-making, it is suggested that their emotion regulation strategies facilitate or impede their ability to do so, by moderating the impact of their distress.

In order to begin to look further at which mechanisms of emotion regulation may be associated with a person achieving their preferred role, exploratory data analysis of the subscales of the Difficulties in Emotion Regulation Scale was carried out. No significant

differences were found between participants who did and did not attain the level of participation that they had preferred. The lack of significant differences between the two groups gives rise to two potential suppositions; firstly, that a cumulative deficit in emotion regulation strategies leads to weakened control over responses; or a significant effect in specific mechanisms was missed in this smaller study.

4.1.5. Patient participation in decision-making, satisfaction with decision and psychological adjustment to cancer

A concordance between preferred and actual role in treatment decision-making was not found to be significantly associated with satisfaction with the decision made, or psychological adjustment. This relationship was not significant immediately following the decision, or at three month follow up.

Previous research has found that active or shared participation in treatment decision-making leads to better satisfaction with the decision (Keating *et al.*, 2006; Fischer *et al.*, 2006), and better psychological adjustment (Deadman *et al.*, 2001; Fallowfield *et al.*, 1994). Other studies have further argued that, regardless of the actual level of participation, achieving a preferred level of participation leads to improved outcomes. The current study does not provide support for this argument. Exploratory data analysis also did not show support for previous research indicating that a shared or active role led to improved outcomes.

The current study's three month follow up was a similar length of time to follow up in previous studies investigating patient satisfaction with decision-making (Keating *et al.*,

2006). However, whereas previous studies employed a simple Likert scale to measure participant satisfaction, the current study employed a validated tool (Holmes-Rovner *et al.*, 1996). While both these factors may support the credibility of the current study, the small quantity of follow up data of the current study (n=13) limits the robustness and ability to make inferences from these findings.

For psychological adjustment, the three month follow up was significantly shorter than some of the previous studies (Fallowfield *et al.*, 1994; Hack *et al.*, 2006), and the sample size considerably smaller. Therefore, caution is required in accepting the current finding that no significant relationship exists between participation in treatment decision-making and psychological adjustment, as the study may not have been sufficiently powerful to detect an effect. The limitations of the study are further discussed in section 4.2.

The focus of research on treatment decision-making has been motivated by health behaviour theory suggesting the benefits of involving patients in their care (Bennett, 2000) and corresponding, supportive, clinical research (Fallowfield *et al.*, 1994; Hack *et al.*, 2006; Keating *et al.*, 2006; Fischer *et al.*, 2006). The current study has shown patients in cancer settings have varied preferences for participation, in line with all previous studies, with a substantial proportion preferring a passive role. The research body has yet to answer the question as to whether supporting a patient to achieve their preferred role, or encouraging active participation, is more beneficial for improving psychosocial outcomes. Establishing this is vital to generate health care guidance, which will lead to improved psychosocial outcomes for patients.

4.1.6. Section summary

Distress is significantly elevated at the time of decisions about treatment for cancer are made, and the current study has established that it is a significant factor to consider in understanding patient participation in decision-making. Higher levels of distress are associated with patients not achieving the level of participation that they would ideally prefer in treatment decision-making. However, in line with theories of emotion regulation, patients' ability to regulate their emotions moderates the association that distress has with their participation in treatment decision-making. However, the current study found no association between participation in treatment decision-making and psychosocial outcomes.

4.2. Evaluation of study design

In order to evaluate the conclusions and clinical implications arising from the current study's findings, it is vital to appraise a design's strengths and weaknesses. Shapiro (1996, p.202) states that "it is ... impossible to design the perfect study. The art of outcome research design thus becomes one of creative compromise based upon explicit understanding of the implications of the choices made". Barker *et al.* (2002) recommend using Cook and Campbell's (1979) framework to explore any imperfections, or threats to validity, of a study's design and the potential consequences of these. Although tailored for experimental, rather than observational studies, the framework is used below to evaluate the strengths and weakness of the current study systematically. Four types of validity are considered: internal validity, external validity, construct validity and statistical conclusion validity.

4.2.1. Internal validity

Internal validity refers to the extent to which the design can answer the study hypotheses (Field & Hole, 2003). The current study's design was an alteration of some previous studies' methodology, in that it measured participant distress at the time of their consultation. This was a strength of the present design as it took account of the difficulties with retrospective design, such as unknown variables affecting participants recall or responses through the passage of time (Field & Hole, 2003).

This choice in design, however, led to two specific compromises. Firstly, there was a potential experimenter effect; recruiting participants at the time of their consultation may

have altered their behaviour in the consultation. Secondly, the design required participants to complete a questionnaire at a time hypothesised to be stressful; the mean score for the measure of distress, placed the sample in the clinical range. The response rate for the current study was lower than previous studies employing a retrospective methodology, which may have been a consequence of the time in the treatment pathway that participants were recruited. The resulting small sample size has implications for statistical validity, discussed in section 4.2.4.

In the current study's design, patients' preferences for participation and actual participation in treatment decision-making were only measured at one time point in their care pathway. As previously mentioned, one of the criticisms of previous research has been the use of a retrospective methodology to measure patient preferences for participation, especially as studies have shown that these preferences are not stable. A strength of the current study is that the prospective design allowed valid and timely measurement of participant's perspective. However, this cross-sectional measurement did not allow the current study to investigate whether the expressed preferences and perception of participation were stable and, centrally, whether the established relationship between distress and attaining a preferred role in decision-making persists at different points in a patient's care pathway. Establishing this would improve the internal validity of the current study's findings that distress is associated with patient's participation in treatment decision-making, and attainment of their preferred role.

The study's main variables were measured using scales with established psychometric validity and reliability. However, in exploring the data, one particular discrepancy was evident: the current sample had significantly lower scores on the Difficulties in Emotion

Regulation Scale compared to the normative data presented by Gratz and Roemer (2004). This leads to the question of whether the current study provided a valid measurement of emotion regulation. There are several possible explanations for the lowered scores. Firstly, in the current study participants were approached during a stressful time. It is possible that potential participants who did not participate, may have had poorer emotion regulation strategies. Secondly, there is an over-representation of women in the current sample; Gratz and Roemer (2004) found that women's scores on the DERS were indicative of better emotion regulation; however this trend was only significant for one subscale. Finally, it is acknowledged that the average age of the participants in the current study was older than the university student population with which the original psychometric analysis was carried out, and it could be hypothesised that emotion regulation strategies improve with age. Therefore, the demographic characteristics of the current study population may have led to lower scores on the Difficulties in Emotion Regulation Scale compared to the normative population.

In answer therefore to the question of the validity of the scale's measurement in the current study, there are several hypothetical explanations for the observed discrepancy. Furthermore, although very little research has investigated how individual differences in emotion regulation affects health behaviour, research that has been carried out established similar findings to the current study (Collie *et al.*, 2005). Nevertheless, further research measuring emotion regulation and its impact on health behaviour would strengthen and provide further validation for the current study's findings.

In any study, there may be extraneous variables that are unaccounted for, but heavily influence the variables of study. Consideration of the literature led to the conclusion that

considering patient participation in treatment decision-making as an expression of static demographic variables was severely limited. As such, it was suggested, in line with the current study's focus that research should focus on intra and interpersonal factors that may influence the process. The current study focused only on intrapersonal processes of distress and emotion regulation. The moderating influence of variables such as external sources of emotion regulation, the doctor's dominant consulting style or the complexity of the treatment decision to be discussed were not assessed. As such, they are suggested as areas for further study, section 4.5.

4.2.2. Construct validity

Construct validity, often associated with the validity of individual measures, refers to whether a measured pattern of relationships is consistent with underlying theory. Certainly the findings of the current study are in line with decision theories, indicating that emotion is associated with disruption in planned decision-making processes. However, there are three limitations of the study in confirming the construct validity of its findings. First, the limited numbers in the study mean that analysis of causal relationships between the variables was not possible. Therefore, the study's statistical analysis cannot lead to the conclusion that distress and poor emotion regulation are causal mechanisms in a person's ability to participate in decision-making.

The second limitation is that the objective quality of decision-making was not measured. The measurement of participation in treatment decision-making was indexed by a self-report tool. The decision preference statements have been widely used and similar to other tools, which use statements to measure decision-making. As they are self-report,

however, they index the perception of the patient only. Although in considering the psycho-social adjustment of the patient, it is their perception, which may be key, a self-report measure may not provide a consistently valid index of shared decision-making, *per se*.

The third limitation of the study is that it does not account for the mechanism by which distress may have been associated with participants not achieving their preferred level of participation, for example by disrupting information processing. The study was restricted to exploring the moderating effect of emotion regulation on the association. The study's findings are therefore limited in being able to account for this relationship, and thereby unable to test the theory that people adapt their decision-making style with the goal of regulating their distress (Janis & Mann, 1977).

4.2.3. External validity

External validity refers to the extent to which the results can be generalised from the study setting (Barker *et al.*, 2002). The study findings echo laboratory studies which have shown the impact that negative emotion is associated with disruption to decision-making processes, however, the natural setting of the current study highlights the potential real life effects.

The study included people diagnosed with cancer, as opposed to other serious illness, at one point in the treatment pathway. Limiting the sample to cancer care is important for the specificity of the study, as Arora and McHorney (2000) have established that different illness types lead to different preferences for participating in decision-making.

However, within cancer care, the inclusion criteria allowed recruitment from lung, breast, colorectal and gastrointestinal clinics. The care pathway for an individual patient depends on their route of referral to the cancer services and the type and severity of cancer they were diagnosed with. Further, even within a care pathway for a specific cancer type, there is great variability as illustrated in Appendix 3. This led to a heterogeneous sample.

From one perspective, the heterogeneity of the current introduces more variables. The amount of information provided to the patient; the complexity of the treatment choices; or the number of treatment choices, may also be important to consider in further research aiming to understand how or whether patients attain their preferred role in decision-making.

Alternatively, it can be argued that the heterogeneity of the sample should increase the representativeness of a study population, and therefore the generalisability of its findings to the wider cancer population. However, the current study's sample was substantially smaller than the majority of previous studies. The response rate (36.11%) was lower also, and it was beyond the scope of the current study to establish if there were any socio-demographic differences, between those who participated, and those who refrained. Furthermore, several populations were over-represented such as females with breast cancer. In summary, therefore, there are real limitations in generalizing from this study; the study's findings would gain further external validity by being replicated in with a larger oncology population.

4.2.4. Statistical conclusion validity

Statistical conclusion validity refers to the extent to which conclusions based on statistical analysis are sound. In assessing this, Barker *et al.* (2002, p. 230) ask three questions: a) was the study sufficiently sensitive to detect real effects in data? b) did the study find true statistical relationships? and c) how meaningful were these relationships?

In answering the first point, the number of participants recruited was substantially below the number calculated as being required to detect real effects in the data. This placed the study at increased risk of Type 2 or β -error that is missing an effect, which is in fact present. For the majority of the hypotheses, despite small numbers, significant effects were detected in the data. However, in evaluating the psychosocial outcomes, especially at three month follow up when the sample size was reduced by attrition, there is a possibility that accepting the null finding would be a Type 2 error.

In answering the second point, the study found a number of statistically significant relationships using parametric tests. The data had previously been assessed as meeting the assumptions required for the validity of these tests. In addition, when multiple analyses were made for post-hoc tests, a Bonferroni correction was applied to the α level required for statistical significance, to reduce the possibility of making Type 1 or α error, detecting a false positive effect. In sum, measures were taken to ensure the validity of the statistical findings.

The final consideration is the meaningfulness of the statistical relationships. Effect sizes calculated for hypotheses that were supported by significant findings showed that the

differences were indicative of medium to large effects. However, a note of caution must again come from the small sample size. While the established effect sizes do indicate that the variables of study co-vary, the current study is limited in its ability to make conclusions about causality between the variables, or the influences of mediating variables due its lack of multivariate analysis.

4.2.5. Section summary

The strengths of the current study lie in its natural setting and real time assessment of variables. The most notable cause of weaknesses in the current study is the small sample size. While the sample size proved sufficient to detect effects in the data, it has not allowed multivariate analyses, to understand the causal relationships of variables; this reduces the confidence in generalizing the current findings to the wider population.

4.3. Reconsidering the study of patient decision-making

Patient participation in treatment decision-making continues to be focus for psychosocial research in cancer. Over the past twenty years, the focus has been on patient preferences for participation, as researchers debate the applicability of the wider health care system shift toward greater patient participation, to oncology populations. It is now heavily established that patients with cancer do not universally want to be involved in treatment decisions, and despite the changing rhetoric of health care, this pattern has not changed over time. This lies behind current guidance that patient participation in decision-making should be facilitated, if this is the patient's preference.

However, considering preferences in isolation is insufficient, as the research has also established that a significant proportion of patients do not achieve the level of participation that they want. Very little research has investigated what influences the actual participation of patients in treatment decision-making, although the current study suggests distress is one contributory factor. Some studies have focused on demographic factors such as age and education, however, these are more likely to be covariates of more telling factors ranging from use of the media, to attitudes to health care to understanding of the disease. It is likely to be a complex combination of intrapersonal, interpersonal and situational factors that will account for patients' participation.

One of the weaknesses of the research at present is the lack of unifying theory from which to test assumptions about patient participation. The Theory of Planned Behaviour may provide a useful preliminary framework for understanding patient intentions or preferences for participation. However, while praised for its parsimony, basic criticisms

of this model, such as its inability to account for the influence of emotion and interpersonal processes, may limit its utility to the field, and ability to account for actual participation. The Communication Model of Decision-making (Siminoff & Stepp, 2005) is more inclusive of relevant factors, therefore providing a useful framework for guiding future research. The model, however, has been conceived inductively, from available research, and does not explain any compounding or co-varying relationships between the variables. The Decision Conflict Theory (Janis & Mann, 1977), alternatively, does suggest a specific process, which can be used to explain patient participation in treatment decision making. However, this model is limited to understanding stress in decision-making, and does not account for variables, which may contribute to this distress such as illness characteristics, or ameliorate this stress, such as interpersonal processes.

Therefore, perhaps a more powerful process model of patient participation in treatment decision-making is required, that can draw on decision theory and account for all the mediating variables in the process of participation, akin to or in line with models developed to explain behaviour related to health. In order to do this, research will be required to establish further the central impeding and facilitating factors. The research, so far, has suffered some methodological limitations such as a focus on static demographic variables, retrospective methodologies, univariate analysis and over-representations of specific patient populations. Nevertheless, its continued study is imperative, given the established association of psychosocial outcomes and participation in treatment decisions, albeit not shown by the current study.

4.4. Clinical implications

Distress in cancer is elevated at diagnosis and can remain elevated throughout the course of the illness. The ubiquitous nature of distress in patients with cancer has led to the recommendation that psychological assessment be carried out at key points in their progress through cancer services (NICE, 2002). The current study is just one illustration of the overlap that a person's psychological needs can have with their medical care, and underlines the importance of assessing patients' emotional well-being.

However, in practice, distress is often not identified, for example, an audit of a mental health service reported a referral rate of approximately 6% of the number of people diagnosed annually (Hallahan & Garland, 2004). Given that up to half of people diagnosed with cancer may experience clinically significant emotional difficulties (Zabora *et al.*, 2001), the authors queried whether this was due to poor detection of psychological morbidity. Therefore, explicit screening for elevated distress at key consultations may facilitate patient participation, treatment decision-making consultations being a case in point.

The persistence of distress in cancer is partly attributable to the diagnosis initiating a catalogue of stresses, the focus of the current study being on the challenges faced at the time of making treatment decisions. Previous discussion has highlighted that although guidance strongly recommends that patients participate in decision to the extent they wish, there is little explicit guidance about how to facilitate this. The current study contributes to the small body of research beginning to uncover factors that may be

associated with the process of people achieving their preferred level of participation, and as such supports the statement by Coulter *et al.* (2008, p.3) that strategies to support patient participation should be a 'plank of health policy'.

The current study has shown that distress is associated with people not achieving their preferred role in treatment decision-making. Theories suggest distress can interfere with cognitive processes, therefore strategies to support these, such as provision of plain language information or the use of decision aids will be useful in empowering patients to participate in treatment decision-making. A Cochrane review of 55 randomised controlled trials of decision aids found that, compared to usual care, decision aids led to greater knowledge; lower decision conflict; a reduced proportion of people feeling uninformed; and a reduced proportion of people passive in decision-making (O'Connor *et al.*, 2006). However, there are two specific issues: firstly, the utility of decision aids is unclear, in that there is little evidence they are being used in routine practice, and do not routinely appear as recommended by SIGN guidelines (SIGN, 2003, 2005a, 2005b, 2006). The second issue is that they have not been found to improve psychosocial outcomes such as satisfaction with the decision-making; anxiety; or improved communication with health professionals (O'Connor *et al.*, 2006). Therefore, practical strategies such as decision-aids may only partly ameliorate the detrimental effects of high levels of distress.

The current study has suggested that emotion regulation processes may moderate the association of distress with participation in treatment decision-making. Returning to the model of emotion regulation by Gross (2003), strategies to reinforce patients' own emotion regulation strategies could be divided into antecedent and response focused

strategies. In terms of antecedent focused strategies, information about what to expect at the clinic, sufficient staffing levels to allow timely appointments and initial contact with a person previously known to the person may all help to reduce distress for patients attending oncology clinics. In terms of response-focused strategies, intrapersonal and interpersonal processes can regulate emotion. The current study has focused on intrapersonal ability to regulate emotion, however, strategies to support patients' emotional well-being through intra-personal processes will also be valuable. NICE (2002) suggest that psychological support is the direct responsibility of all health and social care staff working with people with cancer. One of the key strategies by which health staff can provide emotion regulation is effective communication: communication for health professionals is now a core standard in the management of cancer services (NHS Quality Improvement Scotland, 2008). Communication training has been shown to lead to better recognition of distress; more empathy toward the patient; greater trust between the doctor and the patient; and better assessment of the interplay between the illness and a person's psychosocial circumstances (Klein, 1999, Moore *et al.*, 2004). In the current context, the provision of specific training in the identification of distress and distress management for all people working at oncology clinic, including administration and auxiliary staff, may help ameliorate its potential impact at a key juncture of the care pathway.

4.5. Areas of further study

Although there is a copious amount of research looking at patient participation in treatment decision-making for cancer, few general trends have emerged so far. So far, the research body has focused on patient preferences, which has been useful to

understand the relevance of the theoretical and political shifts towards greater patient involvement in the clinical setting. However, there is significantly less research exploring what factors contribute to a patient's actual participation in treatment decision-making, and more research in this area is required.

The current study has introduced distress as a significant influencing variable to consider in future research, indicating that research needs to focus more in depth on the mechanisms by which distress is associated with participation in treatment decision-making. This also needs to be investigated by methods alternative to cross-sectional surveying, which has dominated the research body to date. It is also acknowledged that the current study focused on intrapersonal emotion regulation strategies only, however, interpersonal factors will also be important in ameliorating the impact of a person's distress, and as such require further investigation.

Aside from patient distress, qualitative research and the Communication Model of Decision-making, described by Siminoff and Stepp (2005), indicate there are many more influencing factors to investigate. Where previous research has been carried out into variables influencing participation in decision-making, there has often been a focus upon demographic variables such as age and education. The author would contend that continuing to place demographic variables at the centre of study might conceal other significant influencing variables, such as attitudes towards health care, which may co-vary with demographic characteristics.

The final area that requires further research, which is evident from the study findings, is whether beneficial outcomes are brought by health professionals encouraging patients to

participate actively in treatment decisions, or enabling patients to participate to the degree that they wish. At present, the evidence is mixed and greater clarity is required to guide any further research into possible interventions.

5. CHAPTER FIVE: CONCLUSION

The current study explored the relationship between patient distress and participation in treatment decisions for cancer. Often decisions about cancer treatments involve complex information and have to be made when the person is adjusting to difficult news; however, patients are increasingly being expected to be active partners with health care professionals in making decisions about their treatment. The current preferred model of treatment decision-making is shared decision-making, whereby the doctor and the patient are equal partners. Research, including the current study, has shown that patients, in fact, have mixed preferences for their level of involvement in making treatment decisions.

Although current guidance states that patients are entitled to participate, should they so wish, in keeping with previous studies, the current study has shown that a proportion of patients are not achieving their preferred role in treatment decision-making. Previous research has focused on demographic variables that may influence the role patients take in treatment decision-making, however, less attention has been paid to contextual factors. The current study found that higher levels of distress were associated with a greater proportion of patients taking a passive or active role, as compared to sharing the decisions. Furthermore, higher levels of distress were associated with patients not taking the role in decision-making, that they stated they preferred.

Emotion regulation is the mechanism by which people modify their emotions in order to achieve a goal. The current study found that greater difficulties with emotion regulation was associated with patients not taking the role in decision-making, that they stated they

preferred. Individual differences in the ability to regulate emotions may moderate the influence of distress on the treatment decision-making process.

One of the motivations for encouraging patient participation in treatment decision-making has been research showing it can lead to improved patient outcomes, particularly for psychosocial variables such as psychological adjustment to illness and satisfaction with the decision made. There is also some research that rather than a more active role, taking a preferred role in treatment decision-making leads to improved outcomes. The current study did not find any evidence for this, with no difference in psychosocial outcomes between participants whose role in decision-making was concordant with their preference, and those whose role was not concordant. Despite the lack of evidence from the current study, resolving the conundrum, of whether enabling patients to participate in decision-making to the degree they wish, or actively encouraging participation leads to better outcomes, should be central to further research.

To conclude, distress is significantly associated with patient involvement in treatment decision-making. In particular, it is associated with patients not taking the role in decision-making they prefer. Given that current policy indicates that patients should be active partners in their health care, and enabled to participate in decision-making if they wish, this finding is of note. Specific attention should be paid to patients' emotional well-being, particularly at key junctions of the care pathway, to ensure patients' psychological needs are met and to avoid detrimental consequences for their health care.

6. CHAPTER SIX: REFERENCES

- Abraham, C. & Sheeran, P. (2003). Implications of goal theories for the theories of reasoned action and planned behaviour. *Current Psychology: Developmental, Learning, Personality, Social*, 22, 3, 264-280.
- Ajzen, I. & Fishbein, M. (1980). *Understanding attitudes and predicting social behavior*. Englewood Cliffs: Prentice Hall.
- Ajzen, I. (1991). The Theory of Planned Behavior. *Organizational Behavior and Human Decision Processes*, 50, 179-211.
- Armitage, C.J., & Conner, M. (2001). Efficacy of the theory of planned behaviour: A meta-analytic review. *British Journal of Social Psychology*, 40, 471-499.
- Armitage, C. J. & Conner, M (2000). Social cognition models and health behaviour: A structured review. *Psychology and Health*, 15, 173-189
- Armitage, C.J. & Christian, J. (2003). From attitudes to behaviour: Basic and applied research on the theory of planned behaviour. *Current Psychology: Developmental, Learning, Personality, Social*, 22, 3, 187-195.
- Armitage, C.J., Connor, M. & Norman, P. (1999). Differential effects of mood on information processing: evidence from the theories of reasoned action and planned behaviour. *European Journal of Social Psychology*, 29, 419-433.
- Arora, N.K. & McHorney, C.A. (2000). Patient preferences for medical decision-making: Who really wants to participate? *Medical Care*, 38, 335-341.
- Baron, R.M. & Kenny, D.A (1986). The moderator- mediator variable distinction in social psychology research: Conceptual, strategic and statistical concepts. *Journal of personality and social psychology*, 51, 1173-1182.

- Barker, C., Pistrang, N. & Elliott, R. (2002). *Research methods in clinical psychology*. Chichester: Wiley.
- Barry, B. & Henderson, A. (1996). Nature of decision-making in the terminally ill patient. *Cancer Nursing*, 19, 384-391.
- Beaver, K. & Booth, C. (2007). Information needs and decision-making preferences: Comparing findings for gynaecological, breast and colorectal cancer. *European Journal of Oncology Nursing*, 11, 5, 405-416.
- Beaver, K., Bogg, J. & Luker, K. (1999). Decision-making preferences and information needs: a comparison of colorectal and breast cancer. *Health Expectations*, 2, 266-276.
- Beaver, K., Luker, K.A., Owens, R.G., Glynn, R., Samuel, J., Degner, L. & Sloan, J. (1996). Treatment decision-making in women newly diagnosed with breast cancer. *Cancer Nursing*, 19, 8-19.
- Benbasset, J., Pilpel, D. & Tidhar, M. (2001). Patients' preferences for participation in clinical decision-making: a review of published surveys. *Behavioral Medicine*, 24, 2, 81-88.
- Bennett, P. (2000). *Introduction to clinical health psychology*. Maidenhead: Open University Press.
- Bilodeau, B.A. & Degner, L.F. (1996). Information needs, sources of information and decisional roles in women with breast cancer. *Oncology Nursing Forum*, 23, 691-696.
- Blanchard, C.G., Labrecque, M.S., Ruckdeschel, J.C. & Blanchard, E.B. (1988). Information and decision-making preferences of hospitalized adult cancer patients. *Social Science & Medicine*, 27, 1139-1145.

- Brennan, J. & Moynihan, C. (2005). *Cancer in Context: A practical guide to supportive care*. Oxford: Oxford University Press.
- Brennan, J. (2001). Adjustment to cancer - coping or personal transition? *Psycho-oncology*, 10, 1, 1-18.
- British Psychological Society (2004). *Guidelines for minimum standards of ethical approval in psychological research*. Leicester: British Psychological Society.
- British Psychological Society (2005). *Good practice guidelines for the conduct of psychological research within the NHS: A guide for managers, LREC members and psychological researchers*. Leicester: British Psychological Society.
- Bruera, E., Willey, J.S., Palmer, J.L. & Rosales, M. (2002). Treatment decisions for breast carcinoma: patient preferences and physician perceptions. *Cancer*, 94, 2076-2080.
- Butow, P.N., Maclean, M., Dunn, S.M., Tattersall, M.H. & Boyer, M.J. (1997). The dynamics of change: cancer patients' preferences for information, involvement and support. *Annals of Oncology*, 8, 857-863.
- Catanzaro, S. J., & Mearns, J. (1990). Measuring generalized expectancies for negative mood regulation: Initial scale development and implications. *Journal of Personality Assessment*, 54, 546-563
- Carlson, L.E., Angen, M., Cullum, J., Goodey, E., Koopmans, J., Lamont, L. *et al.* (2004). High levels of untreated distress and fatigue in cancer patients. *British Journal of Cancer*, 90, 12, 2297-2304.
- Cassileth, B., Zupkis, R. & Sutton-Smith, K. (1980). Information and participation preferences among cancer patients. *Annals of Internal Medicine*, 92, 832-836.
- Chapman, K., Abraham, C., Jenkins, V. & Fallowfield, L. (2003). Lay understanding of terms used in cancer consultations. *Psycho-oncology*, 12, 6, 557-566.

- Charles, C., Gafni, A., & Whelan, T. (2004). Self-reported use of shared decision-making among breast cancer specialists and perceived barriers and facilitators to implementing this approach. *Health Expectations*, 7, 4, 338-348.
- Charles, C.A., Gafni, A., & Whelan, T. (1997). Shared decision-making in the medical encounter: What does it mean? (Or, it takes at least two to tango). *Social Science & Medicine*, 47, 681-692.
- Charles, C.A., Gafni, A., & Whelan, T. (1999). Decision-making in the physician-patient encounter: Revisiting the shared treatment decision-making model. *Social Science & Medicine*, 49, 651-661.
- Charles, C.A., Whelan, T., Gafni, A., Reyno, L. & Redko, C. (1998). Doing nothing is no choice: Lay constructions of treatment decision-making among women with early-stage breast cancer. *Sociology of Health & Illness*, 20, 1, 71-95.
- Clarke, J. & Everest, M. (2006). Cancer in the mass print media: fear, uncertainty and the medical model. *Social Science & Medicine*, 62, 10, 2591-2600.
- Cohen, H. & Britten, N. (2003). Who decides about prostate cancer treatment?: A qualitative study. *Family Practice*, 20, 6, 724-729.
- Collie, K., Wong, P., Tilston, J, Butler, L.D., Turner-Cobb, J., Kreshka, M.A. *et al.* (2005). Self-efficacy, coping and difficulties interacting with health care professionals among women living with breast cancer in rural communities. *Psycho-oncology*, 14, 901-912.
- Cook, T.D. & Campbell, D.T. (1997). *Quasi-experimentation: Design and analysis issues for field settings*. Chicago: Rand-McNally.
- Coulter, A. Parson, S. & Askham, J. (2008). *Where are the patients in decision-making about their own care?* Copenhagen: World Health Organization 2008 and

World Health Organization, on behalf of the European Observatory on Health Systems and Policy.

- Davidson, J.R., Brundage, M. & Feldman-Stewart, D. (1999). Lung cancer treatment decisions: Patients' desires for participation and information. *Psycho-Oncology*, 8, 6, 511-520.
- Davison, B.J., & Degner, L.F. (1997). Empowerment of men newly diagnosed with prostate cancer. *Cancer Nursing*, 20, 3, 187-196.
- Davison, B.J., Parker, P.A., & Goldenberg, S.L. (2004). Patients' preferences for communicating a prostate cancer diagnosis and participating in medical decision-making. *BJU International*, 93, 1, 47-51.
- Deadman J.M., Leinster S.J., Owens, R.G., Dewey, M.E. & Slade, P.D. (2001). Taking responsibility for cancer treatment. *Social Science & Medicine*, 53, 669–77.
- Deber R.B., Kraetschmar N. & Irvine, J. (1996). What role do patients wish to play in treatment decision-making? *Archives of Internal Medicine*, 156, 1414–1420.
- Degner, L.F., Kristjanson, L.J., Bowman, D., Sloan, J.A., Carriere, K.C., O'Neil, J., *et al.* (1997). Information needs and decisional preferences in women with breast cancer. *JAMA*, 277, 18, 1485-1492.
- Degner, L.F. & Sloan, J.A. (1992). Decision-making during serious illness: what role do patients really want to play? *Journal of Clinical Epidemiology*, 45, 9, 941-950.
- De Ridder, D, Geenen, R., Kuijjer, R & van Middendorp, H. (2008). Psychological adjustment to chronic disease. *Lancet*, 372, 246-252.
- Elit, L., Charles, C., Gold, I., Gafni, A., Farrell, S., Tedford, S., *et al.* (2003). Women's perceptions about treatment decision-making for ovarian cancer. *Gynecologic Oncology*, 88, 2, 89-95.

- Elkin, E.B., Kim, S.H., Casper, E.S., Kissane, D.W., & Schrag, D. (2007). Desire for information and involvement in treatment decisions: Elderly cancer patients' preferences and their physicians' perceptions. *Journal of Clinical Oncology*, 25, 33, 5275-5280.
- Emanuel, E.J. & Emanuel, L.L. (1992). Four models of physician-patient relationship. *Journal of American Medical Association*, 267, 16, 2221-2226.
- Ende, J., Kzis, L, Ash, A., & Moskowitz, M. (1989) Measuring patients' desire for autonomy, *Journal of general internal medicine*, 4, 23-30.
- Entwistle, V.A. & Watt, I. (2006). Patient involvement in treatment decision-making: The case for a broader conceptual framework. *Patient Education and Counselling*, 63, 3, 268-278.
- Fagerlin, A., Lakhani, I., Lantz, P.M., Janz, N.K., Morrow, M., Schwartz, K., *et al.* (2006). An informed decision? Breast cancer patients and their knowledge about treatment. *Patient Education & Counselling*, 64, 303-312.
- Fallowfield, L.J., Hall, A., Maguire, P., Baum, M., & A'Hern, R.P. (1994). Psychological effects of being offered choice of surgery for breast cancer. *BMJ*, 309, 6952, 448.
- Faul, F., Erdfelder, E., Lang, A.G. & Buchner, A. (2007). G*Power 3: A flexible statistical power analysis program for the social, behavioral, and biomedical sciences. *Behavior Research Methods*, 39, 175-191.
- Field, A. and Hole, G.J. (2003). *How to design and report experiments*. London: Sage.
- Field, A. P. (2009). *Discovering statistics using SPSS: and sex and drugs and rock 'n' roll* (3rd Ed.). London: Sage.

- Fischer, M., Visser, A., Voerman, B., Garsen, B., van Andel, G., & Bensing, J. (2006). Treatment decision-making in prostate cancer: Patients' participation in complex decisions. *Patient Education & Counselling*, 63, 3, 308-313.
- Folkman, S. & Lazarus, R.S. (1985). If it changes it must be a process: Study of emotion and coping during three stages of a college examination. *Journal of personality and social psychology*, 48, 150-170.
- Gatellari, M., Butow, P.N., & Tattersall, M.H. (2001). Sharing decisions in cancer care. *Social Science & Medicine*, 52, 12, 1865-1878.
- Gatellari, M., Butow, P.N., Tattersall, M.H.N., Dunn, S.M., & MacLeod, C.A. (1999). Misunderstanding in cancer patients: Why shoot the messenger? *European Society for Medical Oncology*, 10, 39-46.
- Goldberg, D. & Williams, P. (1989). General Health Questionnaire-12. In Weinman, J., Wright, S., & Johnston, M. (Eds). *A User's Guide to the GHQ*. Windsor: NFER-Nelson.
- Goldberg, D.P., Gater, R., Sartorius, N., Ustun, T.B., Piccinelli, M., Guerje, O. & Rutter, C. (1997). The validity of two versions of the GHQ in the WHO study of mental illness in general health care. *Psychological Medicine*, 27, 1, 191-197.
- Gratz, K.L. & Roemer, L. (2004). Multidimensional Assessment of Emotion Regulation and Dysregulation: Development, Factor Structure, and Initial Validation of the Difficulties in Emotion Regulation Scale. *Journal of Psychopathology and Behavioral Assessment*, 26, 1, 41-54.
- Gross, J.J. (1998). The emerging field of emotion regulation. An integrative review. *Review of General Psychology*, 2, 271-299.
- Gross, J.J. (1999). Emotion regulation: past, present and future. *Cognition & Emotion*, 13, 551-573.

- Gross, J.J. (2002). Emotion regulation: Affective, cognitive, and social consequences. *Psychophysiology*, 38, 281-291.
- Hack, T.F., Degner, L.F., Watson, P., & Sinha, L. (2006). Do patients benefit from participating in medical decision-making? Longitudinal follow-up of women with breast cancer. *Psycho-Oncology*, 15, 1, 9-19.
- Hack, T.F., & Degner, L.F. (1999). Coping with breast cancer: A cluster-analytic approach. *Breast Cancer Research & Treatment*, 54, 185-194.
- Hack, T.F., Degner, L.F. & Dyck, D.G. (1994). Relationship between preferences for decisional control and illness information among women with breast cancer: a quantitative and qualitative analysis. *Social Science & Medicine*, 39, 279-289.
- Hallahan, B. & Garland, M. (2004). A one-year audit of specialist psycho-oncology services in an Irish tertiary referral centre. *Irish Journal of Psychological Medicine*, 21, 4, 128-130.
- Hawley, S.T., Lantz, P.M., Janz, N.K., Salem, B., Morrow, M., Schwartz, K., *et al.* (2007). Factors associated with patient involvement in surgical treatment decision-making for breast cancer. *Patient Education and Counselling*, 65, 3, 387-395.
- Henman, M.J., Butow, P.N., Brown, R.F., Boyle, F., & Tattersall, M.H.N. (2002). Lay constructions of decision-making in cancer. *Psycho-Oncology*, 11, 4, 295-306.
- Holmes-Rovner, M., Kroll, J., Schmitt, N., Rovner, D.R., Breer, M.L., Rothert, M.L. *et al.* (1996). Patient satisfaction with health care decisions. *Medical Decision-making*, 16, 58-64.
- Hubbard, G., Kidd, L., & Donaghy, E. (2008). Preferences for involvement in treatment decision-making of patients with cancer: A review of the literature. *European Journal of Oncology Nursing*, 12, 4, 229-318.

- Hurley, J., Birch, S. & Eyles, J. (1992). *CHEPA Working Paper 92-21: Information, efficiency and decentralization within health care systems*. Hamilton: McMaster University.
- Husain, L.S., Collins, K., Reed, M., & Wyld, L. (2008). Choices in cancer treatment: A qualitative study of the older women's (>70 years) perspective. *Psycho-Oncology*, 17, 4, 410-416.
- Ingham, R. (1994). Some speculations on the concept of rationality. *Advances in Medical Sociology*, 4, 89-111.
- Janis, I.L. & Mann, L. (1977). *Decision-making: A psychological analysis of conflict, choice and commitment*. New York: Free Press.
- Jansen, S.J., Otten, W. & Stiggelbout, A.M. (2006). Factors affecting patients' perceptions of choice regarding adjuvant chemotherapy for breast cancer. *Breast Cancer Research & Treatment*, 99, 1, 35-45.
- Janz, N.K., Wren, P.A., Copeland, L.A., Lowery, J.C., Goldfarb, S.L., & Wilkins, E.G. (2004). Patient-physician concordance: Preferences, perceptions, and factors influencing the breast cancer surgical decision. *Journal of Clinical Oncology*, 22, 15, 3091-3098.
- Keating, N.L., Guadagnoli, E., Landrum, M.B., Borbas, C., & Weeks, J.C. (2002). Treatment decision-making in early-stage breast cancer: Should surgeons match patients' desired level of involvement? *Journal of Clinical Oncology*, 20, 6, 1473-1479.
- Kenny, P., Quine, S., Shiell, A., & Cameron, S. (1999). Participation in treatment decision-making by women with early stage breast cancer. *Health Expectations*, 2, 3, 159-168.

- Kiesler, D.J., & Auerbach, S.M. (2006). Optimal matches of patient preferences for information, decision-making and interpersonal behavior: Evidence, models and interventions. *Patient Education and Counselling*, 61, 3, 319-341.
- Klein, S. (1999). The effects of participation of patients with cancer in teaching communication skills to medical undergraduates: A randomised study with follow up after two years. *European Journal of Cancer Care*, 35, 10, 1448-1456
- Knowles, G., Tierney, A., Jodrell, D. & Cull, A. (1999). The perceived information needs of patients receiving adjuvant chemotherapy for surgically resected colorectal cancer. *European Journal of Cancer Nursing*, 13, 208-222.
- Kraetschmer, N., Sharpe, N., Urowitz, S., & Deber, R.B. (2004). How does trust affect patient preferences for participation in decision-making? *Health Expectations*, 7, 4, 317-326.
- Lam, W., Fielding, R., Chan, M., Chow, L., & Ho, E. (2003). Participation and satisfaction with surgical treatment decision-making in breast cancer among Chinese women. *Breast Cancer Research & Treatment*, 80, 2, 171-180.
- Lantz, P.M., Janz, N.K., Fagerlin, A., Schwartz, K., Liu, L., Lakhani, I., *et al.* (2005). Satisfaction with surgery outcomes and the decision process in a population-based sample of women with breast cancer. *Health Services Research*, 40, 3, 745-767.
- Liang, W., Burnett, C.B., Rowland, J.H., Meropol, N.J., Eggert, L., Hwang, Y-T. *et al.* (2002). Communication between physicians and older women with localized breast cancer: Implications for treatment and patient satisfaction. *Journal of Clinical Oncology*, 20, 4, 1008-1016.

- Lobb, E.A., Kenny, D.T., Butow P.N. & Tattersall, M.H.N (2001). Women's early preferences for discussion of prognosis in early breast cancer. *Health Expectations*, 4, 48-57.
- Loewenstein, G. (2005). Hot-cold empathy gaps and medical decision-making. *Health Psychology*, 24, 4, Supplement: 49-56.
- Luce, M. F. (2005). Decision-making as coping. *Health Psychology*, 24, 4, Supplement: 23-28.
- Mallinger, J.B., Shields, C.G., Griggs, J.J., Roscoe, J.A., Morrow G.R., Rosenbluth, R.J. *et al.* (2006). Stability of decisional role preference over the course of cancer therapy *Psycho-oncology*, 15, 4, 297-305.
- Maly, R.C., Umezawa, Y., Leake, B., & Silliman, R.A. (2004). Determinants of participation in treatment decision-making by older breast cancer patients. *Breast Cancer Research & Treatment*, 85, 3, 201-209.
- McVea, K.L., Minier, W.C., & Johnson Palensky, J.E. (2001). Low-income women with early-stage breast cancer: physician and patient decision-making styles. *Psycho-oncology*, 10, 2, 137-146.
- Miles, J. & Shevlin, M. (2001). *Applying regression and correlation: A guide for students and researchers*. London: Sage.
- Montgomery, C., Lydon, A. & Lloyd, K. (1999). Psychological distress among cancer patients and informed consent. *Journal of Psychosomatic Research*, 46, 3, 241-245.
- Moore, P.M., Wilkinson, S.S.M. & Solage, R.M. (2004) Communication skills training for health care professionals working with cancer patients, their families or carers. *Cochrane Database of Systematic Reviews*, 2004, 2, CD003751.

- Morris, J., & Royle, G. T. (1988). Offering patients a choice of surgery for early breast cancer: A reduction in anxiety and depression in patients and their husbands. *Social Science & Medicine*, 26, 6, 583-585.
- NHS Quality Improvement Scotland (2008). *Management of core cancer services*. Edinburgh: NHS Quality Improvement Scotland.
- National Comprehensive Cancer Network (2008). Distress and its management (Version.1.2008). Retrieved on 15 October 2009 from www.nccn.org.
- National Institute of Clinical Excellence (2004). *Improving supportive and palliative care for adults with cancer*. London: National Institute for Clinical Excellence.
- Northouse, L.L., Cracchiolo-Caraway, A. & Appel, C.P. (1991). Psychological consequences of breast cancer on the partner and family. *Seminars in Oncology Nursing*, 7, 216–223.
- Oatley, K. & Johnson-Laird, P.N. (1987). Towards a cognitive theory of emotions. *Cognition and Emotion*, 1, 29–50.
- O'Connor, A. M., Bennett, C. L., Stacey, D., Barry, M., Col, N. F., Eden, K. B., *et al.* (2006). Decision aids for people facing health treatment or screening decisions. *Cochrane Database of Systematic Reviews*, 2006, 3, CD001431.
- Ong, L.M.L., Visser, M.R.M., Van Zuuren, F.J., Rietbroek, R.C., Lammes, F.B., De Haes, J.C.J.M. (1999). Cancer patients' coping styles and doctor-patient communication. *Psycho-oncology*, 8, 2, 155-166.
- Osborne, R.H., Elsworth, G.R., Kissane, D.W., Burke, S.A. & Hopper, J.L. (1999). The mental adjustment to cancer scale: replication and refinement in 632 breast cancer patients. *Psychological Medicine*, 29, 6, 1335-1345.
- Parsons, T. (1951). *The Social System*. Glencoe, IL: Free Press.

- Peterson, S., Schwartz, R.C., Sherman-Slate, E., Frost, H., Straub, J.L. & Damjanov, N. (2003). Relationship of depression and anxiety to cancer patients' medical decision-making. *Psychological Reports*, 93, 2, 323-334.
- Petrisek, A.C., Laliberte, L.L., Allen, S. M., & Mor, V. (1997). The treatment decision-making process: Age differences in a sample of women recently diagnosed with nonrecurrent, early-stage breast cancer. *Gerontologist*, 37, 5, 598-608.
- Pinguart, M., Eberhardt, B., Silbereisen, R.K. & Miltner, W. (2004). Correlates of adult cancer patients decision-making behaviors about treatment. *Journal of Psychosocial Oncology*, 22, 3, 1-20.
- Ramfelt, E. & Lutzen, K. (2005). Patients with cancer: their approaches to participation in treatment plan decisions. *Nursing Ethics*, 12, 2, 143-155.
- Ramfelt, E., Lutzen, K., & Nordstrom, G. (2005). Treatment decision-making in a group of patients with colo-rectal cancer before surgery and a one-year follow-up. *European Journal of Cancer Care*, 14, 4, 327-335.
- Ramfelt, E., Langius, A., Björvell, H. & Nordström, G. (2000). Treatment decision-making and its relation to the sense of coherence and the meaning of the disease in a group of patients with colorectal cancer. *European Journal of Cancer Care*, 9, 3, 158-165.
- Richards, J.M. & Gross, J.J. (2000). Emotion regulation and memory: The cognitive costs of keeping one's cool. *Journal of Personality & Social Psychology*, 79, 410-424.
- Rothenbacher, D., Lutz, M.P. & Porzsolt, F. (1997). Treatment decisions in palliative cancer care: patient preferences for involvement and doctors' knowledge about it. *European Journal of Cancer*, 33, 1184-1189.

- Sainio, C., & Lauri, S. (2003). Cancer patients' decision-making regarding treatment and nursing care. *Journal of Advanced Nursing*, 41, 3, 250-260.
- Sainio, C., Eriksson, E., & Lauri, S. (2001). Patient participation in decision-making about care: The cancer patient's point of view. *Cancer Nursing*, 24, 3, 172-179.
- Salkeld, G., Solomon, M., Short, L., & Butow, P.N. (2004). A matter of trust - patient's views on decision-making in colorectal cancer. *Health Expectations: An International Journal of Public Participation in Health Care & Health Policy*, 7, 2, 104-114.
- Sanders, T., & Skevington, S. (2003). Do bowel cancer patients participate in treatment decision-making? Findings from a qualitative study. *European Journal of Cancer Care*, 12, 2, 166-175.
- Say, R., Murtagh, M. & Thomson, R. (2006). Patients' preference for involvement in medical decision-making: A narrative review. *Patient Education and Counselling*, 60, 2, 102-114.
- Schwartz, C.E., Daltroy, L.H., Brandt, U., Friedman, R. & Stolbach, L. (1992). A psychometric analysis of the Mental Adjustment to Cancer Scale. *Psychological Medicine*, 22, 1, 203-210.
- Scottish Executive (2003). *Partnership for care: Scotland's health white paper*. Edinburgh: Scottish Executive.
- Scottish Executive (2006). *Research governance framework for health and community care*. Edinburgh: Scottish Executive.
- Scottish Government (2008). *Better Cancer Care: A discussion*. Edinburgh: Scottish Government.
- Scottish Intercollegiate Guidelines Network (2003). *Management of colorectal cancer*. Edinburgh: Scottish Intercollegiate Guidelines Network.

- Scottish Intercollegiate Guidelines Network (2005a). *Management of breast cancer in women*. Edinburgh: Scottish Intercollegiate Guidelines Network.
- Scottish Intercollegiate Guidelines Network (2005b). *Management of patients with lung cancer*. Edinburgh: Scottish Intercollegiate Guidelines Network.
- Scottish Intercollegiate Guidelines Network (2006). *Management of oesophageal and gastric cancer*. Edinburgh: Scottish Intercollegiate Guidelines Network.
- Shapiro, D.E., Boggs, S.R., Melamed, B.G. & Graham Pole, J. (1992). The effect of varied physician affect on recall, anxiety, and perceptions in women at risk for breast cancer: An analogue study. *Health Psychology*, 11, 61-66.
- Shapiro, D.A. (1996). Outcome research. In G. Parry & F.N. Watts (Eds). *Behavioural and mental health research: A handbook of skills and methods* (2nd Ed.). Hove: Lawrence Erlbaum Associates.
- Sheehan, J., Sherman, K.A., Lam, T. & Boyages, J. (2007). Association of information satisfaction, psychological distress and monitoring coping style with post-decision regret following breast reconstruction. *Psycho-oncology*, 16, 4, 342-351.
- Sheeran, P., Trafimow, D. & Armitage, C. (2003). Predicting behaviour from perceived behavioural control: Tests of the accuracy assumption of the theory of planned behaviour. *British Journal of Social Psychology*, 42, 393-410.
- Siminoff, L.A. & Step, M.M. (2005). A communication model of shared decision-making: Accounting for cancer treatment decisions. *Health Psychology*, 24, 4, Supplement: 99-105.
- Siminoff, L.A. & Fetting, J.H. (1991). Factors affecting treatment decisions for a life-threatening illness: The case of medical treatment of breast cancer. *Social Science and Medicine*, 32, 7, 813-818.

- Simon, H.A. (1957). *Models of man*. New York: Wiley.
- Slevin, M.L., Stubbs, L., Plant, H.J., Wilson, P., Gregory, W.M., Armes, P.J. & Downer, S.M. (1990). Attitudes to chemotherapy: comparing view of patients with cancer with those of factors, nurses and general public. *BMJ*, 300, 1458-1460.
- SPSS (2005). *SPSS 14.0 for Windows, Release date 18.11.2005*. Chicago: SPSS Inc.
- Stewart, D.E., Wong, F., Cheung, A.M., Dancey, J., Meana, M., Camerson, J.I. *et al.* (2000). Information needs and decisional preferences among women with ovarian cancer. *Gynecologic Oncology*, 77, 3, 357-361.
- Stiggelbout, A.M. & Kiebert, G.M. (1997). A role for the sick role: Patient preferences regarding information and participation in clinical decision-making. *CMAJ*, 157, 4, 383-389.
- Street R.L., & Gordon, H. S. (2006). The clinical context and patient participation in post-diagnostic consultations. *Patient Education and Counselling*, 64, 1, 217-224.
- Street, R.L. & Voigt, B. (1997). Patient participation in deciding breast cancer treatment and subsequent quality of life. *Medical Decision-making*, 17, 3, 298-306.
- Street, R.L., Gordon, H., Ward, M.M., Krupat, E. & Kravitz, R. (2005). Patient participation in medical consultations: Why some patients are more involved than others. *Medical Care*, 43, 10, 960-969.
- Strull, W.B., Lo, B. & Charles, G. (1984). Do patients want to participate in medical decision-making? *JAMA*, 252, 2990-2994.
- Sutherland, H.J. (1990). Are we getting informed consent from patients with cancer? *Journal of the Royal Society of Medicine*, 83, 439-443.
- Sutherland, H.J., Llewelyn-Thomas, H.A., Lockwood, G.A., Trichtler, D.L. & Till, J.E. (1989). Cancer patients: their desire for information and participation in treatment decisions. *Journal of the Royal Society of Medicine*, 82, 5, 260-263.

- Tversky, A. & Kahneman, D. (1981). The framing of decisions and the psychology of choice. *Science*, 211, 4481, 453-458.
- Vogel, B.A., Helmes, A.W., & Hasenburg, A. (2008). Concordance between patients' desired and actual decision-making roles in breast cancer care. *Psycho-Oncology*, 17, 2, 182-189.
- Von Neumann, J. and Morgensten, O. (1947). *Theory of games and economic behaviour* (2nd Ed). Princeton: Princeton University Press.
- Wallberg, B., Michelson, H., Nystedt, M., Bolund, C., Degner, L. F., & Wilking, N. (2000). Information needs and preferences for participation in treatment decisions among Swedish breast cancer patients. *Acta Oncologica*, 39, 4, 467-476.
- Watson, M. Greer, S., Young, J., Inayat, Q., Burgess, C. & Roberston, B. (1988). Development of a questionnaire measure of adjustment to cancer: the MAC scale. *Psychological Medicine*, 18, 1, 203-209.
- Watson, M., Greer, S. & Bliss, S. (1989). Mental Adjustment to Cancer (MAC) Scale. In Weinman, J., Wright, S. & Johnston, M. (Eds.) *Measures in health psychology: A user's portfolio*. Windsor: NFER Nelson.
- Weinberg, S.L. & Abarmowitz, S.K. (2009). *Statistics using SPSS: An integrative approach* (2nd Ed). Cambridge: Cambridge University Press.
- Weinfurt, K. (2003). Outcomes research related to patient decision-making in oncology. *Clinical Therapeutics*, 25, 2, 671-683.
- Weisman, A.D. & Worden, J.W. (1976). The existential plight in cancer: significance of the first 100 days. *International Journal of Psychiatry in Medicine*, 7, 1, 1-15.

- Winkleman, P., Knutson, B., Paulus, M. & Trujillo, J.L. (2007). Affective influence on judgements and decisions: Moving towards core mechanisms. *Review of General Psychology*, 11, 2, 179-192.
- Wong, F., Stewart, D.E., Dancey, J., Meana, M., McAndrews, M.P., Bunston, T., *et al.* (2000). Men with prostate cancer: Influence of psychological factors on informational needs and decision-making. *Journal of Psychosomatic Research*, 49, 1, 13-19.
- Zabora, J., BrintzenhofeSzoc, K., Curbow, B., Hooker, C. & Piantadosi, S. (2001). The prevalence of distress by cancer site. *Psycho-oncology*, 10, 1, 19-28.

7. CHAPTER SEVEN: APPENDICES

Appendix One: Correspondence from ethics committee

**Dumfries and Galloway
NHS Board**

Research Ethics Committee

Mid North
The Crichton
Bankend Road
Dumfries
DG1 4TG

Extension: 32708
Direct Dial: 01387 272708
Fax: 01387 262075
Email: jan.mcculloch@nhs.net



Miss F Scrutton
Trainee Clinical Psychologist
Department of Clinical Psychology
Nithbank
Dumfries
DG1 2SA

Dear Miss Scrutton

Full title of study: Patient Distress and Participation in and Satisfaction
With Treatment Decision Making in Cancer
REC reference number: 08/S0401/10

The Research Ethics Committee reviewed the above application at the meeting held on 25 April 2008. Thank you for attending to discuss the study.

Ethical opinion

Members debated the proposal that patients should be asked to provide you with a reason if they decide not to take part in the study. After discussion, it was agreed that patients should not have to provide you, or anyone else, with any reasons for deciding not to take part in the study. This is because of the vulnerability of the group of patients and their potentially dependant relationship with you as a psychologist who might be involved in their care at future periods in their cancer journey. This should be removed from your protocol.

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Ethical review of research sites

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

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission at NHS sites ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance

arrangements. Guidance on applying for NHS permission is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Application		09 April 2008
Investigator CV		
Protocol		08 April 2008
Covering Letter		
Summary/Synopsis		
Letter from Sponsor		19 February 2008
Peer Review		
Compensation Arrangements		20 July 2007
Interview Schedules/Topic Guides		08 April 2008
Questionnaire: Validated - Autonomy Preference		
Questionnaire: Validated - Brief Symptom Inventory 18		
Questionnaire: Princess Margaret Hospital Satisfaction with Physician		
Questionnaire: Perceived Involvement in Care Scale		
Questionnaire: Difficulties in Emotional Regulation Scale		
Questionnaire: Medical Outcomes Study Social Support Survey		
Questionnaire: Satisfaction with Decision Scale		
Questionnaire: Mental Adjustment to Cancer Scale		
Questionnaire: Non-Validated - Factors affecting treatment decision making	1	
Sample Diary/Patient Card		
GP/Consultant Information Sheets	1	11 March 2008
Participant Information Sheet: For Main Study	1	08 April 2008
Participant Information Sheet: For Focus Groups	1	08 April 2008
Participant Information Sheet: For Case Studies	1	08 April 2008
Participant Consent Form: For Main Study	1	08 April 2008
Participant Consent Form: For Focus Groups	1	08 April 2008
Participant Consent Form: For Case Studies	1	08 April 2008
Psychological Services Leaflet		01 May 2006
Cancer Information and Support Centre Leaflet		01 February 2007
Review Emails		

Membership of the Committee

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

Statement of compliance

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

After ethical review

Now that you have completed the application process please visit the National Research Ethics Website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

08/S0401/10 correspondence	Please quote this number on all
-------------------------------	---------------------------------

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

Yours sincerely

Dr Peter Hutchison
Chair

*Enclosures: List of names and professions of members who were present at the meeting and those who submitted written comments
"After ethical review – guidance for researchers"
Site approval form (SF1)*

*Copy to: Professor Mick Power
Research and Development Unit, NHS Dumfries and Galloway*

Dumfries & Galloway Research Ethics Committee

Attendance at Committee meeting on 25 April 2008

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Mrs Elizabeth Griggs	Lay Member	No	
Mrs Edna Hunter	Lay Member	Yes	
Dr Peter Hutchison	GP	Yes	
Dr Johannes C Leuvenink	Consultant Psychiatrist	Yes	
Dr Andrew Mitra	Consultant paediatrician	Yes	
Dr Gary Morrison	Consultant Psychiatrist	No	
Mrs Sheena Newberry	Lay Member	No	
Mrs Rosie Rutherford	Lay Member	Yes	
Miss Elisabeth Smart	Public Health Specialist	Yes	
Dr Bryce Watson	Consultant Anaesthetist	No	

Written comments received from:

<i>Name</i>	<i>Position</i>
Mrs Sheena Newberry	Lay Member

Dumfries & Galloway Research Ethics Committee

LIST OF SITES WITH A FAVOURABLE ETHICAL OPINION

For all studies requiring site-specific assessment, this form is issued by the main REC to the Chief Investigator and sponsor with the favourable opinion letter and following subsequent notifications from site assessors. For issue 2 onwards, all sites with a favourable opinion are listed, adding the new sites approved.

REC reference number:	08/S0401/10	Issue number:	1	Date of issue:	19 May 2008
Chief Investigator:	Miss F Scrutton				
Full title of study:	Patient Distress and Participation in and Satisfaction With Treatment Decision Making in Cancer				
<i>This study was given a favourable ethical opinion by Dumfries & Galloway Research Ethics Committee on 25 April 2008. The favourable opinion is extended to each of the sites listed below. The research may commence at each NHS site when management approval from the relevant NHS care organisation has been confirmed.</i>					
<i>Principal Investigator</i>	<i>Post</i>	<i>Research site</i>	<i>Site assessor</i>	<i>Date of favourable opinion for this site</i>	<i>Notes ⁽¹⁾</i>
Miss F Scrutton	Trainee Clinical Psychologist	NHS Dumfries and Galloway	Dumfries & Galloway Research Ethics Committee	07/05/2008	

Approved by the Chair on behalf of the REC:

..... (Signature of Chair/Co-ordinator) (delete as applicable) *JAN M. COWISH* (Name)

(1) *The notes column may be used by the main REC to record the early closure or withdrawal of a site (where notified by the Chief Investigator or sponsor), the suspension or termination of the favourable opinion for an individual site, or any other relevant development. The date should be recorded.*

Research & Development
Support Unit

Miss Frances Scrutton
Department of Psychology
Nithbank
Dumfries
DG1 2SA

Ground Floor
Dumfries and Galloway
Royal Infirmary
Bankend Road
Dumfries
DG1 4AP



Tel: 01387 241165 Date: 26th May 2008

Dear Miss Scrutton

**PATIENT DISTRESS AND PARTICIPATION IN AND SATISFACTION WITH
TREATMENT DECISION MAKING IN CANCER**

Thank you for sending me details of your study with a request for management approval I can confirm that the study review team has reviewed the documentation and on that basis I am pleased to inform you that your study has management approval for commencement within NHS Dumfries and Galloway.

It is a condition of this approval that everyone involved in this study abides by the guidelines/protocols laid down by this Health Board in respect of confidentiality and Research Governance. It is your responsibility to ensure you are familiar with these, please do not hesitate to seek advice if you are unsure (copies of Research Governance Framework document available via the website www.schd.scot.nhs.uk/cso and then choose the publications link).

As part of the Health Board's responsibilities under Research Governance a sample of studies will be monitored, it is therefore important that all records, in connection with the study, are kept up to date and available for review should monitoring be required.

Please advise the R&D Support unit immediately if you require to alter your protocol in any way. I understand that performance of this study will not infringe on your own/department's ability to deliver your usual level of service.

May I take this opportunity to wish you every success with your project. Please do not hesitate to seek help and advice from the R&D Support Unit (ext 33164 and 33165) if there is anything which you feel you would like assistance with. I look forward to hearing about your work as it progresses.

JP
J.R. Lawrence
R&D Director

**Dumfries and Galloway
NHS Board**

Research Ethics Committee

Mid North
The Crichton
Bankend Road
Dumfries
DG1 4TG

Extension: 32708
Direct Dial: 01387 272708
Fax: 01387 252375
Email: jan.mcculloch@nhs.net



08 July 2008

Miss F Scrutton
Trainee Clinical Psychologist
Department of Clinical Psychology
Nithbank
Dumfries
DG1 2SA

Dear Ms Scrutton

Study title: Patient Distress and Participation in and Satisfaction
With Treatment Decision Making in Cancer
REC reference: 08/S0401/10
Amendment number: 1
Amendment date: 13th June 2008

The above amendment was reviewed at the meeting of the Committee held on 27 June 2008.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Questionnaire	2	
Notice of Substantial Amendment (non-CTIMPs)		
Covering Letter		
Protocol	5	19/05/08

Membership of the Committee

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

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

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

08/S0401/10:	Please quote this number on all correspondence
--------------	--

Yours sincerely



Enclosures

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

Copy to:

Research and development Unit, DGRI

Research & Development
Support Unit

Ground Floor
Dumfries and Galloway Royal Infirmary
Bankend Road
Dumfries
DG1 4AP

Frances Scrutton
Dept Psychology
Nithbank Hospital
Dumfries



Director
Dr J R Lawrence
Research Scientist
Dr. Gwen Baxter
Secretary
Stacey Carter

Enquiries to Dr Baxter
Direct Line 01387 241165
Date 1st July 2008

**Patient Distress and participation in and satisfaction with treatment decision making in cancer
REC 08/S0401/10**

Dear Ms Scrutton

I have reviewed the amendments in connection with the above project and am pleased to inform you that this amendment has management approval for commencement within NHS Dumfries and Galloway.

It is a condition of this approval that everyone involved in this study abides by the guidelines/protocols laid down by this Health Board in respect of confidentiality and Research Governance. It is your responsibility to ensure you are familiar with these; please do not hesitate to seek advice if you are unsure (Copies of Research Governance Framework document available via the website www.sehd.scot.nhs.uk/eso and then use the publications link).

Thank you for keeping us informed about your study.

Yours sincerely,



Appendix Two: Tables for literature review

Reference	Method and instrument used to measure decision-making preference	Participants and response rate	Summary of preferred roles in decision-making	Summary of actual roles in decision-making	Associations with patient preference investigated ✓ = significant ✗ = not significant				
					Age	Education	Sex	Emotional well-being	Other sig. associations
Barry & Henderson (1996)	Semi-structured interviews; Control Preferences (Degner & Sloan, 1992)	7 palliative cancer patients; likely to be terminal in 6 months	-	-	-	-	-	-	Disease progression*
Beaver & Booth (2007)	Cross-sectional; structured interview; Control Preferences (Degner & Sloan, 1992)	53 gynaecological cancer patients; 24-82 years; average 16 weeks since diagnosis	20.8% Active; 32.1% Shared; 47.2% Passive	22.7% Active; 18.9% Shared; 58.5% Passive	✗	-	-	-	-
Beaver et al. (1996)	Cross-sectional survey; Control Preferences (Degner & Sloan, 1992)	150 female breast cancer patients; newly diagnosed	20% Active 28% Shared 52% Passive	15.3% Active 24.0% Shared; 60.7% Passive	✓	✓	-	-	Social class
Blanchard et al. (1988)	Mixed methodology: observational study combined with survey; Instrument adapted from Cassileth et al. (1980)	439 cancer inpatients	69% preferred to participate 31% preferred to leave decision up to doctor	-	✓	-	✓	-	Prognosis Physical well-being Cancer type
Bruera et al. (2002)	Cross-sectional survey; Questionnaire based on Degner et al. (1997)	57 female breast cancer at diagnosis; 79% response rate	22.8% active; 66.7 shared 10.5% passive	-	✗	✗	-	-	Previous treatment
Butow et al. (1997)	Cross-sectional survey; Decision preferences statements (Sutherland et al. 1989)	20 males and 60 female cancer patients; 89.9% response rate; 18-87 years	22.6% active; 36.3% shared; 41.3% passive	-	✗	-	✓	-	First consultation Religious locus of control
Davison & Degner (1997)	Randomised Controlled Trial; Control Preferences (Degner & Sloan, 1992)	60 male prostate cancer patients;	25% active; 43.3% shared; 31.7% passive	-	✗	✗	-	-	-

Table 14: Summary of quantitative studies looking at factors associated with patient preferences for participation; *only descriptive statistics reported

Reference	Method and instrument used to measure decision-making preference	Participants and response rate	Summary of preferred roles in decision-making	Summary of actual roles in decision-making	Associations with patient preference investigated ✓ = significant ✗ = not significant				
					Age	Education	Sex	Emotional well-being	Other sig. associations
Davison <i>et al.</i> (2004)	Cross-sectional survey Control Preferences (Degner & Sloan, 1992)	87 male prostate cancer patients; 87% response rate, 46-84 years; at time of diagnosis	42.5% active; 47.1% shared; 11.4% passive	-	✗	✗	-	-	-
Degner & Sloan (1992)	Cross-sectional survey; Own instrument	209 female and 227 male cancer patients; average 75 days post diagnosis	12% active; 29% shared; 59% passive	-	✓	✓	✓	-	-
Degner <i>et al.</i> (1997)	Cross-sectional survey; Control Preferences (Degner & Sloan, 1992)	1012 female breast cancer patients; 4 days to 32.4 years post-diagnosis; 85% response rate	22% active, 44% shared 34% passive	-	✓	✓	-	-	Previous experience Time since diagnosis
Elkin <i>et al.</i> (2007)	Cross-sectional; structured interviews; Control Preferences (Degner & Sloan, 1992)	73 cancer patients over 70 years old; within 16 weeks of metastatic diagnosis	25% active; 23% shared; 52% passive	-	✗	✗	✗	-	-
Hack & Degner (1999)	Cross sectional structured interview Cluster Analysis Control Preferences (Degner & Sloan, 1992)	70 female breast cancer patients 1.5-6 months post diagnosis	25.7% active; 48.6% shared; 25.7% passive	-	-	-	-	✓	-
Hack <i>et al.</i> (1994)	Mixed design: cross-sectional survey and semi-structured interviews; Card Sort (Degner & Sloan, 1992))	35 female breast cancer patients; 32-82 years; 2-6 months post diagnosis	22.9% active; 57.1% shared; 20% passive	-	✗	✓	-	-	Desire for information about diagnosis and treatment procedures

Table 14 (continued): Summary of quantitative studies looking at factors associated with patient preferences for participation

Reference	Method and instrument used to measure decision-making preference	Participants and response rate	Summary of preferred roles in decision-making	Summary of actual roles in decision-making	Associations with patient preference investigated ✓ = significant ✗ = not significant				
					Age	Education	Sex	Emotional well-being	Other sig. associations
Jansen, <i>et al.</i> (2006)	Cross-sectional; survey; Decision preference statements (Sutherland <i>et al.</i> 1989)	446 cancer patients; 62% response rate; 32-89 years	18.7% active; 34.5% shared; 29.6% passive	-	-	-	-	-	Perception of treatment choice
Janz <i>et al.</i> (2004)	Cross-sectional; structured interviews Control Preferences (Degner & Sloan, 1992)	101 female breast cancer patients prior to treatment decision meeting	39.4% active; 47.5% shared; 13.1% passive	61.7% active; 30.3% shared; 8.1% passive	✗	✓	-	✗	-
Kraetschmar <i>et al.</i> (2004)	Cross-sectional survey; Problem Solving Decision-making Scale (Deber <i>et al.</i> 1996)	606 female breast cancer, prostate cancer and fracture patients; various stages of disease; 99% response rate	2.9% active; 67.3% shared; 29.7% passive	-	-	-	-	-	Perceived knowledge of condition Trust in physician
Lam <i>et al.</i> (2003)	Cross-sectional survey; Researcher's own measure	154 female breast cancer patients; 28-79 years; 1 to 10 months post diagnosis; 89.5% response rate	33.1% active 59.1% shared 7.8% passive	-	✓	✗	-	-	-
Lobb <i>et al.</i> (2001)	Cross-sectional survey; Likert scale based on Control Preferences (Degner & Sloan, 1992)	100 female breast cancer patients; within 2 months of diagnosis	23% active 54% shared 23% active	-	✓	✗	✗	-	-
Ong <i>et al.</i> (1999)	Cross-sectional survey; Decision preference statements (Sutherland <i>et al.</i> 1989)	102 female and 21 male cancer patients;	15.8% active 51.6% shared 19.6% passive	-	-	-	-	✓	-

Table 14 (continued): Summary of quantitative studies looking at factors associated with patient preferences for participation

Reference	Method and instrument used to measure decision-making preference	Participants and response rate	Summary of preferred roles in decision-making	Summary of actual roles in decision-making	Associations with patient preference investigated ✓ = significant ✗ = not significant				
					Age	Education	Sex	Emotional well-being	Other sig. associations
Petrisek et al. (1997)	Cross-sectional survey; Researcher's own measure	179 female breast cancer patients; 3 to 12 months post diagnosis; 78.9% response rate	5% would have liked someone to make the decision	-	✓	-	-	-	-
Ramfelt et al. (2000)	Cross sectional; structured interviews; Control Preferences (Degner & Sloan, 1992)	85 newly diagnosed colorectal patients; 47.6% male, 52.3% female; 87.6% response rate	5.9% active; 62.4% shared; 31.7% passive	7.1% active; 16.4% shared; 76.5% passive	✗	✗	✗	-	-
Ramfelt et al. (2005)	Cross sectional; structured interviews; Control Preferences (Degner & Sloan, 1992)	55 colorectal patients 1 year post diagnosis	1.8% active; 74.5% shared; 21.8% passive	-	✓	✓	-	-	-
Rothenbacher et al. (1997)	Cross sectional; structured interviews; Control Preferences (Degner & Sloan, 1992)	59 advanced cancer patients; 86 non malignant palliative care patients; 115 non-hospitalised patients	Patients with cancer: 9% active 73% shared 18% passive	-	✓	✓	✗	-	Occupation
Sainio & Lauri (2003)	Cross-sectional survey; Own instrument	273 cancer patients; 2 months to 15 years post diagnosis; 90% response rate	31% not at all important to make own decisions; 72% important to share decisions	7% made decisions themselves; 70% shared decision to some extent	✗	✗	✓	✗	Physical condition
Salkeld et al. (2004)	Cross-sectional survey; Questionnaire based on Degner et al. (1997)	102 male and 73 female colorectal cancer patients; 6 months to 2 years post surgery; 80% response rate	15.4% active; 28.6% shared; 53.7% passive	-	✓	✗	✓	-	Patient has received radiotherapy

Table 14 (continued): Summary of quantitative studies looking at factors associated with patient preferences for participation

Reference	Method and instrument used to measure decision-making preference	Participants and response rate	Summary of preferred roles in decision-making	Summary of actual roles in decision-making	Associations with patient preference investigated ✓ = significant ✗ = not significant				
					Age	Education	Sex	Emotional Well-being	Other sig. associations
Stewart <i>et al.</i> (2000)	Cross-sectional survey; Instrument designed based on Cassileth <i>et al.</i> (1980) and Degner <i>et al.</i> (1997)	105 ovarian cancer patients; 21-87 years; 75.5% response rate	Diagnosis: 14.3% active 62.9% shared 22.9% passive Treatment: 17.3% active 59.6% shared 21.9% passive After treatment: 15.2% active 61.9% shared 21.9% passive	-	✗	-	-	-	Condition perceived as serious Metastases present
Stiggelbout & Kiebert (1997)	Cross-sectional survey; Decision preferences statements (Sutherland <i>et al.</i> 1989)	55 cancer patients (91.2% response rate), 53 people accompanying them, 53 surgical patients, 36 people accompanying them;	For cancer patients: 13.5% active; 25.0% shared; 61.5% passive	-	✓	-	✓	-	Being a current patient
Sutherland <i>et al.</i> (1989)	Cross-sectional survey; own instrument	35 female and 17 male cancer patients	9.6% active 26.9% shared; 63.5% passive	-	-	-	-	-	Information seeking behaviour
Vogel <i>et al.</i> (2008)	Cross-sectional; Control Preferences (Degner & Sloan, 1992)	137 female breast cancer patients following treatment decision meeting; 19-75 years	30.6% active; 29.2% shared; 40.2% passive	35.8% active; 12.7% shared; 51.5% passive	-	-	-	✓	Perception of treatment choice

Table 14 (continued): Summary of quantitative studies looking at factors associated with patient preferences for participation

Reference	Method and instrument used to measure decision-making preference	Participants and response rate	Summary of preferred roles in decision-making	Summary of actual roles in decision-making	Associations with patient preference investigated ✓ = significant ✗ = not significant				
					Age	Education	Sex	Emotional well-being	Other sig. associations
Wallberg <i>et al.</i> (2000)	Cross-sectional survey; Control Preferences (Degner & Sloan, 1992)	201 female breast cancer patients; immediately prior or following treatment decision-making; 77% response rate	16% active 18% shared 66% passive	-	✓*	✓*	-	-	-
Wong <i>et al.</i> (2000)	Cross-sectional questionnaire survey; instrument designed past research including Cassileth <i>et al.</i> (198); Degner and Sloan (1992)	101 male prostate cancer patients; 63.5% response rate	11-21% active; >60% shared; 13-25% passive	-	✗	✗	-	✗	-

Table 14 (continued): Summary of quantitative studies looking at factors associated with patient preferences for participation; *only descriptive statistics reported

Reference	Data collection and analysis	Participants and response rate	Reliability/ Validity	Key findings
Charles <i>et al.</i> (1998)	Open ended, in depth personal interviews; Thematic coding using computer programme NUD*IST	20 female breast cancer patients; 42-78 years	Independent review of analysis by experienced researcher; audit trail; presentation of representative quotes	<ul style="list-style-type: none"> • Most preferred shared decision-making; a few preferred a passive role. • Doctors seen as the 'experts' and treatment decisions as requiring expertise, knowledge and clinical experience. Some respondents felt that they should therefore be passive. • There is a reluctance to question doctors for fear of appearing distrustful or losing confidence in the decision. • Participating in treatment decision can provide a feeling of control. • Women viewed that decision-making could be 'right' or 'wrong' and the 'decision-maker' may be responsible for this.
Cohen and Britten (2003)	Semi-structured interviews; Thematic analysis using computer programme ATLAS	19 male prostate cancer patients; 58-88 years	Independent thematic analysis by 2 researchers	<ul style="list-style-type: none"> • Difficult to concentrate on decision-making due to distress of diagnosis in same consultation. • A directive role welcomed, as the decision was seen to require expertise • Trust can be placed in the professional. • Some men anxious about assuming responsibility for the outcome. • Some wanted to be viewed as a 'good patient' and felt being more active or questioning may be disrespectful.
Elit <i>et al.</i> (2003)	In-depth, semi-structured interviews; thematic coding using computer programme NVivo	21 female ovarian cancer patients; 47-77 years	Independent thematic analysis by 2 researchers	<ul style="list-style-type: none"> • Most wanted to be involved in the treatment decision-making. • Knowledge is necessary for the treatment decision. • Trust was put in the doctor's expertise. • Post-operative procedure overwhelming; difficulty concentrating at the time the treatment decision was made. • Some felt frightened and pressured into a treatment decision.

Table 15: Summary of qualitative studies exploring factors affecting patient preferences for participation

Reference	Data collection and analysis	Participants and response rate	Reliability/ Validity	Key findings
Hack <i>et al.</i> (1994)	Semi-structured interviews; Content analysis	35 female breast cancer patients; 32-82 years; 2-6 post diagnosis	Not discussed	<ul style="list-style-type: none"> • Desire to be kept informed of the treatment plan in spite of role • Important to place faith and trust in doctors because of their expertise. • Some passive patients described that pressure to be more active in decision-making was anxiety-provoking. • Reasons for assuming a passive role included mental infirmity, lack of education, and difficulty accepting the cancer diagnosis. • Other factors that influenced the preference of an active or passive role included faith in the physician, will to live, and general coping style in response to threatening situations.
Henman <i>et al.</i> (2002)	Semi-structured telephone interviews; Thematic coding using computer programme NUD*IST	20 female cancer patients 2-4 weeks post diagnosis	Author consensus, presentation of representative quotes	<ul style="list-style-type: none"> • Half of the sample wanted to make decisions with their doctors. • Four themes emerged as to what was felt to be critical in reaching the right decision: doctor's specialist knowledge; feeling listened to; feeling included in the decision-making process and trust and confidence.
Husain <i>et al.</i> (2008)	In depth qualitative interviews; Framework analysis	21 female breast cancer patients; over 76-91 years; 70% response rate	Independent analysis by 2 researchers	<ul style="list-style-type: none"> • Many remained silent in front of medical team. • Main approach to decision-making was to rely heavily on advice and opinion of health care team. Factors affecting role in decision-making included trust in doctor, reliance on doctor's expertise and previous personal experiences of cancer.
Kenny <i>et al.</i> (1999)	Semi-structured interviews; content and thematic analysis	40 female breast cancer patients; 1 year post treatment	Independent coding and analysis by 2 researchers	<ul style="list-style-type: none"> • Respondents differed in preference for participation. • A passive role was associated with lack of medical knowledge and expertise, placing trust and faith in doctors and anxiety about making the 'wrong' decision as influencing factors. • A more active role was associated with feeling that they should take responsibility for their own bodies, and recognising that doctors could be fallible.

Table 15 (continued): Summary of qualitative studies exploring factors affecting patient preferences for participation

Reference	Data collection and analysis	Participants and response rate	Reliability/ Validity	Key findings
Sainio <i>et al.</i> (2001)	Focused interviews; content analysis using computer programme ATLAS	18 male and 16 female cancer patients; at least 2 months post diagnosis	Use of software, parallel analysis by researchers	<ul style="list-style-type: none"> • Patient factors which promoted participation were good health, adequate information, ability to confront situations, personality, assertiveness, social support. • Patient factors which limited participation were poor physical and mental health, lack of knowledge, fear and age.
Sanders & Skevington (2003)	Semi-structured interviews and observation; Coding according to Grounded theory	24 male and 13 female colorectal cancer patients	Not discussed	<ul style="list-style-type: none"> • Many informants felt that decision was not their responsibility because they were not the expert. • Some informants did not want to participate for fear of finding out anxiety provoking information. • Most patients did not perceive that there was a choice to make.

Table 15 (continued): Summary of qualitative studies exploring factors affecting patient preferences for participation

Reference	Method and instrument used to measure decision-making role	Participants and response rate	Summary of preferred roles in decision-making	Summary of actual roles in decision-making	Associations with actual patient role ✓ = significant * = not significant				
					Age	Education	Sex	Emotional well-being	Other sig. associations
Bilodeau & Degner (1996)	Cross-sectional survey; Scale based on Degner and Sloan (1992)	74 women with breast cancer	20% active 37% shared 43% passive	19% active 24% shared 57% passive	✓	-	-	-	-
Fischer et al. (2006)	Longitudinal survey; Scale based on Degner and Sloan (1992)	126 prostate cancer patients; various stages of illness	-	18% active 60% shared 22% passive	✓	-	-	* (coping style)	• Known stage of disease
Hawley et al. (2007)	Cross-sectional survey; Scale based on Degner and Sloan (1992)	1038 breast cancer patients; 270 surgeons	-	39% active 38% shared 22% passive	*	-	-	-	• Treatment options discussed
Liang et al. (2002)	Cross-sectional survey; Perceived Participation in Care Scale (Lerman et al., 1990)	613 breast cancer patients paired with their surgeons	-	-	*	-	-	-	• Physician training • Treatment options identified • Social support
Maly et al. (2004)	Cross-sectional survey; Own statements	222 breast cancer patients; over 55 years; average 7.1 months since diagnosis	-	53.2% self as final decision maker; 36.9% doctor as final decision maker 10.0% other as final decision maker	*	-	-	-	• Emotional support • Direct invitation for participation • Self-efficacy
Peterson et al. (2003)	Cross-sectional survey; Own instrument	79 cancer patients; waiting for treatment to start	-	33% Information seeking 23% Information processing 42% Advice following 3% ruminating	-	-	-	*	-

Table 16: Summary of quantitative studies investigating factors affecting patients' actual participation in decision-making

Reference	Method and instrument used to measure decision-making role	Participants and response rate	Summary of preferred roles in decision-making	Summary of actual roles in decision-making	Associations with actual patient role ✓ = significant * = not significant				
					Age	Education	Sex	Emotional well-being	Other sig. associations
Pinquhart et al. (2004)	Cross-sectional survey; Own instrument	140 cancer patients; 57% male; 18-83 years; 1 week post-diagnosis	-	-	✓	✓	*	*	<ul style="list-style-type: none"> • Cognitive abilities • Belief in powerful others
Sainio & Lauri (2003)	Cross-sectional survey; Own instrument	273 cancer patients; 2 months to 15 years post diagnosis; 90% response rate	31% not at all important to make own decisions; 72% important to share decisions	7% made decisions themselves; 70% shared decision at least to some extent	*	*	*	*	<ul style="list-style-type: none"> • Physical condition • Marital status
Siminoff & Fetting (1991)	Observational Study & semi-structured interview	100 breast cancer patients; at oncology decision-making meeting	-	80% accepted physicians primary treatment recommendation	-	✓	-	-	<ul style="list-style-type: none"> • Knowledge • Strength of physician recommendation
Street & Gordon (2006)	Observational study; behavioural coding of audio-transcripts	62 initial consultations for lung cancer and 88 post-angiogram consultations	-	One fifth of utterances by lung cancer patient indicative of active participation	-	-	-	-	<ul style="list-style-type: none"> • Length of appointment • Physician facilitation • Ethnicity

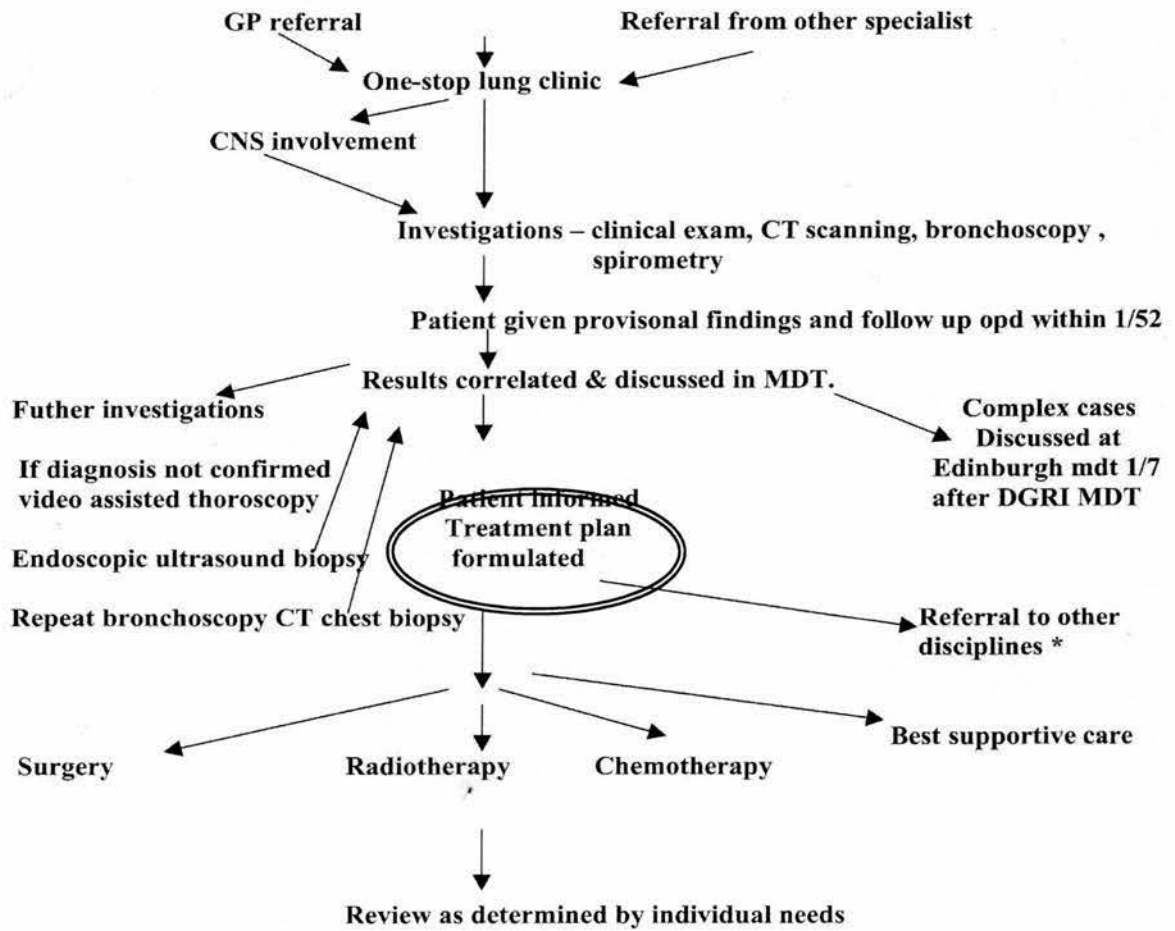
Table 16 (continued): Summary of quantitative studies investigating factors affecting patients' actual participation in decision-making

Reference	Data collection and analysis	Participants and response rate	Reliability/ Validity	Key findings
McVea <i>et al.</i> (2001)	Semi-structured interviews and thematic analysis	25 women 1.8 years post diagnosis on average breast cancer	Independent coding analysis by three researchers	<ul style="list-style-type: none"> • More than half of participants played a passive role in decision-making. • Perceiving a choice was determined by medical factors or doctor offering choice. • Intense emotional distress affected decision-making ability. • Participants who did engage in a rational decision-making process based choices on concerns about body image and fear of recurrence. • Adjustment to the diagnosis made it difficult for them to understand or remember information about treatment options.

Table 17: Summary of qualitative studies investigating factors affecting patients' actual participation in decision-making

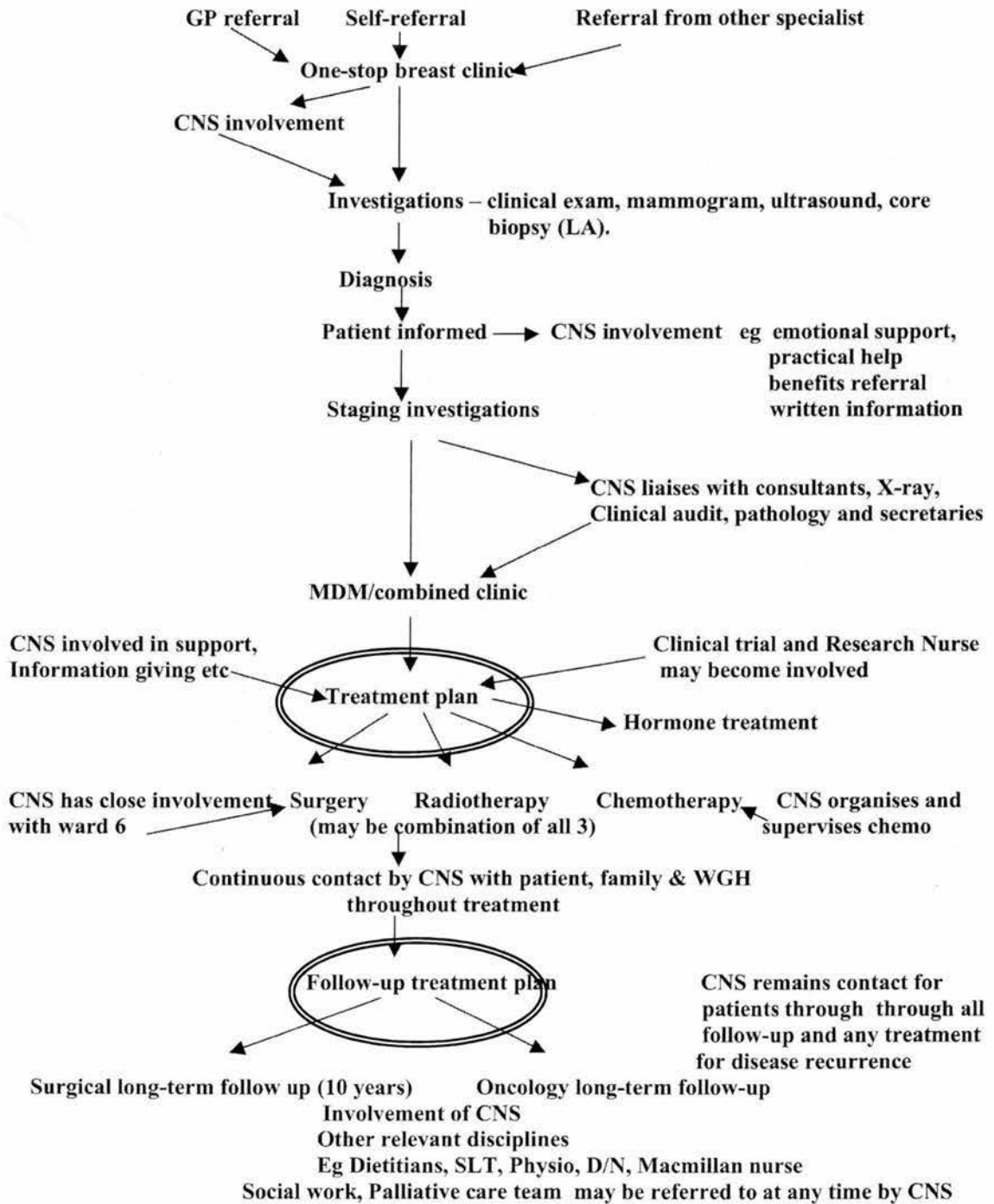
Appendix Three: Patient pathways for each cancer type with oncology consultation highlighted

Patient Pathway Lung Cancer

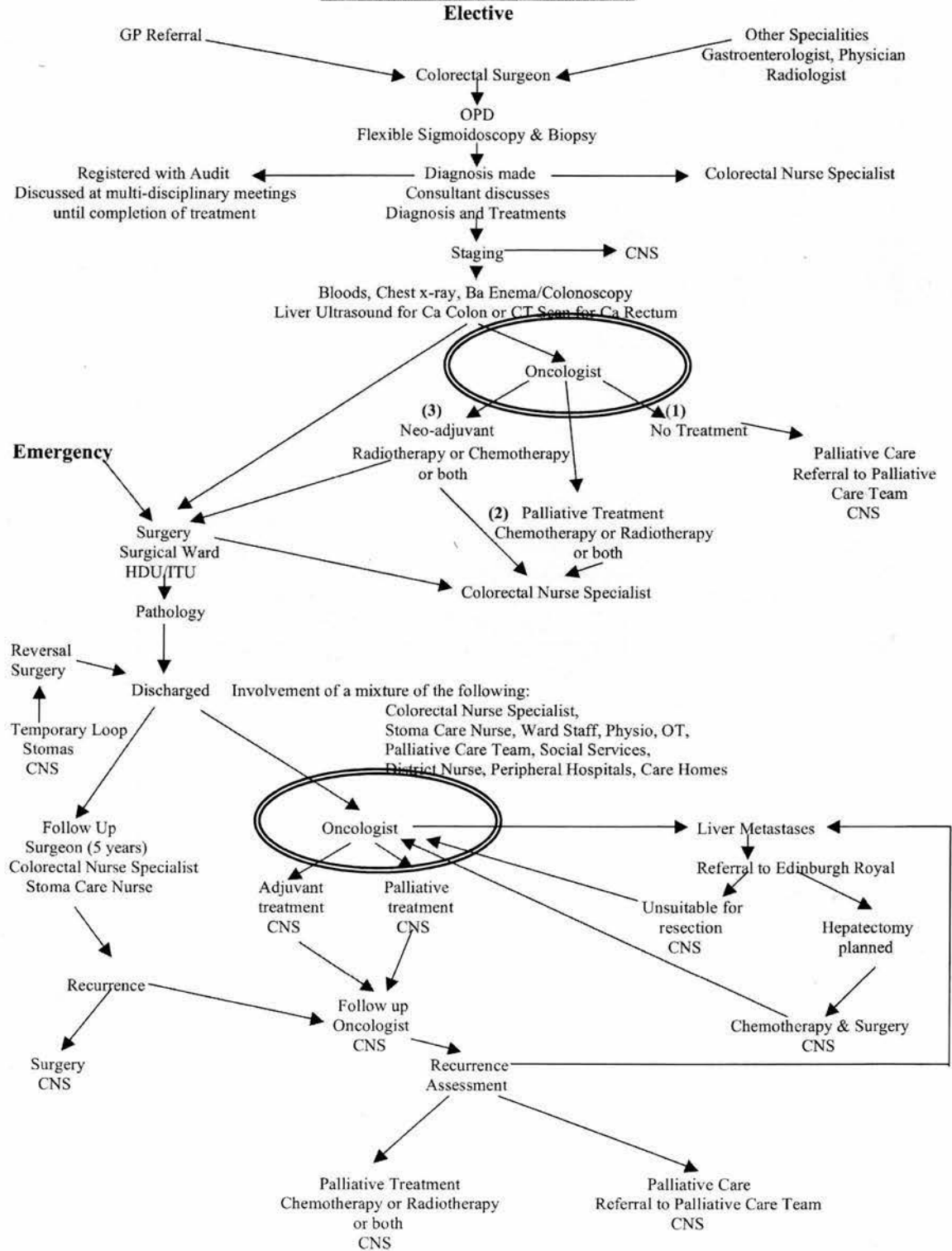


* Appliance, District Nurse, Dietician, Macmillan, Occupational Therapy, Palliative Services, Physiotherapy, Social Work.

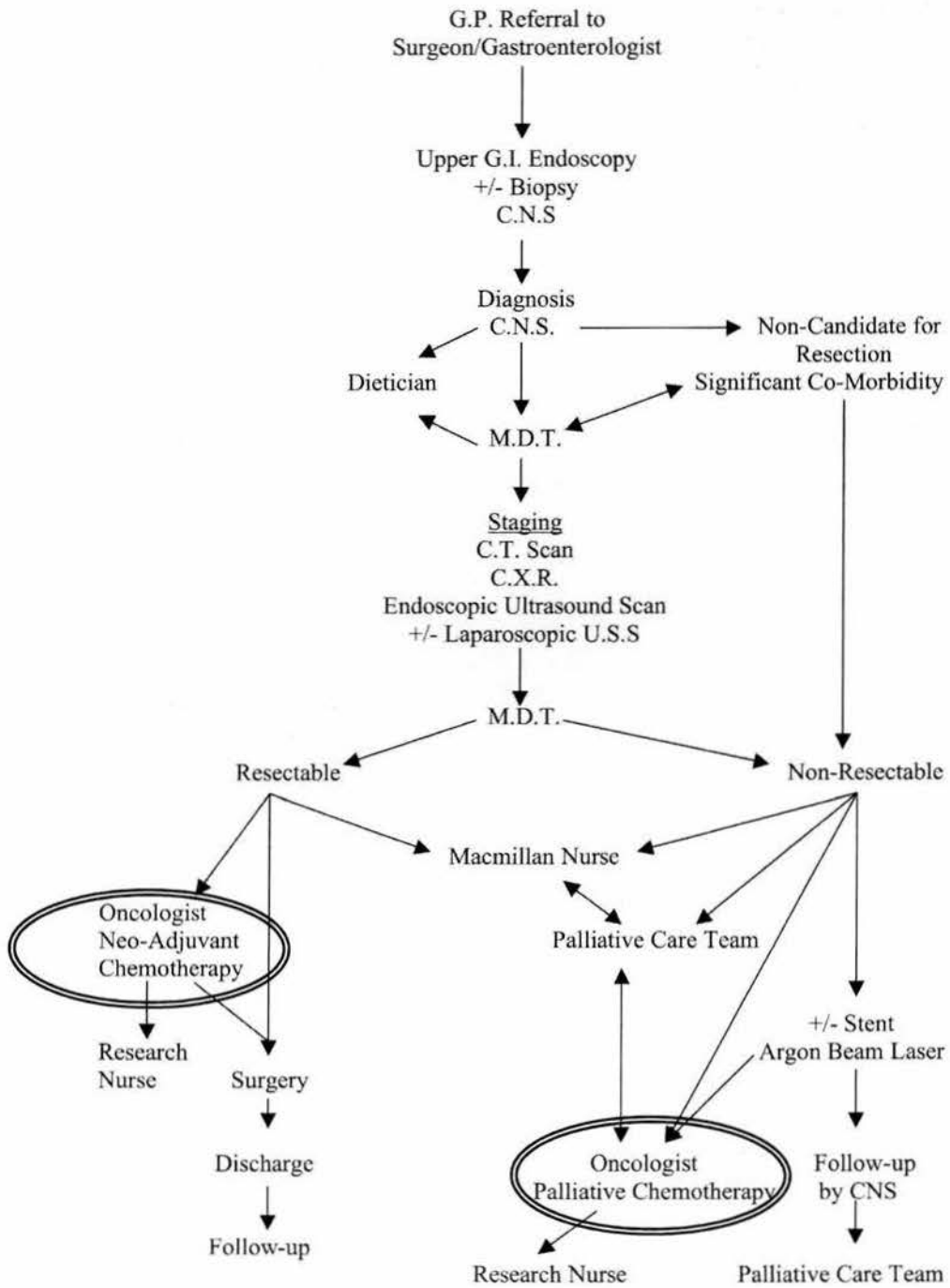
Patient Pathway – Breast Cancer



Colorectal Cancer Patient Pathway



Oesophageal and Gastric Cancer



First contact at Endoscopy or Diagnosis and continued input throughout patient journey

Appendix Four: Participant information (reformatted)

Patient Involvement in Treatment Decisions

Information about the research: For Potential Participants

The Department of Psychological Services and Research would like to invite you to take part in a research study.

Before you decide, *please take the time to read the following information carefully*. Feel free to ask us if there is anything that is not clear or if you would like more information.

What is the research about?

The research study is looking at patients' views on their involvement in decisions about their treatment for cancer and how people cope with their emotions at this time. We are also interested in whether being involved in treatment making decisions affects how people adjust to having cancer. The research will help us learn more about how patients would like to make decisions about their treatment as well as what may affect this. In the future, this will help us to make this process easier for patients.

What does it involve?

At your next clinic appointment, a researcher will speak with you. She will ask you if you have decided to take part. If you agree to participate, you will be given a short questionnaire to fill in before your consultation with the doctor.

You will also be given a questionnaire to complete in your own time. You can return these questionnaires in the stamped addressed envelope, directly to the researcher or to the reception desk at the Macmillan Centre.

The first questionnaire asks about your preferences for participating in decision making about your health care as well as your emotions at this time. This should take you about 5-10 minutes.

The second questionnaire (the one you take home with you) asks about how you felt your consultation went, as well as questions about coping at difficult times and with your illness. In total this should only take you about 15-25 minutes.

In 3 months time, we will send you a further questionnaire to complete by post. This will again ask how you are coping with your illness. This will only take about 10-15 minutes. Again you will be able to return it in a stamped addressed envelope, directly to the researcher or to the main reception desk at the Macmillan Centre.

If you would like further information about the questionnaires or what is involved, please contact **Frances Scrutton** on [REDACTED]

Deciding to take part

It is up to you to decide whether to take part in this study. We genuinely value your opinion and the more people who contribute, the more meaningful the results will be. We intend to use the findings of this research to shape future services to support people with cancer and their families.

At your next clinic appointment, the researcher will ask you if you have decided to take part. At this time, she will ask you to sign a consent form to show you have agreed to take part and give you the questionnaires. Once we have received all your questionnaires, your answers will be separated from your consent form and your responses will be anonymous and confidential

Your Consultant, Clinical Nurse Specialist and G.P. will **NOT** be informed of your responses. Only if we have concern regarding your safety or that of another will information be passed on. In this case, you would be contacted by the researcher to discuss in more detail the concerns you have raised.

**IF YOU DO NOT WISH TO BE APPROACHED BY THE RESEARCHER TO ASK
IF YOU WOULD LIKE TO PARTICIPATE PLEASE LET YOUR NURSE OR THE
SECRETARY KNOW ON THE CLINIC DAY**

If you do decide to take part, this will not affect your access to services in the future from NHS Dumfries and Galloway. Also, please note that you can withdraw from the project at any time, without giving a reason.

How will I find out the results of the research?

All the replies will be collated and a report will be written summarising everyone's thoughts. This report will be available to you in autumn 2009. In addition, you will receive an invitation to an evening which will be held to present the findings of the research and to address any questions.

All research in the NHS is looked at by an independent group of people, called the Research Ethics Committee to protect your safety, rights and wellbeing.

NHS Dumfries and Galloway Research Ethics Committee have reviewed this study. However, if you have a concern about any aspects of this study, please speak to researchers who will do their best to answer you questions.

If you have any questions not answered by this information, please contact **Frances Scrutton** on [REDACTED]

Further Information

For further information, please contact researcher

FRANCES SCRUTTON

DEPARTMENT OF PSYCHOLOGY

NITHBANK

DUMFRIES

DG1 2SA

Tel: [REDACTED]

**For independent advice, please contact Gwen Baxter, NHS Dumfries and Galloway
Research and Development, Dumfries and Galloway Royal Infirmary, [REDACTED]**

Appendix Five: P-P plots and histograms for main variables and homogeneity of variance statistics

Normal P-P Plot of Distress

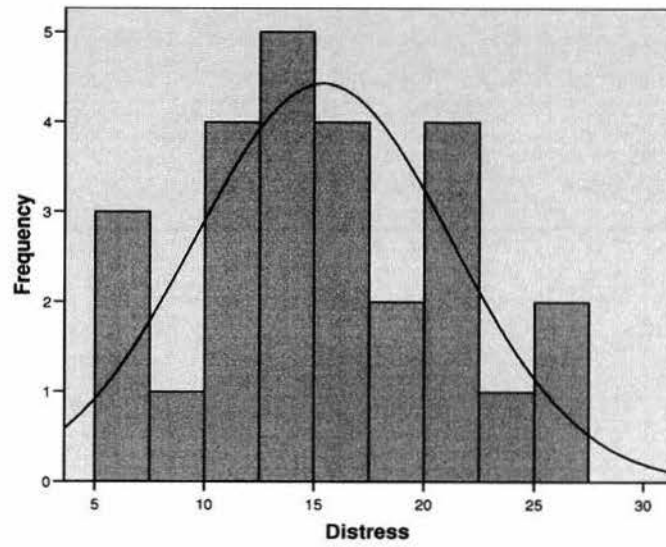
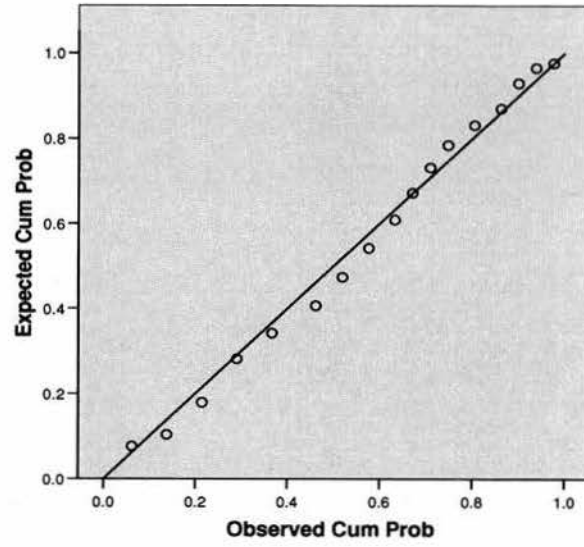


Figure 12: P-P plot and histogram for distress measured by GHQ-12

Normal P-P Plot of Emotion Regulation

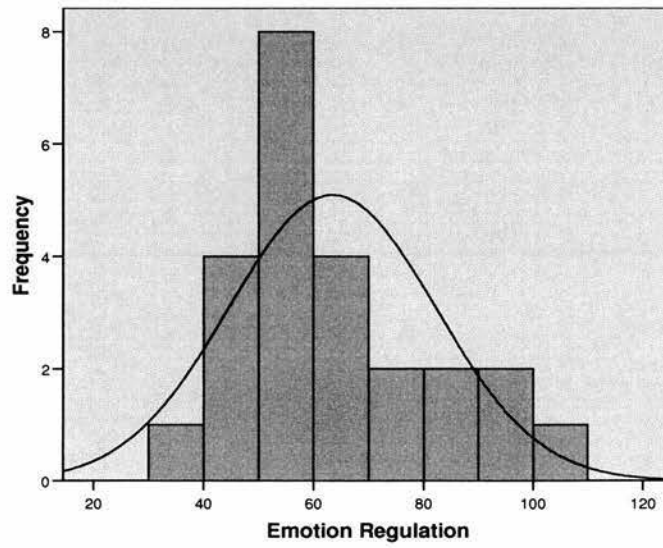
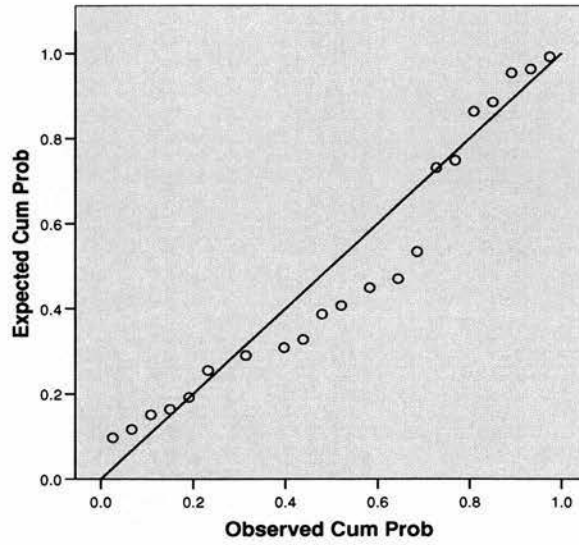


Figure 13: P-P plot and histogram for emotion regulation measured by DERS

Normal P-P Plot of Psychological Adjustment

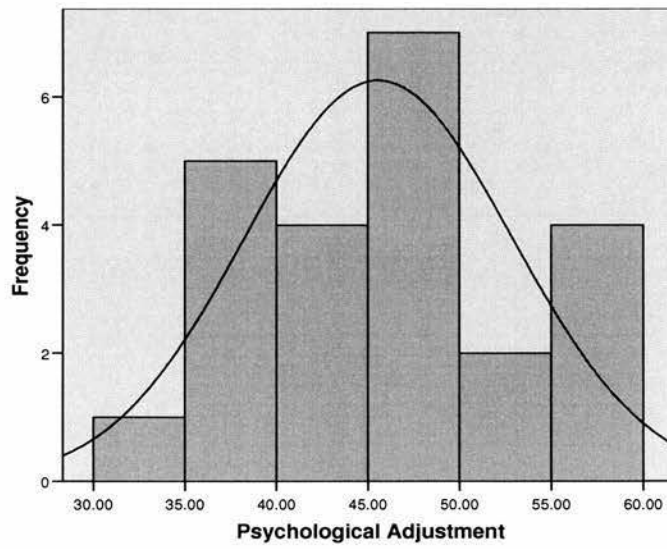
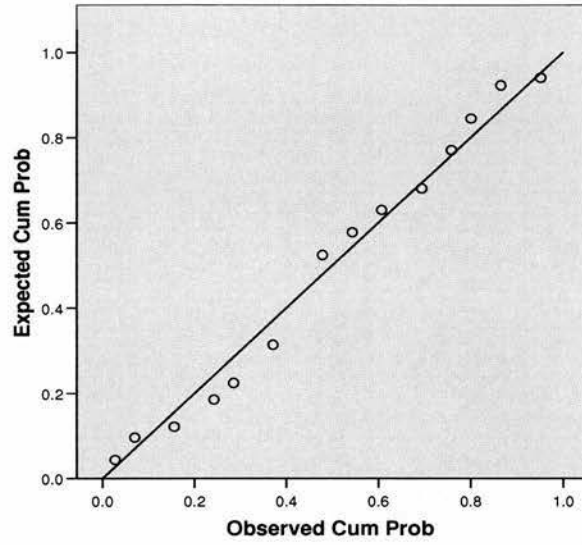


Figure 14: P-P plot and histogram for psychological adjustment measured by Fighting Spirit/ Helpless-hopeless Subscale

Normal P-P Plot of Psychological Adjustment - Follow up

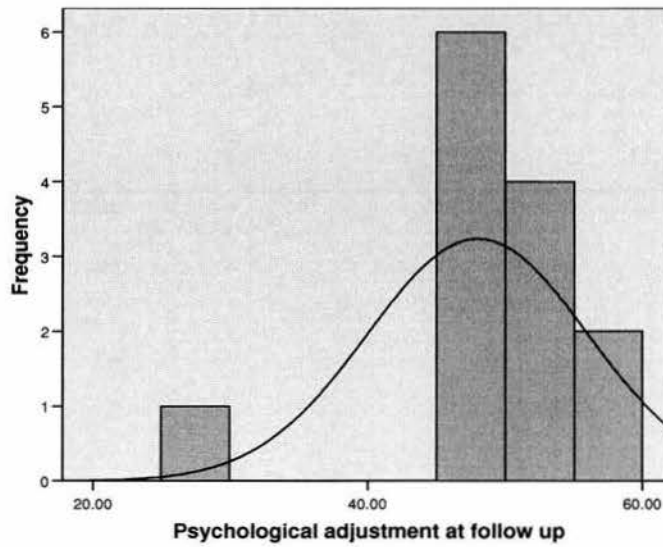
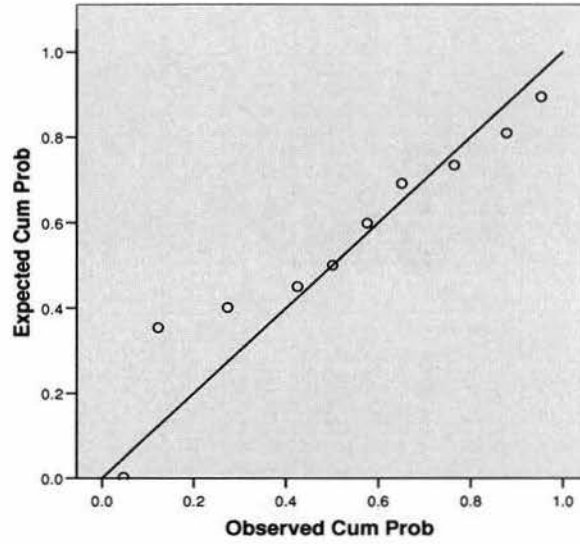


Figure 15: P-P plot and histogram for psychological adjustment measured by FS/H-H subscale at three month follow up

Normal P-P Plot of Satisfaction with Decision

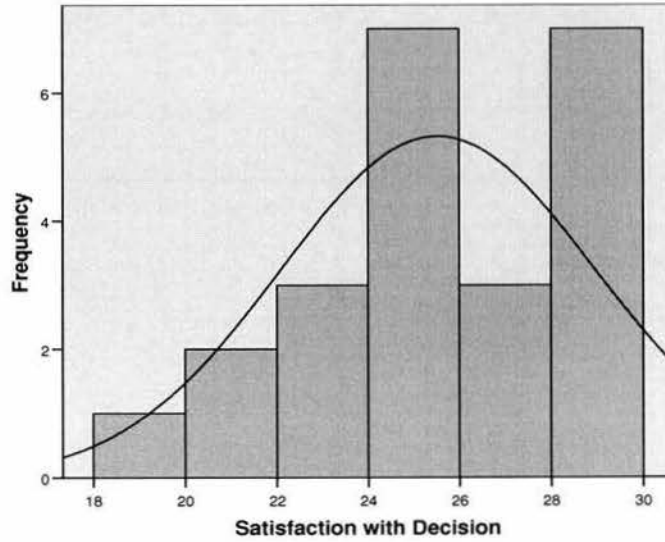
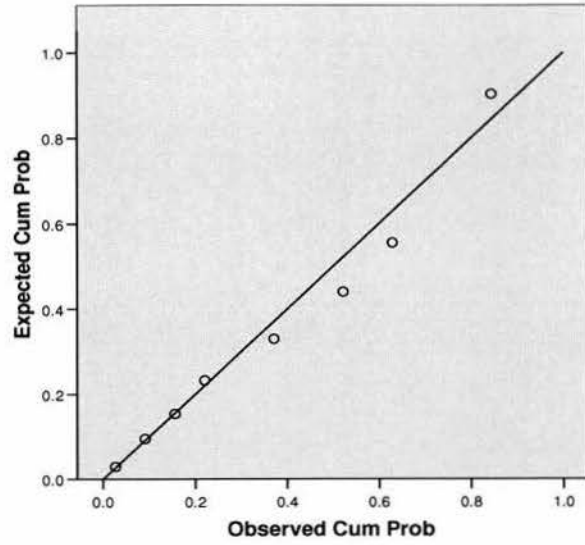


Figure 16: P-P plot and histogram for satisfaction with decision measured by Satisfaction with Decision Scale

Normal P-P Plot of Satisfaction with Decision - Follow up

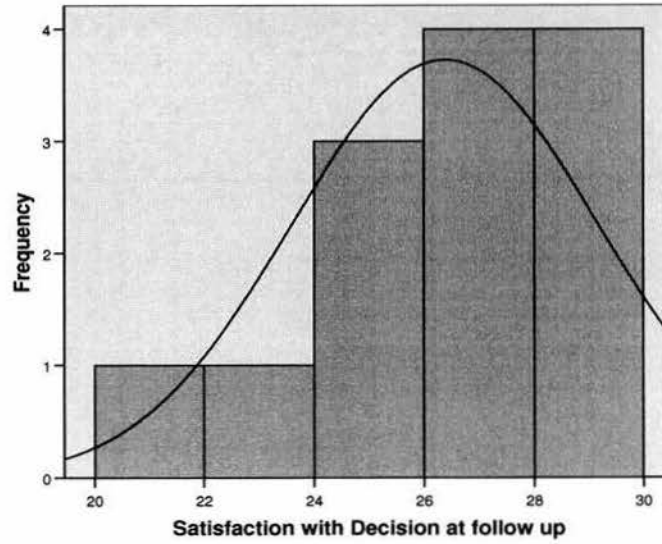
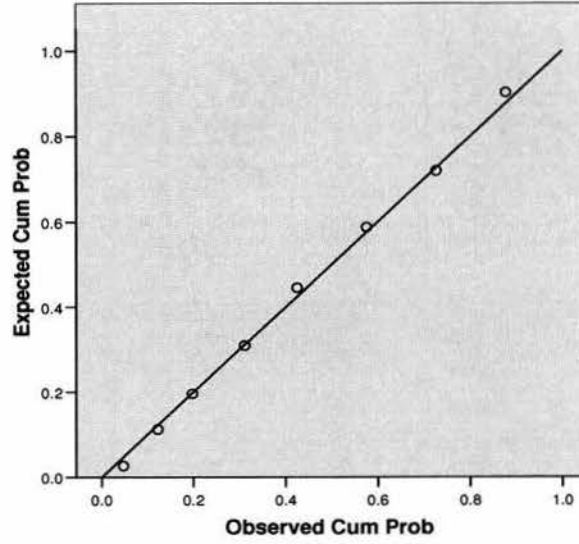


Figure 17: P-P plot and histogram for satisfaction with decision measured by Satisfaction with Decision Scale at three month follow-up

		Levene Statistic	df1	df2	Sig.
Distress	Based on Mean	.142	1	11	.713
	Based on Median	.139	1	11	.716
	Based on Median and with adjusted df	.139	1	10.133	.717
	Based on trimmed mean	.146	1	11	.710
Emotion Regulation	Based on Mean	1.895	1	11	.196
	Based on Median	1.833	1	11	.203
	Based on Median and with adjusted df	1.833	1	10.995	.203
	Based on trimmed mean	1.907	1	11	.195
Psychological Adjustment	Based on Mean	.648	1	11	.438
	Based on Median	.561	1	11	.470
	Based on Median and with adjusted df	.561	1	10.975	.470
	Based on trimmed mean	.651	1	11	.437
Psychological Adjustment at follow up	Based on Mean	.234	1	11	.638
	Based on Median	.413	1	11	.534
	Based on Median and with adjusted df	.413	1	9.464	.536
	Based on trimmed mean	.235	1	11	.638

Table 18: Table showing Levene's test for homogeneity of variance between groups of participants based on matched or unmatched roles. Continued overleaf.

		Levene Statistic	df1	df2	Sig.
Satisfaction with Decision	Based on Mean	.100	1	11	.758
	Based on Median	.122	1	11	.734
	Based on Median and with adjusted df	.122	1	9.253	.735
	Based on trimmed mean	.109	1	11	.748
Satisfaction with decision at follow up	Based on Mean	.003	1	11	.958
	Based on Median	.016	1	11	.903
	Based on Median and with adjusted df	.016	1	9.159	.903
	Based on trimmed mean	.004	1	11	.951

Table 18 (continued): Table showing Levene's test for homogeneity of variance between groups of participants based on matched or unmatched roles