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The relationship between uncertainty in illness and anxiety in patients with cancer

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The Relationship Between Uncertainty in Illness and Anxiety in Patients With
Cancer

by

Naima Vera

A thesis submitted in partial fulfillment
of the requirements for the degree of
Master in Science
College of Nursing
University of South Florida

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Dedication

This is dedicated to my wonderful family. To my husband Eric, thank you for your endless patience, your sincere love and for believing in me. To my parents, Manuel and Myrna, who encouraged me to pursue my dreams and gave me enough tools to achieve them. To my siblings, Alina, Gaby and Yusef, who constantly give me energy, who fill my life with joy and laughter since the first day we met. Thank you all for adding so many positive things to my life.

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ABSTRACT

Anxiety is a common problem for patients with cancer. Anxiety may have a negative impact on decision making and overall emotional well being of patients and may be related to the uncertainties faced by people with cancer. This study examined the relationship between uncertainty in illness and anxiety in patients with cancer.

The sample consisted of 30 patients, predominantly males (n=23), being treated as outpatients in the Clinical Research Unit at a National Cancer Institute designated cancer center in Florida. After agreeing to participate, patients completed the State-Trait Anxiety Inventory as well as Mishel's Uncertainty in Illness Scale.

Participants' ages ranged from 21 to 86, with a mean age of 64 years. Forty percent of the patients completed high school, 30% had some college education and almost 30% had a bachelor's degree or higher. Almost 47% of the sample had melanoma, other patients had renal cancer (n=3), or pancreatic cancer (n=2), acute myeloid leukemia (n=2), sarcoma (n=2), lung cancer (n=2),

myeloma (n=2), chronic myeloid leukemia (n=1), glioblastoma (n=1), and rectal cancer (n=1). Seventy percent of the patients had stage IV disease.

The results of the study showed a significant positive relationship between uncertainty and both state anxiety ($r=0.52$, $p=0.00$.) and trait anxiety ($r=0.61$, $p=0.000$). A significant positive relationship was also found between the uncertainty subscale of ambiguity and both, state anxiety ($r=0.538$, $p=0.002$) and trait anxiety ($r=0.56$, $p=0.001$). Both state anxiety ($r=0.39$, $p=0.034$) and trait anxiety ($r=0.64$, $p=0.000$) were positively related to the uncertainty subset of inconsistency.

Although the sample size was small and not demographically diverse, the findings of this study are supportive of previous studies. The implications of this study in nursing are significant because they examine two emotional aspects that evidently exist among cancer patients, and that very likely cause distress to this population. The findings of this study suggest that additional focus in uncertainty and anxiety should take place in the clinical outpatient setting.

Chapter One Introduction

Cancer represents the second most common cause of death in the Western world (American Cancer Society, 2008). Despite the progress in medicine, cancer is often considered a synonym of death, pain and suffering (Powe & Finne, 2003). Cancer is not considered a single event but a permanent condition with ongoing ambiguity, or uncertainty, delayed effects of the disease and its treatments and concurrent psychological issues (Zebrack, 2000).

A diagnosis of cancer is a life changing and potentially fatal event that can be associated with feelings of uncertainty (Shaha, Cox, Talman, & Kelly, 2008) leading to anxiety. Notions of uncertainty concerning the cancer experience have been associated with anxiety (Decker et al., 2007) in that 48% of lymphoma patients reported levels of anxiety high enough to be diagnosed with an anxiety disorder (Stark et al., 2002).

Mishel (1988) defined uncertainty in illness as the inability to determine the meaning of illness-related events. Uncertainty is a component of all illness experiences and it is believed to affect psychosocial adaptation and outcomes of disease (McCormick, 2002). High levels of uncertainty are related to high emotional distress, anxiety and depression (McCormick, 2002).

Anxiety can be defined as a state of uneasiness to a potential threat that is inconsistent with the expected events (Bay & Algase, 1999) and can be associated with feelings of fear, dread, and uneasiness (National Cancer Society, 2008). The threat of cancer may elicit this state of uneasiness. Higher anxiety levels have been found in cancer patients who are aware of their diagnosis compared to a group of patients without awareness (Tavoli, Mohagheghi, Montazer, Roshan, Rasool, and Omidvari, 2007).

Problem Statement

Defining the relationship between uncertainty and anxiety is important because it can lead to further studies that focus on the simultaneous management of uncertainty and anxiety as well as their impact on quality of life (QOL). Uncertainty remains one of the single greatest source of stress for people affected by a life-threatening illness such as cancer (Santacroce, 2002). Stark et al. studied anxiety in 178 patients with lymphoma, renal cell carcinoma, melanoma and plasma cell dyscrasia. They found that 48% of these patients had levels of anxiety high enough to qualify for anxiety disorder. According to Pitcealhy et al. (2009) most cancer patients report distress within the first year of diagnosis and up to 40% develop anxiety which impairs the quality of life for the patient.

Uncertainty and anxiety are experienced by most patients with cancer due to the inability to determine the meaning of illness-related events and to the potential threat that the cancer diagnosis poses. Although anxiety and

uncertainty are important factors and are commonly experienced by cancer patients, little research was found during the review of literature that focused on evaluating a relationship between the two. The purpose of this study was to examine the relationship between uncertainty in illness and anxiety in patients with cancer.

If a relationship between uncertainty and anxiety is defined, there is a possibility that decreasing uncertainty may in turn decrease anxiety. Although things may never be normal after a patient is diagnosed with cancer, oncology nurse practitioners should have effective and clear communication as a simple but successful way to reduce uncertainty, and simultaneously decrease anxiety. A relationship between uncertainty and anxiety may give rise to future research to reduce uncertainty and anxiety during all stages of cancer.

Research Questions

The following questions guided this study:

1. Is there a significant positive relationship between uncertainty and trait anxiety in outpatients in a cancer center who have been diagnosed with cancer?
2. Is there a significant positive relationship between uncertainty and state anxiety in outpatients in a cancer center who have been diagnosed with cancer?
3. Are there significant positive relationships between uncertainty in illness subscales and either state or trait anxiety?

Definitions of Terms

Uncertainty in illness. Uncertainty is an inability to determine meaning in illness situations (Mishel, 1988). Uncertainty in cancer is directly related to not knowing about cancer. Uncertainty is influenced by factors that change from person to person. Therefore, the definition of uncertainty in illness is individual and specific to one person. The term itself is directly related to not knowing. The concept is taken a step further when referring to uncertainty in cancer. Uncertainty remains one of the single greatest source of stress for people affected by a life-threatening illness such as cancer (Santacroce, 2002).

Anxiety. Two types of anxiety have been defined; *state* anxiety and *trait* anxiety. State anxiety is a temporary condition in response to a stressful situation, like a cancer diagnosis. Trait anxiety is defined as a more general and long-standing quality (Spielberger, 1983).

Anxiety is a reaction to stress due to the thought of negative consequences of the illness. Anxiety is a threat to homeostasis, a presence of impending change, a sense of loss, uneasiness or increased apprehension. Anxiety has been defined as a heightened state of uneasiness to a potential threat that is inconsistent with the expected events and results when there is a mismatch between the next likely event and the actual event (Bay & Algase, 1999).

Anxiety can interfere with personal growth, physical health and behavior. Clinical expression of anxiety may include increasing tension, worry, fright,

trembling, quivering voice, arousal and jitters (Bay & Algase, 1999). Many times the source of anxiety is unknown; however in cancer, the source of anxiety is related to the impact of the diagnosis in one's life.

Significance to Nursing

This study may contribute to the future enhancement of the clinical treatment of anxiety in cancer patients in any stage of disease and treatment modality. In addition, this study may contribute to the limited research in uncertainty and anxiety of cancer patients. Good clinical guidelines are currently lacking in the identification and treatment of uncertainty, and early recognition may help reduce the associated anxiety. Enhanced awareness of the potential problems associated with the uncertainty frequently experienced by cancer patients may motivate nurses to develop better management strategies.

Chapter Two Review of Literature

This chapter presents the background for the study. A review of relevant research literature in uncertainty and anxiety is presented. This is followed by a summary and implications for nursing. Finally, gaps in the literature are presented.

Uncertainty in Illness

Uncertainty in illness has been studied using several different frameworks. Mishel (1981) has widely studied the concept of uncertainty in cancer using the Mishel's Uncertainty in Illness Scale (MUIS) to measure uncertainty. The scale presents four major factors which are: ambiguity, unpredictability, complexity and inconsistencies. Many have studied the concept of uncertainty in cancer and have based their studies on Mishel's Theory of Uncertainty in Illness. Mishel's model suggests coping is initiated to reduce uncertainty, especially when danger is perceived. In addition, coping is initiated to maintain the belief in a positive outcome when uncertainty is appraised as an opportunity.

A study conducted by Wallace et al., (2007) explored the three main domains established by Mishel, which include: uncertainty about disease and treatment, danger appraisal, and opportunity appraisal. The investigators used older men with prostate cancer undergoing watchful waiting as their population.

The defining features of uncertainty about disease and treatment were found to be: few signals to monitor progression of disease, lack of physical discomforts made it hard to believe that the cancer was there, lack of symptoms created uncertainty as cancer was perceived as related to pain and suffering, physician unable to tell how fast tumors grow, elevated PSA levels do not always indicate cancer, stable levels do not always indicate stable disease. Danger appraisals were found to be: treatment decision making was found as an appraisal of danger, lack of clear guideline and multiple alternatives, the newness of watchful waiting made them wonder if it was aggressive enough.

Interestingly, Wallace's (2007) study also noted that while uncertainty was consistently present in all patients after making the decision of watchful waiting, this offered the opportunity to manage their uncertainty by continuing to work, self-caring, keeping options open, using alternative medicine and praying, imagining cancer as small, by envisioning the smallness of their localized tumor, watch and wait provided an option to aggressive therapy or surgery that many times lead to poor outcomes and poor quality of life.

Mishel's re-conceptualization of Uncertainty in Illness Theory has also been used to study and explain the relationship between uncertainty and post traumatic stress syndrome. Lee (2006) conducted a study to examine the relationship between uncertainty and post traumatic stress syndrome in young adults, survivors of childhood cancer. It was found that post traumatic stress syndrome develops and is adopted by the survivors of childhood cancer as a

maladaptive strategy to manage uncertainty when they lack of sufficient resources for coping with the challenges of survivorship. Furthermore, avoidance and arousal, which are two symptom clusters of post traumatic stress disorder, were found to be related to uncertainty. Once again the study suggests that providing health related information appropriately (without ambiguity, low complexity, and no unpredictably) could potentially help alleviate or decrease uncertainty in cancer survivors.

Uncertainty throughout the cancer experience. Uncertainty does not diminish beyond diagnosis; therefore, uncertainty should continue to be addressed even throughout survivorship (Decker, Haase & Bell, 2007). In their study, Decker, et.al., (2007) used Michel's uncertainty model to study uncertainty in cancer patients. They found that there are no significant differences in the overall level of uncertainty among the newly diagnosed, diagnosed 1 to 4 years and diagnosed more than 5 years. However, newly diagnosed patients scored high uncertainty for future pain, unpredictable illness course, staff responsibility, and concerns about caring for themselves. Those diagnosed 1 - 4 years and 5 or more years, had high uncertainty about the multiple meanings of communication from the doctors. Those diagnosed 5 years or more had higher uncertainty about knowing what was wrong, had more unanswered questions and had higher uncertainty regarding the probability of successful treatment. Their study emphasizes the importance of certainty to provide open communication beyond

diagnosis and the cancer treatment phase. In addition, results suggests that the type of information needed changes during each stage of the cancer experience.

Mishel, along with Gil, Belyea, Germino, Porter, and Clayton (2006) reported significant benefit in providing cognitive behavioral strategies and self help manuals to increase recurrence free breast cancer survivor knowledge. Mishel et al. (2006) conducted a study that found that even after 10 months of no interventions, these women were able to integrate the changes and skill gained during intervention even without the direct guidance.

This same patient sample was used to gather data regarding triggers of uncertainty (memories, feelings, concerns) about cancer recurrence and physical symptoms from treatment side effects. The study found that hearing about someone else's cancer and pains, was the most frequent trigger of uncertainty. It was also found that in both Caucasian and African Americans, the most frequent symptoms linked to long-term treatment side effects were fatigue, joint stiffness, and pain. In 2006, Lee studied post traumatic stress disorder and uncertainty. This study found that there is a relationship between post traumatic stress disorder (PTSD) and uncertainty suggesting that cancer survivors adopt PTSD as a way to manage uncertainty.

Ethnic differences and uncertainty. Ethnic differences were also evaluated in research. Caucasian women were found to be more likely than African American women to report that their fears of recurrence were triggered by hearing about someone else's cancer while for African American the most

common trigger was new symptoms. The study also concluded that uncertainty remains after cancer diagnosis and treatment and that these survivors experienced triggers of uncertainty on a regular basis, with an average of 2 triggers per month (Gil, et al., 2006).

The study helps to better understand that during cancer survivorship uncertainty should still be identified, monitored and managed along with emotional distress. Giving specific information about symptoms that are commonly experienced as late effects of treatment is important in reducing anxiety in patients. Education, counseling and support should be offered to help patients cope with unexpected encounters that trigger uncertainty of recurrence as these triggers are often found in daily occurrences.

Germino et al., (2007) found that ethnic differences exist in the relationship of uncertainty to a number of quality of life and coping variables. In a study of female breast cancer survivors (Gil et al., 2006), the investigators found that the women were not only benefiting from being able to identify and use information about their illness, but they were also able to integrate this information without direct guidance.

Communication. In a study by Clayton, Mishel and Belyea (2006) the concept of uncertainty and how communication with health care providers may help women reduce uncertainty and improve both emotional and cognitive well-being was investigated. A positive association was found between health care provider communication and thoughts of recurrence. More than half of the

sample indicated that they were unable to achieve their desired decision-making role with health care providers. An interesting finding that health care providers might be offering information that contributes to thoughts of recurrence is a possibility raised by the study.

Anxiety in Cancer

According to Stark et al. (2002) anxiety is a response to a threat and given that cancer is a threat, many patients with cancer experience anxiety. Stark et al. (2002) studied anxiety in 178 patients with lymphoma, renal cell carcinoma, melanoma and plasma cell dyscrasia. They found that 48% of these patients had levels of anxiety high enough to qualify for anxiety disorder. This study also found that the most accurate screening questionnaires for anxiety include the State-Trait Anxiety Inventory and the Hospital Anxiety and Depression Scale. Symptoms of anxiety are common among cancer patients and therefore, it is appropriate to screen for anxiety and understand the impact of anxiety in cancer patients' quality of life.

Tavoli et al. (2007) found that psychological distress is higher in patients who are aware of their cancer diagnosis when compared to those patients who are not aware of their diagnosis. Tavioli et al. conducted a cross-sectional study to examine anxiety in 142 patients with gastrointestinal cancer patients and investigated whether the knowledge of cancer diagnosis affects patients' psychosocial status. Of these cancer patients, 52% were not aware of their diagnosis and 48% were aware of having cancer. The mean anxiety score was

7.6 (SD= \pm 4.5) and 47.2 % of the patients had high anxiety score. A significant difference was noted between those who knew their diagnosis (anxiety means score of 9.1) versus those who did not know (anxiety means score of 6.3); $P < 0.001$. After performing regression analysis it was found that anxiety showed strong relationships with knowledge of cancer diagnosis.

It is important to be aware of the role that intrusive cognition plays in anxiety and adaptation of the experience of living with a cancer diagnosis. In a study conducted by Whitaker et al. (2007) patients with cancer classified as anxious reported intrusive or disturbing imagery significantly more times than non-anxious patients ($P < 0.01$). Anxious patients also reported more intrusive thoughts ($P < 0.01$) and more intrusive memories ($P < 0.05$). No correlation was found between intrusive cognition and disease stage ($P = 0.98$). The study also found that intrusive imagery in these cancer patients is a factor in psychological morbidity.

Patient symptom reporting is important and significant in guiding treatment and diagnosis of cancer. A study published by Leventhal, Schmitz, Rabin, and Ward (2001) found that anxiety is positively related with vague symptom reporting and not related to concrete symptom reporting in patients undergoing chemotherapy treatment. The study findings suggest that trait anxiety was positively related with over reporting of symptoms and supports that although trait-anxious individuals pay closer attention to symptoms as they occur, the symptom reporting is often vague rather than concrete (Leventhal et al., 2001).

Studies have found that psychological interventions at time of diagnosis may promote adjustment in newly diagnosed cancer patients. Pitceathly et al. (2008) studied 313 patients newly diagnosed with cancer. These patients were free of anxiety or depressive disorders at the time of diagnosis. The patients were separated in high risk of developing anxiety and low risk. Patients were then randomized to receive immediate psychological interventions, delayed psychological intervention or no psychological intervention. The study reports that twelve months after intervention, patients at high risk who received intervention were less likely to develop an anxiety disorder. In the low risk group no differences were noted.

Gattellari, Butow, and Tattersall (2001) studied 233 patients with cancer who were visiting their oncologist for first time. They found that anxiety levels significantly decreases pre consultation and post consultation when patients preferred and perceived roles matched. Nevertheless, they found that most cancer patients fail to achieve their desired level of involvement in their care. Their result also supported that less involvement than patient preferred, appears to be more detrimental to anxiety levels than more involvement than preferred.

Summary of Literature Reviewed

In regard to uncertainty, the review of literature suggests that the concept of uncertainty is a dynamic one that is mostly determined by the present situation and its factors (Mishel, 1981). In regard to anxiety, the literature proposes that patients diagnosed with cancer and aware of their disease have higher levels of

anxiety (Tavoli et al., 2008). The relationship between uncertainty and anxiety was not directly addressed in the literature reviewed.

Literature reviewed related to anxiety and psychological distress in cancer patients is higher in cancer patients aware of their diagnosis (Tavoli et al., 2008). The study encourages early implementation of methods to reduce anxiety after giving a cancer diagnosis and constant assessment of anxiety is crucial in the care of cancer patients. Whitaker et al., (2007) concluded that intrusive cognitions were associated with person's own experience of having cancer and that intrusive cognition was most strongly associated with anxiety. The study makes providers aware of the role that intrusive cognition plays in anxiety and adaptation of the experience of living with a cancer diagnosis.

In uncertainty, the literature findings focused on assessment and management of uncertainty in cancer patients. Decker and colleagues (2007) clearly suggest that uncertainty is related to quality of life and psychological health outcomes. Furthermore, their study found that uncertainty is present in all stages of illness and can be reduced using effective communication and taking into consideration ethnic and cultural differences. Decker and colleagues demonstrated that the degree of uncertainty changes during each stage of the cancer experience and that it continues throughout survivorship. Interestingly, Clayton et al., (2006) found that there is a possibility that healthcare providers contribute to thoughts of recurrence, increasing patients' feelings of uncertainty.

To identify a relationship between uncertainty and anxiety would be valuable to nursing and to cancer patients. If a positive relationship is found between the two, it would be possible to do further research in the simultaneous assessment and management of both co-morbidities and the impact that one has on the other. The literature reviewed emphasized the importance of uncertainty and anxiety in health outcomes and quality of life, justifying further research in this area.

Implications for Nursing

The field of oncology has much to gain from further studies in uncertainty and anxiety in patients diagnosed with cancer. Ways to manage uncertainty have been thoroughly studied in many areas and stages of cancer. The studies reviewed consistently demonstrate that healthcare providers can contribute to decreasing uncertainty in our patients. For example, the data analyzed by Gil et al. (2006) demonstrated that a group of female breast cancer survivors were able to integrate the changes and skills gained during guided uncertainty intervention even without the direct guidance. If a positive relationship between uncertainty and anxiety is defined, further research can be done in the management of anxiety in oncology. In nursing, understanding the concept of uncertainty and anxiety and its possible relationship is important because proper management of these can allow patients to participate in their decision making process throughout their illness as well as it can eliminate a huge barrier to patients' participation in their care.

Gaps in the Literature

There is a noticeable gap in the literature regarding assessment and management of anxiety specifically in patients with cancer. Much is said about anxiety in general, but little is related specifically to the oncology population and healthcare providers. The current literature does have plenty of information about uncertainty in illness, and specifically in cancer. The literature has studies about uncertainty in the different stages of a cancer experience; at diagnosis, during treatment and in survivorship. Studies on managing uncertainty are lacking.

Finding a relationship between uncertainty and anxiety may be able to fill some gaps, specifically regarding anxiety and cancer. The relationship may also encourage further research in the simultaneous assessment and management of both, uncertainty and anxiety.

Chapter Three Methods

A descriptive cross-sectional design was used to identify the relationship between uncertainty and anxiety in patients with cancer. A literature review on uncertainty and anxiety in patients with cancer sustains the belief that a positive relationship between uncertainty and anxiety might exist. The study design, tools used, procedure and statistical analysis are discussed in this chapter.

Setting and Sample

The sample for this study was gathered from patients in the Clinical Research Unit (CRU) outpatient setting of a National Cancer Institute designated center in southwest Florida. Thirty patients were accrued to the study.

Patients enrolled in the study met the following inclusion criteria: over eighteen years old, able to read, write and understand English, pathologically diagnosed with cancer for at least 4 weeks prior to study enrollment as located on pathology report in patients' medical record, aware of cancer diagnosis for at least 4 weeks prior to study enrollment as documented by physician in patients' medical record.

The following criteria excluded patients: being an inpatient at the time of encounter, being unaware of their cancer diagnosis, having untreated and/or

symptomatic brain metastasis or psychiatric diagnosis. Information about psychiatric diagnosis was abstracted from the medical record.

Instruments

Mishel's Uncertainty in Illness Scale (MUIS). The Uncertainty in Illness Scale (Mishel, 1983) was used to measure uncertainty (Appendix A). The MUIS is a 33-item self-administered tool designed to measure acuity of uncertainty in illness. This instrument has four subscales: ambiguity or cues about the state of illness being vague and indistinct, tending to overlap (13 items, coefficient of .91), complexity or cues about treatment and system of care are multiple, intricate and varied (7 items, coefficient alpha of .75), inconsistency or information that changes frequently or is not in accord with information previously received (5 items, coefficient alpha of .71), and unpredictability (6 items, coefficient alpha of .70). Scores for ambiguity can range from 13 to 65. Scores for inconsistency can range from 7 to 35. Scores for complexity can range from 7 to 25. Scores for unpredictability can range from 5 to 25.

To complete the questionnaire, subjects selected the degree to which they agreed or disagreed with thirty-three statements related to uncertainty. Items are scored on a five point Likert-type scale that ranges from 'strongly agree' to 'strongly disagree'. The highest possible total score is one hundred and sixty with higher scores indicating greater levels of uncertainty.

State Trait Anxiety Inventory (STAI). The State Trait Anxiety Inventory (STAI) was used to measure anxiety (Appendix A & B). It is a self administered

tool that differentiates between temporary condition of anxiety (state) and a long standing anxious quality (trait). The STAI has a total of 40 questions; 20 testing state and 20 testing trait. Each question has four possible answers. Items are scored on a 4-point Likert-type scale, with response going from 1 (not at all) to 4 (very much so). The highest score is 160; the lowest is 40. High scores indicate higher levels of anxiety. The alpha coefficients for the state anxiety scale ranges from 0.83 to 0.94. The trait anxiety scale has a median alpha coefficient of 0.90 (Spielberger, 1983).

Procedures

The study was approved by the Scientific Review Committee of the cancer center and the University of South Florida Institutional Review Board. The investigator identified the patients via the medical record for inclusion criteria. Once identified, patients were invited to participate and the study was explained. Patients who agreed to participate signed an informed consent form (Appendix F). The demographic data was retrieved via the medical record and recorded on a hard copy data form. The participants complete two study questionnaires during the research encounter with the primary investigator. The research encounter required approximately 30 minutes after consent process. Patients were instructed that the interviews could be stopped at any time. The interviews were held in a private area in the clinical research unit. Personal identifiers were removed from all study related paperwork except for the informed consent form.

Original copies of the signed ICF and all study related paperwork are kept in the study binder and securely locked.

Data Analysis

The research questions that guided this study were: Is there a significant positive relationship between uncertainty and trait anxiety in outpatients in a cancer center who have been diagnosed with cancer?, Is there a significant positive relationship between uncertainty and state anxiety in outpatients in a cancer center who have been diagnosed with cancer?, Are there significant positive relationships between uncertainty in illness subscales and either state or trait anxiety.

Descriptive statistics, including means, standard deviations, frequencies and percentages, were used to describe the patient sample. To address the questions, Pearson correlation were used to determine the relationship of uncertainty and state and trait anxiety, as well as the relationship between uncertainty subscales and state and trait anxiety.

Chapter Four Results, Discussion and Conclusions

This chapter presents the findings of the study to include: results, discussion of the results, implications for nursing, conclusion and suggestions for future research.

Results

Demographic data. The sample consisted of 30 patients with ages ranging from 21 to 86 years, with a mean age of 64. Twenty three males participated in the study while only 7 females agreed to participate (Table 1).

Table 1

Frequency and Percent of Participants by Gender

Gender	Frequency	Percentage
Female	7	23.3
Male	23	76.7

Educational background of the sample was varied. Three percent of the sample did not complete high school, 40% had a high school diploma, 30% completed some college, almost 17% had a bachelor's degree, 2 patients had a doctoral degree and 1 had a master's degree (Table 2).

Table 2

Frequency and Percent of Participants by Level of Education

Level of Education	Frequency	Percentage
Some High School	1	3.3
High School Diploma	12	40.0
Some College	9	30.0
Bachelor's	5	16.37
Master's	1	3.3
Doctorate	2	6.7

Almost 47% of the sample had melanoma, other patients had renal (n=3), pancreatic (n=2), acute myelogenous leukemia (n=2), sarcoma (n=2), lung cancer (n=2), myeloma (n=2), chronic myelogenous leukemia (n=1), glioblastoma (n=1), and rectal cancer (n=1). Seventy percent of the patients had stage IV disease. (Table 3).

Table 3

Frequency and Percent of Participant's Diagnosis and Stage

Diagnosis	Frequency	Percent
Melanoma	14	46.7
Renal	3	10.0
Pancreatic	2	6.7
Acute myelogenous leukemia	2	6.7
Sarcoma	2	6.7
Lung	2	6.7
Myeloma	2	6.7
Chronic myelogenous leukemia	1	3.3
Glioblastoma	1	3.3
Rectal	1	3.3
Stage		
I	2	0.1
III	4	0.1
IV	21	0.7
UNKNOWN	3	0.1

Time since diagnosis ranged from less than 6 months to over 5 years (Table 4). Twenty percent of the patient had been diagnosed between 1-2 years from time of enrollment. Thirteen percent had been diagnosed within 6 months, and almost 17 % of the sample was diagnosed within 3 to 4 years. Seventeen percent of the sample was diagnosed within the last 6 months to a year. Seventeen percent of the sample was diagnosed more than five years from the time of enrollment, and only 10% of the patients were diagnosed for 2 to 3 years.

Table 4

Frequency and Percent of Participants' Time Since Diagnosis and State Anxiety, Trait Anxiety and MUIS Mean Scores and Standard Deviations by Time of Diagnosis.

Time since diagnosis	Frequency (%)	State Anxiety Mean (Standard Deviation)	Trait Anxiety Mean (Standard Deviation)	MUIS Mean (Standard Deviation)
< 6 months	4 (13.3)	33.8 (12.1)	29.8 (7.4)	90.5 (13.2)
6 months to 1year	5 (16.7)	33.0 (9.9)	30.6 (8.3)	84.0 (8.9)
1 to 2 years	6 (2.0)	29.8 (10.0)	28.3 (10.6)	83.8 (11.4)
2 to 3 years	3 (10.0)	35.0 (7.0)	33.3 (2.5)	80.3 (6.1)
3 to 4 years	5 (16.7)	36.8 (11.3)	35.8 (9.7)	94.4 (7.6)
4 to 5 years	2 (6.7)	21.0 (1.4)	24.0 (.0)	81.5 (9.2)
5 years or more	5 (16.7)	28.6 (8.6)	33.6 (10.5)	86.0 (9.5)
Total	30 (100.0)	31.8 (9.7)	31.2 (8.6)	86.4 (11.4)

State-Trait Anxiety. The State-Trait Anxiety Inventory was used to measure state and trait anxiety. The mean score of the state anxiety inventory was 31.8 with a standard deviation of 9.7. The mean score of the trait anxiety inventory was 31.2 with a standard deviation of 8.6 (Table 4). No relationship was found between anxiety and age, gender, diagnosis, stage, educational level and time since diagnosis. Nevertheless, there was a trend towards higher mean scores in state anxiety, and trait anxiety in patients diagnosed within three to four years (Table 4).

Table 5

Correlations of Uncertainty with State and Trait Anxiety

	R	P
State Anxiety	0.52	0.003
Trait Anxiety	0.61	0.000

Uncertainty in illness. Mishel's Uncertainty in Illness Scale was used to measure uncertainty. No significant correlation was found between uncertainty and age, gender, diagnosis, stage, educational level and time of diagnosis. Interestingly, patients diagnosed within three to four years had slightly higher mean scores on the MUIS (Table 4).

The subscales ambiguity, complexity, inconsistency and unpredictability were also measured. The mean score for ambiguity was 31.1 with a standard deviation of 11.4. The mean score for complexity was 27.2, with a standard deviation of 4.2. The mean score for inconsistency was 13.8, with a standard

deviation of 4.8. Finally, the mean score for predictability was 12.3 with a standard deviation of 2.6.

Relationship between uncertainty and anxiety. A significant positive relationship was found between ambiguity and state ($r=0.53$, $p=0.002$) and trait anxiety ($r=0.56$, $p=0.001$) (Table 6, 7). A significant positive relationship was also found between inconsistency and state ($r=0.389$, $p=0.034$) and trait anxiety ($r=0.64$, $p=0.000$) (Table 6, 7). No relationship was found between state- trait anxiety and complexity and unpredictability (Table 6, 7). Trait anxiety was significantly higher in people with higher levels of uncertainty ($r=0.61$, $p=0.000$) (Table 5). State anxiety was also positively related with higher levels of anxiety ($r=0.52$, $p=0.003$) (Table 5).

Table 6

Correlation of Four Factors of Uncertainty and State Anxiety

	R	P
Ambiguity	0.54	0.002
Complexity	-0.26	0.162
Inconsistency	0.39	0.034
Unpredictability	0.07	0.716

Table 7

Correlation of Four Factors of Uncertainty and Trait Anxiety

	R	P
Ambiguity	0.562	0.001
Complexity	-0.298	0.109
Inconsistency	0.642	0.000
Unpredictability	-0.064	0.735

Discussion

Sample. Participants were recruited from the Clinical Research Unit at an NCI designated cancer center. Data was collected during the month of April 2009. The lack of heterogeneity was a limitation of the sample. The majority of the sample accrued to the study had stage IV cancer and was receiving experimental therapy in the clinical research unit, in an outpatient basis. The median age was 66, and the majority of the patients completed high school. The sample was predominantly male, and almost half of the sample was diagnosed with melanoma. Over 13% of the sample had been diagnosed within 5 months of enrollment and more than 16% were aware of their diagnosis for 5 years or longer.

The results of this study cannot be generalized to other cancer patients receiving standard therapy for an early stage disease. The anxiety and uncertainty levels of the sample being studied could largely differ from the levels

of a cancer population with a better prognosis and receiving standard therapy with curative intent. Also, the sample was significantly dominated by males, so the representation of females was low.

State-Trait Anxiety. In a study conducted on healthy and normal working adults (Spielberger, et al., 1983), the mean score for state anxiety was 35.7 and standard deviation of 10.4. Based on Spielberger's results, the anxiety levels found in the present study sample were slightly lower than in healthy adults.

Spielberger's STAI is a very well tested instruments ad has been used previously in patients with cancer. It is difficult to speculate reasons why anxiety levels in this study sample were lower than the one found by Spielberger in healthy adults. It is possible that this study sample, being predominantly stage VI cancer patients, had resigned themselves to their illness and accepted it as life-limiting, therefore decreasing their anxiety levels. Conversely, being in the Clinical Research Unit might have made them feel hopeful, and therefore, less anxious. Further study is needed to evaluate unmeasured variable to include unequal gender representation, spirituality and hope.

Uncertainty in illness. Uncertainty scores were calculated using the four factors to include ambiguity, complexity, inconsistency and unpredictability. The total mean score for uncertainty was obtained by adding the scores of all four factors. The mean total score found in the study sample was 86.4 with a standard deviation of 11.4. The total scale mean score in Mishel's composite cancer population had a total mean score of 69.46 with a standard deviation of 15.9

(Mishel, 1987). This higher uncertainty mean score in the present sample may be due to the receiving of experimental treatment with little information regarding the treatment outcomes. It is possible that patients who choose experimental treatment are different from other patients in some unknown way. Perhaps, these patients feel more hopeful that experimental therapy will help, but at the same time more uncertain about it.

It is also important to remark that due to the amount of intricate and varied information provided during experimental therapy, one would expect that the complexity mean score of the study sample would be higher than the mean score of a generalized cancer population undergoing standard of care treatment. Nevertheless, Mishel's composite cancer population had complexity mean score (25.33 with standard deviation of 5.3) comparable to the mean score found on this study (27.17 with a standard deviation of 4.202).

The Relationship between Uncertainty in Illness and Anxiety

The findings of this study suggest that the levels of state and trait anxiety are higher among cancer patients with higher levels of uncertainty. This means that there is a positive relationship between uncertainty and state and trait anxiety. It is important to note that, unexpectedly, trait anxiety shows a stronger relationship to uncertainty than state anxiety. However, the study sample was small and further research is needed.

The results of this study also found that two out of four subcategories (factors) of uncertainty, ambiguity and inconsistency, were positively related to

both, state and trait anxiety. Both subcategories, ambiguity and inconsistency, demonstrated a stronger relationship with trait anxiety. Given that trait anxiety was found to have a stronger relationship with general uncertainty, as well as with specific factors of uncertainty (ambiguity and inconsistency), the results could suggest that patients who tend to have higher anxiety at all times (trait) may be less able to tolerate uncertainty. Nevertheless, it is state anxiety that will most likely be amenable to interventions by nurse practitioners.

Among the cancer population multiple studies have looked at the concepts of uncertainty and anxiety. Nevertheless, the relationship between the two concepts has not been widely studied. The only relevant study in the literature (Kaminsky, 1991) showed similar results.

Implications for nursing

The findings of this study have implications for nursing. Assessment of both uncertainty and anxiety at baseline as well as during patients' cancer should be incorporated in the clinical practice. Given that a positive relationship was found between uncertainty and anxiety, assessing uncertainty can predict the presence of higher or lower level of anxiety, and vice versa. The study supports that uncertainty and anxiety are present in the oncology population, and may cause additional emotional distress.

A significant part of the nurses' role is to be patient advocates and have a holistic approach in caring for patients. Research should be conducted further in the areas of uncertainty and anxiety in order to develop guidelines for effective

management of uncertainty. Furthermore, studies can research the effect of proper uncertainty management in anxiety and the incorporation of such managements in nursing education.

Conclusion

Anxiety levels were found to be higher in patients with higher levels of uncertainty. The data suggests that this relationship is stronger between uncertainty and trait anxiety. Two of the four uncertainty factors, ambiguity and inconsistency, were found to be positively related to anxiety. Significant relationships between anxiety or uncertainty and age, gender, diagnosis, stage or educational level were not found.

Recommendation for future research

The findings of this study suggest the need for development of studies to develop evidence-based clinical guidelines to better manage uncertainty and anxiety. It would also be useful to study the effects that decreasing ambiguity and inconsistency would have on anxiety levels.

The study could potentially be replicated with a larger sample, to include inpatients and an equal sample of males and females. It would also be useful to compare two groups, one undergoing standard of care therapy versus a group on experimental therapy. Experimental interventions to decrease ambiguity and inconsistencies could be designed and implemented to see their impact in the levels of anxiety. A study could also be conducted to include the practitioner's

perception of the patients' level of uncertainty and anxiety versus the patients' actual levels.

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Appendices

Appendix A: Mishel Uncertainty in Illness Scale (MUIS)

MISHEL UNCERTAINTY IN ILLNESS SCALE – ADULT FORM

INSTRUCTIONS:

Please read each statement. Take your time and think about what each statement says. Then place a “X” under the column that most closely measures how you are feeling TODAY. If you agree with a statement, then you would mark under either “Strongly Agree” or “Agree”. If you disagree with a statement, then mark under either “Strongly Disagree” or “Disagree”. If you are undecided about how you feel, then mark under “Undecided” for that statement. Please respond to every statement.

1. I don't know what is wrong with me.

Strongly Agree (5)	Agree (4)	Undecided (3)	Disagree (2)	Strongly Disagree (1)
_____	_____	_____	_____	_____

2. I have a lot of questions without answers.

Strongly Agree (5)	Agree (4)	Undecided (3)	Disagree (2)	Strongly Disagree (1)
_____	_____	_____	_____	_____

3. I am unsure if my illness is getting better or worse.

Strongly Agree (5)	Agree (4)	Undecided (3)	Disagree (2)	Strongly Disagree (1)
_____	_____	_____	_____	_____

4. It is unclear how bad my pain will be.

Strongly Agree (5)	Agree (4)	Undecided (3)	Disagree (2)	Strongly Disagree (1)
_____	_____	_____	_____	_____

5. The explanations they give about my condition seem hazy to me.

Strongly Agree (5)	Agree (4)	Undecided (3)	Disagree (2)	Strongly Disagree (1)
_____	_____	_____	_____	_____

Appendix A: Mishel Uncertainty in Illness Scale (MUIS) (Continued)

6. The purpose of each treatment is clear to me.

Strongly Agree (5)	Agree (4)	Undecided (3)	Disagree (2)	Strongly Disagree (1)
-----------------------	--------------	------------------	-----------------	--------------------------

7. When I have pain, I know what this means about my condition.

Strongly Agree (5)	Agree (4)	Undecided (3)	Disagree (2)	Strongly Disagree (1)
-----------------------	--------------	------------------	-----------------	--------------------------

8. I do not know when to expect things will be done to me.

Strongly Agree (5)	Agree (4)	Undecided (3)	Disagree (2)	Strongly Disagree (1)
-----------------------	--------------	------------------	-----------------	--------------------------

9. My symptoms continue to change unpredictably.

Strongly Agree (5)	Agree (4)	Undecided (3)	Disagree (2)	Strongly Disagree (1)
-----------------------	--------------	------------------	-----------------	--------------------------

10. I understand everything explained to me.

Strongly Agree (5)	Agree (4)	Undecided (3)	Disagree (2)	Strongly Disagree (1)
-----------------------	--------------	------------------	-----------------	--------------------------

11. The doctors say things to me that could have many meanings.

Strongly Agree (5)	Agree (4)	Undecided (3)	Disagree (2)	Strongly Disagree (1)
-----------------------	--------------	------------------	-----------------	--------------------------

12. I can predict how long my illness will last.

Strongly Agree (5)	Agree (4)	Undecided (3)	Disagree (2)	Strongly Disagree (1)
-----------------------	--------------	------------------	-----------------	--------------------------

Appendix A: Mishel Uncertainty in Illness Scale (MUIS) (Continued)

13. My treatment is too complex to figure out.

Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
(5)	(4)	(3)	(2)	(1)

14. It is difficult to know if the treatments or medications I am getting are helping.

Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
(5)	(4)	(3)	(2)	(1)

15. There are so many different types of staff; it's unclear who is responsible for what.

Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
(5)	(4)	(3)	(2)	(1)

16. Because of the unpredictability of my illness, I cannot plan for the future.

Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
(5)	(4)	(3)	(2)	(1)

17. The course of my illness keeps changing. I have good and bad days.

Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
(5)	(4)	(3)	(2)	(1)

18. It's vague to me how I will manage my care after I leave the hospital.

Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
(5)	(4)	(3)	(2)	(1)

19. I have been given many differing opinions about what is wrong with me.

Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
(5)	(4)	(3)	(2)	(1)

Appendix A: Mishel Uncertainty in Illness Scale (MUIS) (Continued)

20. It is not clear what is going to happen to me.

Strongly Agree (5)	Agree (4)	Undecided (3)	Disagree (2)	Strongly Disagree (1)
-----------------------	--------------	------------------	-----------------	--------------------------

21. I usually know if I am going to have a good or bad day.

Strongly Agree (5)	Agree (4)	Undecided (3)	Disagree (2)	Strongly Disagree (1)
-----------------------	--------------	------------------	-----------------	--------------------------

22. The results of my tests are inconsistent.

Strongly Agree (5)	Agree (4)	Undecided (3)	Disagree (2)	Strongly Disagree (1)
-----------------------	--------------	------------------	-----------------	--------------------------

23. The effectiveness of the treatment is undetermined.

Strongly Agree (5)	Agree (4)	Undecided (3)	Disagree (2)	Strongly Disagree (1)
-----------------------	--------------	------------------	-----------------	--------------------------

24. It is difficult to determine how long it will be before I can care for myself.

Strongly Agree (5)	Agree (4)	Undecided (3)	Disagree (2)	Strongly Disagree (1)
-----------------------	--------------	------------------	-----------------	--------------------------

25. I can generally predict the course of my illness.

Strongly Agree (5)	Agree (4)	Undecided (3)	Disagree (2)	Strongly Disagree (1)
-----------------------	--------------	------------------	-----------------	--------------------------

26. Because of the treatment, what I can do and cannot do keeps changing.

Strongly Agree (5)	Agree (4)	Undecided (3)	Disagree (2)	Strongly Disagree (1)
-----------------------	--------------	------------------	-----------------	--------------------------

Appendix A: Mishel Uncertainty in Illness Scale (MUIS) (Continued)

27. I'm certain they will not find anything else wrong with me.

Strongly Agree (5)	Agree (4)	Undecided (3)	Disagree (2)	Strongly Disagree (1)
-----------------------	--------------	------------------	-----------------	--------------------------

28. The treatment I am receiving has a known probability of success.

Strongly Agree (5)	Agree (4)	Undecided (3)	Disagree (2)	Strongly Disagree (1)
-----------------------	--------------	------------------	-----------------	--------------------------

29. They have not given me a specific diagnosis.

Strongly Agree (5)	Agree (4)	Undecided (3)	Disagree (2)	Strongly Disagree (1)
-----------------------	--------------	------------------	-----------------	--------------------------

30. My physical distress is predictable; I know when it is going to get better or worse.

Strongly Agree (5)	Agree (4)	Undecided (3)	Disagree (2)	Strongly Disagree (1)
-----------------------	--------------	------------------	-----------------	--------------------------

31. I can depend on the nurses to be there when I need them.

Strongly Agree (5)	Agree (4)	Undecided (3)	Disagree (2)	Strongly Disagree (1)
-----------------------	--------------	------------------	-----------------	--------------------------

32. The seriousness of my illness has been determined.

Strongly Agree (5)	Agree (4)	Undecided (3)	Disagree (2)	Strongly Disagree (1)
-----------------------	--------------	------------------	-----------------	--------------------------

33. The doctors and nurses use everyday language so I can understand what they are saying.

Strongly Agree (5)	Agree (4)	Undecided (3)	Disagree (2)	Strongly Disagree (1)
-----------------------	--------------	------------------	-----------------	--------------------------

Appendix B: State Anxiety Inventory

For use by Naima Vera only. Received from Mind Garden, Inc. on January 12, 2009

SELF-EVALUATION QUESTIONNAIRE STAI Form Y-1

Please provide the following information:

Name _____ Date _____ S _____
 Age _____ Gender (Circle) M F T _____

DIRECTIONS:

A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate how you feel *right now*, that is, *at this moment*. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

VERY MUCH SO
 MODERATELY SO
 SOMEWHAT
 NOT AT ALL

- | | | | | |
|--|---|---|---|---|
| 1. I feel calm | 1 | 2 | 3 | 4 |
| 2. I feel secure | 1 | 2 | 3 | 4 |
| 3. I am tense | 1 | 2 | 3 | 4 |
| 4. I feel strained | 1 | 2 | 3 | 4 |
| 5. I feel at ease | 1 | 2 | 3 | 4 |
| 6. I feel upset | 1 | 2 | 3 | 4 |
| 7. I am presently worrying over possible misfortunes | 1 | 2 | 3 | 4 |
| 8. I feel satisfied | 1 | 2 | 3 | 4 |
| 9. I feel frightened | 1 | 2 | 3 | 4 |
| 10. I feel comfortable | 1 | 2 | 3 | 4 |
| 11. I feel self-confident | 1 | 2 | 3 | 4 |
| 12. I feel nervous | 1 | 2 | 3 | 4 |
| 13. I am jittery | 1 | 2 | 3 | 4 |
| 14. I feel indecisive | 1 | 2 | 3 | 4 |
| 15. I am relaxed | 1 | 2 | 3 | 4 |
| 16. I feel content | 1 | 2 | 3 | 4 |
| 17. I am worried | 1 | 2 | 3 | 4 |
| 18. I feel confused | 1 | 2 | 3 | 4 |
| 19. I feel steady | 1 | 2 | 3 | 4 |
| 20. I feel pleasant | 1 | 2 | 3 | 4 |

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Appendix C: Trait Anxiety Inventory

For use by Naima Vera only. Received from Mind Garden, Inc. on January 12, 2009

SELF-EVALUATION QUESTIONNAIRE

STAI Form Y-2

Name _____ Date _____

DIRECTIONS

A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate how you *generally* feel.

ALMOST NEVER
SOMETIMES
OFTEN
ALMOST ALWAYS

- | | | | | |
|---|---|---|---|---|
| 21. I feel pleasant | 1 | 2 | 3 | 4 |
| 22. I feel nervous and restless | 1 | 2 | 3 | 4 |
| 23. I feel satisfied with myself | 1 | 2 | 3 | 4 |
| 24. I wish I could be as happy as others seem to be | 1 | 2 | 3 | 4 |
| 25. I feel like a failure | 1 | 2 | 3 | 4 |
| 26. I feel rested | 1 | 2 | 3 | 4 |
| 27. I am "calm, cool, and collected" | 1 | 2 | 3 | 4 |
| 28. I feel that difficulties are piling up so that I cannot overcome them | 1 | 2 | 3 | 4 |
| 29. I worry too much over something that really doesn't matter | 1 | 2 | 3 | 4 |
| 30. I am happy | 1 | 2 | 3 | 4 |
| 31. I have disturbing thoughts | 1 | 2 | 3 | 4 |
| 32. I lack self-confidence | 1 | 2 | 3 | 4 |
| 33. I feel secure | 1 | 2 | 3 | 4 |
| 34. I make decisions easily | 1 | 2 | 3 | 4 |
| 35. I feel inadequate | 1 | 2 | 3 | 4 |
| 36. I am content | 1 | 2 | 3 | 4 |
| 37. Some unimportant thought runs through my mind and bothers me | 1 | 2 | 3 | 4 |
| 38. I take disappointments so keenly that I can't put them out of my mind | 1 | 2 | 3 | 4 |
| 39. I am a steady person | 1 | 2 | 3 | 4 |
| 40. I get in a state of tension or turmoil as I think over my recent concerns and interests | 1 | 2 | 3 | 4 |

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Appendix D: Letter of Approval from Moffitt Scientific Review Committee



February 2, 2009

Naima Vera-Sommers
H. Lee Moffitt Cancer Center & Research Institute
University of South Florida
12902 Magnolia Drive
Tampa, FL 33612

Dear Dr. Vera-Sommers:

The Behavioral Subcommittee of the Scientific Review Committee (SRC) has reviewed your response for your research protocol entitled, "**The Relationship Between Uncertainty and Anxiety in Patients with Cancer**" (MCC 15764). The protocol version 1 dated 1/28/2009 is approved as written for use at the Moffitt Cancer Center pending approval of the Institutional Review Board (IRB) and satisfaction of institutional operational and financial review requirements. Please be aware that after you receive IRB approval, you must submit a copy of the IRB approval letter to the Protocol Review and Monitoring System and request study activation before you commence any study activities. The Protocol Review and Monitoring System will ensure that all applicable institutional reviews have been completed. You will then be issued an activation letter. Upon receipt of the activation letter, you will be able to conduct your study.

It is your responsibility to ensure that all Moffitt staff (nursing, pharmacy, data management, etc.) is informed and aware of the details of the project. The committee encourages the use of in-services for those projects that are complex or require special attention.

All changes made to protocols approved by the SRC must be submitted to the Protocol Review and Monitoring System. Changes made to the protocol document require SRC review and approval. Minor changes (i.e. changes to personnel, non-scientific changes, changes that do not affect patient participation) will be expedited through the SRC review process.

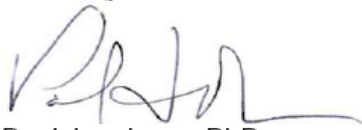
If this project is not being managed by the Clinical Trials Office or Clinical Research Unit, then it is your responsibility to follow through with all requirements

Appendix D: Letter of Approval from Moffitt Scientific Review Committee
(Continued)

for submission to the IRB. All IRB approvals are required to be documented in Oncore, and all associated regulatory documentation (signed applications, IRB approval letters and IRB approved consent forms, etc.) are to be saved in the appropriate study folder in the e-binders directory at J:\ebinders.

Oncore is the Cancer Center's mechanism for required submission and review of materials requiring IRB review as well as items requiring review by the Scientific Review and Protocol Monitoring Committees. If you are not currently reporting the necessary research activities, such as patient accrual, changes in procedure, adverse events and continuing reviews in Oncore, please contact Jeryl Madden, Oncore Coordinator, at 745-6964 for direction.

Sincerely,



Paul Jacobsen, PhD
Chair, Behavioral Subcommittee
Scientific Review Committee

Appendix E: Letter of Approval from USF Institutional Review Board



DIVISION OF RESEARCH INTEGRITY AND COMPLIANCE
Institutional Review Boards, FWA No. 000016
12901 Bruce B. Downs Blvd., MDC035 • Tampa, FL 33612-4
(813) 974-5638 • FAX (813) 974-5638

March 12, 2009

Naima Vera
College of Nursing
16114 Ancroft Court
Tampa, FL 33647

RE: **Expedited Approval** for Initial Review
IRB#: 107739 G
Title: *The Relationship between Uncertainty and Anxiety*
Study Approval Period: 03/11/2009 to 03/10/2010

Dear Ms. Vera:

On March 11, 2009, Institutional Review Board (IRB) reviewed and **APPROVED** the above protocol **for the period indicated above**. It was the determination of the IRB that your study qualified for expedited review based on the federal expedited category number five (5) and seven (7).

Approval included with the adult informed consent form.

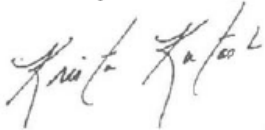
Please note, if applicable, the **enclosed informed consent/assent documents are valid during the period indicated by the official, IRB-Approval stamp located on page one of the form**. Valid consent must be documented on a copy of the most recently IRB-approved consent form. Make copies from the enclosed original.

Please reference the above IRB protocol number in all correspondence regarding this protocol with the IRB or the Division of Research Integrity and Compliance. In addition, we have enclosed an Institutional Review Board (IRB) Quick Reference Guide providing guidelines and resources to assist you in meeting your responsibilities in the conduction of human participant research. Please read this guide carefully. It is your responsibility to conduct this study in accordance with IRB policies and procedures and as approved by the IRB.

Appendix E: Letter of Approval from USF Institutional Review Board (Continued)

We appreciate your dedication to the ethical conduct of human subject research at the University of South Florida and your continued commitment to human research protections. If you have any questions regarding this matter, please call 813-974-9343.

Sincerely,

A handwritten signature in black ink, appearing to read "Krista Kutash". The signature is written in a cursive style with some loops and flourishes.

Krista Kutash, Ph.D., Chairperson
USF Institutional Review Board

Enclosures: (If applicable) IRB-Approved, Stamped Informed Consent/Assent Documents(s)

Cc: Anna Davis/cd, USF IRB Professional Staff
Susan McMillan, PhD

SB-IRB-Approved-EXPEDITED-0801

Appendix F: Informed Consent Form



Informed Consent to Participate in Research and Authorization to Collect, Use and Share Your Health Information

Information to Consider Before Taking Part in this Research Study

IRB Study # _____

Researchers at the University of South Florida (USF) and Moffitt Cancer Center study many topics. To do this, we need the help of people who agree to take part in a research study. This form tells you about this research study.

We are asking you to take part in a research study that is called:
The Relationship between Uncertainty and Anxiety in Patients with Cancer.

The person who is in charge of this research study is Naima Vera. This person is called the Principal Investigator. However, other research staff may be involved and can act on behalf of the person in charge.

The research will be done at Moffitt Cancer Center.

Purpose of the study

The purpose of this study is to:

- Study the relationship of uncertainty and anxiety in patients with cancer.

This study is being conducted as partial fulfillment of the requirements for the Principal Investigator's degree of Masters in Science of Nursing.

Study Procedures

If you take part in this study, you will be asked to:

- Complete two study questionnaires during the research encounter with the primary investigator.

Your participation in the study is expected to last approximately 1 hour. The interview and completion of the questionnaires can be stopped at any time. The interview will be held in a private area in the clinical research unit. The completed questionnaires will be de-identified and kept in a locked file, in a locked office. Personal identifiers will be removed from all study related paperwork except for the consent form. Original copies of the signed consent form will be kept in the study regulatory binder and securely locked.

Alternatives

You have the alternative to choose not to participate in this research study.

IRB Number: _____
IC Adult Minimal Risk RA Template – SocBeh Rev: 2008-10-14

IRB Consent Rev. Date: _____
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Appendix F: Informed Consent Form (Continued)

Benefits

We don't know if you will get any benefits by taking part in this study.

Risks or Discomfort

This research is considered to be minimal risk. That means that the risks associated with this study are the same as what you face every day. There are no known additional risks to those who take part in this study.

Compensation

We will not pay you for the time you volunteer while being in this study.

Confidentiality of Information Used in the Study

Who will see the information that you give?

In our research, we use and share your health information to the extent authorized by you. We know that this information is private. The federal privacy regulations of the Health Insurance Portability & Accountability Act (HIPAA) protect your identifiable health information. If you authorize us to use your information we will protect it as required by the law.

Research at Moffitt Cancer Center is conducted jointly with the University of South Florida. By signing this form, you are permitting Moffitt Cancer Center and the University of South Florida to use personal health information collected about you for research purposes within Moffitt Cancer Center health care system.

You are also allowing Moffitt Cancer Center to share your personal health information with individuals or organizations other than USF and Moffitt Cancer Center who are also involved in this research and listed below.

Who will disclose (share), receive, and/or use your information?

To do this research, USF and the people and organizations listed below may use or share your information. They may only use and share your information:

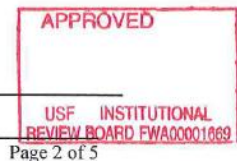
- **With the people and organizations on this list.**
- **With you or your personal representative.**
- **As allowed by law.**

USF and the people and organizations listed below may be able to see information about you and may use the information to do this research:

- The medical staff that takes care of you.
- The research team, including the Principal Investigator, study coordinator, research nurses, and all other research staff.
- All health care and other USF and Moffitt Cancer Center staff who treat and serve you as a part of this research.
- Every research site for this study. This includes the research and medical staff at each site and USF.
- The National Cancer Institute in evaluating the ongoing research of the Moffitt Cancer Center as a Comprehensive Cancer Center and may see information about you.

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Appendix F: Informed Consent Form (Continued)

- Any agency of the federal, state, or local government that regulates this research. This includes the Department of Health and Human Services (DHHS) and the Office for Human Research Protection.
- The USF Institutional Review Board and its related staff who have oversight responsibilities for this study, staff in the USF Office of Research, USF Division of Research Integrity and Compliance, and other USF offices who oversee this research.
- The designated peer review committees such as the Protocol Review and Monitoring Committee and the Data and Safety Monitoring Board.

Who else can use and share this information?

Anyone listed above may use consultants in this research, and for the purpose of this study may share your information with them. If you have questions about who they are, you can ask us. Those recipients who receive your health information for this research may not be required by HIPAA to protect it and may share your information with others without your permission, but if permitted by the laws governing them. Example: The sponsor may share your information. If the sponsor or others share your information, your information may no longer be protected under HIPAA.

How Will My Information Be Used?

By signing this form, you are giving your permission to use and/or share your health information as described in this document for any and all study/research related purposes. Your authorization (permission) to use your health information will not expire until the end of this research study unless you revoke this authorization in writing.

As part of this research, USF may collect, use, and share the following information:

- Your whole research record
- All of your past, current or future medical and other health records held by USF, other health care providers or any other site affiliated with this study. This includes, but is not limited to, HIV/AIDS, mental health, substance abuse, and/or genetic information.
- You can list any particular information that you do not want us to use or share in the space below. If you list nothing here, we can use and share all of the information listed above for this research but for nothing else.

For the Research Participant (you) to complete:

I am asking USF and the researchers not to include, use, or share the following health information in this research (if blank, then no information will be excluded):

We may publish what we learn from this study. If we do, we will not let anyone know your name. We will not publish anything else that would let people know who you are.

Your Rights:

You can refuse to sign this form. If you do not sign this form:



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Appendix F: Informed Consent Form (Continued)

- You will not be able to take part in this research and therefore not be able to complete the two study questionnaires. However, you can receive your regular medical treatment.
- This will not change your health care outside of this study.
- This will not change your health care benefits.
- This will not change the costs of your health care.

How Do I Withdraw Permission to Use My Information?

You can revoke this form at any time by sending a signed letter to USF at the address given below, clearly stating that you wish to withdraw your consent to participate in the research and to the use of your information in the research. If you revoke this form:

- You will no longer be a participant in this research study.
- We will stop collecting new information about you.
- The information that we have collected before you tell us to stop may already have been used or shared, or we may need it to complete and protect the validity of the research so you cannot withdraw your consent to let us use that information.

Staff may follow-up with you if there is a medical reason to do so.

To revoke this form, you must tell us in writing. Please write to:

Principal Investigator
For IRB Study # [Insert IRB Study #]
12901 Bruce B. Downs Blvd, MDC 22
Tampa, FL 33612

Voluntary Participation / Withdrawal

You should only take part in this study if you want to volunteer. You should not feel that there is any pressure to take part in the study, to please the investigator or the research staff. You are free to participate in this research or withdraw at any time. There will be no penalty or loss of benefits you are entitled to receive if you stop taking part in this study.

Questions, concerns, or complaints

If you have any questions, concerns or complaints about this study, call Naima Vera at 813-431-7777.

If you have questions about your rights as a participant in this study, general questions, or have complaints, concerns or issues you want to discuss with someone outside the research, call the Division of Research Integrity and Compliance of the University of South Florida at (813) 974-9343.

If you experience an unanticipated problem related to the research call Naima Vera at 813-431-7777.



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Appendix F: Informed Consent Form (Continued)

**Consent to Take Part in this Research Study and
Authorization to Collect, Use and Share Your Health Information**

It is up to you to decide whether you want to take part in this study. If you want to take part, please sign the form, if the following statements are true.

I freely give my consent to take part in this study and authorize that my health information as agreed above, be collected/disclosed in this study. I understand that by signing this form I am agreeing to take part in research. I have received a copy of this form to take with me.

Signature of Person Taking Part in Study

Date

Printed Name of Person Taking Part in Study

Statement of Person Obtaining Informed Consent and Research Authorization

I have carefully explained to the person taking part in the study what he or she can expect.

I hereby certify that when this person signs this form, to the best of my knowledge, he or she understands:

- What the study is about.
- What procedures/interventions/investigational drugs or devices will be used.
- What the potential benefits might be.
- What the known risks might be.

Signature of Person Obtaining Informed Consent / Research Authorization

Date

Printed Name of Person Obtaining Informed Consent / Research Authorization

