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The relationship between anxiety and spirituality in persons undergoing chemotherapy for cancer

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The Relationship Between Anxiety and Spirituality in Persons Undergoing Chemotherapy for Cancer

by

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

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Keywords: oncology, nursing, psycho-social, psycho-oncology, psychology

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Dedication

This is dedicated to my wonderful family. To my husband Todd, thank you for always believing in me and supporting my decision to continue my education. To my daughter Summer, thanks for helping me see the world through your eyes and for giving me someone to try to set an example for. To my mother, Naomi, thank you for providing lots of very practical help when I stretched myself too thin and for teaching me about what is truly valuable in life. To my father, Gary, thanks for always encouraging me to work hard and dream big. I am honored and blessed to have each of you in my life!
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The Relationship Between Anxiety And Spirituality In Cancer Patients Undergoing Chemotherapy

Cindy Tofthagen

ABSTRACT

Anxiety is a common problem for cancer patients, especially those who must receive chemotherapy. Anxiety may have a negative effect on quality of life, interrupting sleep, causing uncomfortable physical symptoms, and inhibiting sound decision-making. This study examined the relationship between spiritual well-being and anxiety in patients on chemotherapy for cancer.

The convenience sample consisted of 30 patients, 15 male and 15 female, receiving chemotherapy in a two physician private medical oncology practice in Southwest Florida. Patients completed the State-Trait Anxiety Inventory and the Functional Assessment of Chronic Illness Therapy-Spiritual Well-Being Scale.

Participants ranged in age from 31 to 88, with a mean age of 59.7 years. Almost 60% were getting chemotherapy with the goal of slowing down the growth of cancer (n=15) or relief of symptoms (n=2) and did not consider their cancer to be curable. Participants had been given an average of 15 chemotherapy treatments. Ninety percent were Catholic or non-Catholic Christian. Sixty percent were not heavily involved in organized religion.
The results of this study show strong negative relationships between spiritual well-being and both state anxiety (r= -0.463, p=0.010) and trait anxiety (r= -0.524, p=0.003). A strong positive relationship was found between level of involvement in organized religion and level of spiritual well-being (r= 0.545, p=0.002). Trait anxiety was also significantly negatively associated with involvement in organized religion (r= -0.38, p=0.037).

Although the sample size was small and homogenous, the results support findings of previous studies. This study is important for nursing because it examines key aspects of psychological distress in cancer patients undergoing chemotherapy. Findings suggest the need for evidence-based studies focusing on designing appropriate assessment and pertinent interventions.
Anxiety is a pervasive problem for people who are undergoing treatment for cancer. It is believed to be the most common form of psychological distress, occurring in up to 50% of cancer patients (Holland & Gooen-Piels, 2000). A lack of attention to anxiety in research and in clinical practice has been recognized (Schmidt, 2003).

In contrast, depression in cancer patients has been studied extensively, particularly at the end-of-life. The concepts of depression and anxiety are often referred to as psychological distress, and studied as one entity. Although anxiety and depression often coexist, they are distinct phenomena, which can independently increase distress for patients (Schmidt, 2003).

Anxiety, characterized by persistent fear, can be accompanied by hyper vigilance, poor concentration (Holland & Gooen-Piels, 2000), nervousness, and agitation (Schmidt, 2003). When experienced as a normal response to a known or perceived threat, anxiety often dissipates when the threat is removed. In the case of someone diagnosed with cancer, the threat is often insidious and may continue after treatments are completed. Fear of recurrence of cancer and/or death can loom in a person’s mind causing chronic anxiety and apprehension about the future.

Anxiety in cancer patients can be related to frightening aspects of treatment or to the uncertainty of coping with a potentially life threatening diagnosis. People with preexisting anxiety disorders tend to experience exacerbations in their disorder when
confronted with a cancer diagnosis. Research shows that certain events result in increased vulnerability and susceptibility to increased anxiety such as discovering a new suspicious symptom; first being diagnosed; awaiting test results; beginning a new treatment; experiencing a change in treatment; ending treatment; having a treatment failure; being discharged from the hospital; learning the disease has progressed; experiencing stresses of survivorship; and facing the end-of-life (Holland & Gooen-Piels, 2000).

A cancer diagnosis often causes individuals to reexamine the meaning of their lives, their relationships with others, their relationship with the universe, and with their creator. Spiritual needs often go unaddressed by health care professionals, who have had little training in providing spiritual care and may not feel comfortable assuming that role (Allgar, Neal & Pascoe, 2003)

Numerous studies validate that a strong sense of spiritual well-being in cancer patients is associated with better quality of life and less psychological distress (Bauer-Wu & Farran, 2005; Chibnall, Videen, Duckro, & Miller, 2002; Krupski, et al., 2005; McClain, Rosenfeld, & Breitbart, 2003; McClain-Jacobson, et al., 2004). Research suggests that because of the strong relationship between psychological and spiritual well-being, these concepts should be referred to as psycho-spiritual functioning (Bauer-Wu & Farran, 2005).

**Problem Statement**

Although several studies have been conducted to examine the relationship between spirituality and emotional distress in cancer patients, most of these studies have focused on the terminally ill (Chibnall, Videen, Duckro, & Miller, 2002; McClain, Rosenfeld, & Breitbart, 2003; McClain-Jacobson, et al., 2004). Chemotherapy is reported to increase
the risk of anxiety related to fears about treatments, side effects, and uncertainty about the future (Schreier & Williams 2004). Some patients are able to find a great deal of comfort in their spirituality. Conversely, patients may suffer from spiritual distress, questioning the meaning of life, and their relationships with God and with others. More research is needed to examine psycho-spiritual aspects of cancer care. The purpose of this study was to explore the relationship between anxiety and spirituality in persons with cancer.

**Research Questions**

The following research questions were addressed in this study:

1. Is there a significant relationship between spiritual well-being and severity of state and trait anxiety in persons with cancer receiving chemotherapy?

2. Are there significant relationships between anxiety in chemotherapy patients and their age, gender, marital status, education, involvement in organized religion, and what the patient believes the goal of treatment to be?

3. Are there significant relationships between spiritual well-being in chemotherapy patients and their age, gender, marital status, education, involvement in organized religion, and what the patient believes the goal of treatment to be?

**Definitions of Terms**

For the purpose of this study the following terms are defined:

*Anxiety*: “a continuous state of tension with the expectation of disaster” (Carroll-Johnson, Gorman, & Bush, 1998, p.126).

*Spiritual well-being*: a sense of harmony with oneself and others, the world, and a perceived higher power (Ackley & Ladwig, 2002).
Spiritual distress: Disruption in life principles that creates a sense of disharmony with oneself or others, the world, or a perceived higher power (Ackley & Ladwig, 2002).

Chemotherapy patient: A person with a cancer diagnosis who is being treated with antineoplastic medications for the purpose of prevention of recurrence, cure, disease control, or palliation of symptoms.

Significance to Nursing

Nurses are committed to providing holistic care to patients. In order to provide holistic care to patients, nurses must recognize that anxiety causes patients a great deal of distress and that it is a nursing responsibility to treat it. Assessment of available spiritual support and ensuring patient access to sources of spiritual support are important topics for nursing. Methods of helping patients utilize their spirituality to find comfort, peace, and meaning in life should be explored.

This study may shed light on whether there is a strong relationship between spiritual well-being and anxiety. If those people who have a higher degree of spiritual well-being experience less anxiety, then assessing anxiety and spiritual well-being will help nurses develop interventions to enhance quality of life in these patients.
Chapter II

Review of the Literature

This chapter reviews current empirical literature relevant to anxiety and spirituality in cancer patients. First is a review of the empirical literature pertaining to anxiety in cancer patients, particularly those receiving chemotherapy. This is followed by a review of current studies focusing on spirituality in cancer patients, and ends with a summary of findings.

Anxiety

Several studies have examined anxiety in cancer patients. A study by Keller, et al. (2004) sought to determine the prevalence of anxiety and depression in 189 newly admitted patients scheduled for cancer surgery and to evaluate how accurate medical and nursing staff are in recognizing those who are experiencing psychological distress. Patients were evaluated prior to surgery using a psychiatric interview, the Hospital Anxiety and Depression Scale, and a nurse and physician evaluation. Results showed 28% of the patients in the study had a psychiatric diagnosis. Physicians recognized significant distress in 77% of the severe cases. Nurses recognized significant distress in 75% of the severe cases. Unfortunately, the rate of referral for psychosocial support was only 40% of those with a DSM-IV disorder and 31% of those demonstrating high levels of psychological distress according to the Hospital Anxiety and Depression Scale (Keller, et al. 2004).
A prospective study reported by Iconomou, Mega, Koutras, Iconomou, and Kalofonos, (2004) examined the rates and clinical course of emotional distress, cognitive impairment, and quality of life in cancer patients who had never received chemotherapy. This study evaluated 80 patients in Greece before the initiation of chemotherapy and again at the completion of chemotherapy. Quality of life was evaluated by the European Organization for Research and Treatment of Cancer QLQ-C30. Cognitive function was measured using the Folstein Mini- Mental State Examination. The Hospital Anxiety and Depression Scale was used to assess psychological distress. Results showed cognitive function was not affected by chemotherapy, type of cancer, or stage of disease. Quality of life parameters did not change significantly over time, except for fatigue, which was more severe at the end of treatment. Of the patients surveyed, 31.25% had high levels of anxiety before the initiation of chemotherapy and 26.25% had high levels of anxiety at the end of chemotherapy, showing no significant difference. These results confirm that anxiety is a common symptom for patients receiving chemotherapy and remains at high levels throughout the course of treatment.

A study examining anxiety and quality of life in 48 breast cancer patients receiving chemotherapy and radiation therapy was completed by Schreier and Williams (2004). The participants were asked to participate in the study before starting chemotherapy or radiation. Telephone interviews were conducted at baseline, again at four weeks, 12 weeks, and after one year. Seventeen of the women had radiation and thirty-one women had chemotherapy. The Ferrans and Powers Quality of Life Index was administered at the start of treatment and a year later to evaluate quality of life. Anxiety was assessed using the State-Trait Anxiety Inventory. The results of this study indicated that chemotherapy
patients experience more anxiety than radiation therapy patients. High anxiety levels were associated with decreased quality of life both at the start of treatment and at the one year mark. The study highlights the need to initiate nursing interventions to reduce anxiety at the beginning of chemotherapy (Schreier & Williams 2004).

Another study examining anxiety in 250 cancer patients receiving chemotherapy was conducted by Tchekmedyian, Kallich, McDermott, Fayers, and Erder (2003). This study examined the relationship between changing levels of anxiety and depression with changes in fatigue levels in anemic lung cancer patients receiving platinum-based chemotherapy. Patients were given darbepoetin alfa or a placebo. Anxiety and depression were evaluated using the Brief Symptom Inventory, depression and anxiety subscales. Fatigue was measured using the Functional Assessment of Cancer Therapy fatigue subscale. The study showed that as fatigue improved, there was corresponding improvement in levels of anxiety and depression. Results showed that darbepoetin alfa therapy is helpful for treatment of anemia and the associated fatigue in this group of patients. The placebo group demonstrated higher anxiety levels at the end of the study. By treating the anemia, practitioners may see improvement in not only fatigue but in anxiety and depression as well.

A randomized clinical trial of 227 women with breast cancer who received chemotherapy by Andersen and colleagues (2004), examined the effects of a psychosocial intervention on psychological distress, social adjustment, health behaviors, adherence to the chemotherapy regimen, and immune assays. Patients were evaluated before and after four months of group therapy sessions. The sessions included traditional psychosocial elements as well as discussions on diet, exercise, smoking, and adherence to
treatment. The Profile of Mood States was used to assess anxiety, depression, anger, fatigue, and confusion. The Social Network Index and Perceived Social Support Scales for Friends and Family were used to assess perceived social support. The Food Habits Questionnaire, Seven-Day Exercise Recall of the Stanford Heart Disease Prevention Program, and a questionnaire related to smoking habits were used to assess health behaviors. Chemotherapy non-adherence was documented. Functional status was evaluated using the Karnofsky Performance Status Scale. Blood tests were done before and after the intervention for immune assays. The results showed a significant reduction in anxiety in the intervention group as well as improvement in perceived social support, dietary habits, and smoking. The intervention group was more adherent to the prescribed chemotherapy regimen. There was improvement in immune responses in the intervention group Andersen, et al (2004).

*Spirituality*

Three studies were found that address spirituality among terminally ill cancer patients. A study by McClain, Rosenfeld, and Breitbart (2003) attempted to assess the relationship between spiritual well-being and end of life despair. One hundred-sixty cancer patients with a life expectancy of three months or less were studied over an eighteen month period. This study examined whether spiritual well-being was associated with depression, hopelessness, attitudes toward hastened death, functional support, and performance status. Instruments used in the study were Functional Assessment of Chronic Illness Therapy-Spiritual Well-Being Scale, Mini-Mental State Examination, Hamilton Depression Rating Scale, Beck Hopelessness Scale, Schedule of Attitudes toward Hastened Death, Functional Social Support Questionnaire, Memorial Symptom
Assessment Scale, and Karnofsky Performance Rating Scale. Results showed that spiritual well-being was strongly associated with less hopelessness, end of life despair, and suicidal ideation. Depression was highly associated with desire for hastened death in patients who experienced low spiritual well-being but not for those who experienced high levels of spiritual well-being.

A subsequent study by McClain-Jacobson, et al. (2004) was conducted on 276 terminally ill cancer patients to determine whether a belief in the afterlife was associated with lower levels of end-of-life despair, anxiety, and depression. Patients were asked whether they believed in an afterlife, whether their beliefs about an afterlife were comforting, and whether their beliefs about an afterlife were distressing. Results showed that most patients (63.4%) reported belief in an afterlife, 17.0% reported no belief in the afterlife and 19.6% were unsure about their beliefs. Spiritual well-being was assessed with the Functional Assessment of Chronic Illness Therapy-Spiritual Well-being Scale. Depression was measured using the Hamilton Depression Rating Scale and Hospital Depression Scale. Anxiety was measured using the Hospital Anxiety Scale. Hopelessness was measured using the Beck Hopelessness Scale. Belief in an afterlife, spiritual well-being and end of life despair in patients with advanced cancer were measured using the Schedule of Attitudes Toward Hastened Death. This study concluded that belief in an afterlife was associated with lower levels of hopelessness, suicidal ideation, and desire for hastened death but was not associated with anxiety or depression.

A randomized controlled trial by Chibnall, Videen, Duckro, and Miller (2002) was completed to identify individual factors associated with death related anxiety and depression and to evaluate the effectiveness of support groups on the psychosocial and
spiritual well-being of patients with life threatening conditions. Members of the intervention group attended monthly support groups for one year. Three hundred and fifty people with serious, life threatening medical conditions were invited to participate in the study. Participants were randomly assigned to either an intervention group or a control group. Sixty - seven patients completed the study. Out of those 67 patients who completed the study, 24% had a diagnosis of cancer. All participants were asked to complete a baseline questionnaire packet including the State-Trait Anxiety Inventory, the Beck Depression Inventory, the Spiritual Well-Being Scale, the Illness Disability Index, the Perceived Social Support Inventory, and the Modified City of Hope Questionnaire, and the Death Anxiety and Death Depression Scales. The Illness Disability index measures illness-related interference with function. The Modified City of Hope Questionnaire measured physical symptom severity, emotional and spiritual well-being, perceived quality of personal relationships, medical and nursing care (Chibnall, Videen, Duckro, & Miller, 2002).

This study revealed that higher levels of death distress were associated with more depressive symptoms, less spiritual well-being, less perceived communication with their physician, and with living alone. Higher levels of death anxiety and death depression were correlated with lower levels of spiritual well-being. The sample size was not large enough to evaluate differences between the intervention group and the control group (Chibnall, et al., 2002).

A cross-sectional study by Bauer-Wu and Farran (2005) compared personal meaning in life, spirituality, stress, and psychological distress in breast cancer patients to a group of healthy patients. There were seventy-eight women who participated in the study
ranging from 35 to 55 years of age. Most participants had a high socioeconomic status, were Caucasian, and married. Thirty-nine were breast cancer survivors and thirty-nine had no personal history of cancer or other chronic or life threatening illness (Bauer-Wu & Farran, 2005).

All participants completed questionnaires including three measures of personal meaning: the Personal Meaning Index; the Existential Vacuum, and the Ladder of Life Index at Present. One measure of spirituality, the Index of Core Spiritual Experiences was used. Perceived stress was measured with the Perceived Stress Scale. Psychological distress was measured using the brief Profile of Mood States (Bauer-Wu & Farran, 2005).

The study concluded that there is a correlation between perceived meaning in life and spirituality. These elements have an inverse correlation with psychological distress and perceived stress. Another interesting finding was that personal meaning in life and spirituality were lower and psychological distress was higher in breast cancer survivors without children compared to breast cancer patients with children (Bauer-Wu & Farran, 2005).

A similar study by Krupski, et. al. (2005) was conducted on prostate cancer patients of low socioeconomic class to determine whether spirituality is associated with health related quality of life or psychosocial health. Health related quality of life was measured using the RAND Medical Outcomes Study Short Form 12-Item Health Survey, version 2. Anxiety was evaluated using an unnamed instrument validated in leukemia survivors. Emotional well-being was assessed with the Medical Outcomes Study 5 item Mental Health Index. Symptom distress was measured using the Symptom Distress Scale. The Functional Assessment of Chronic Illness Therapy-Spiritual Well-Being scale was
utilized to evaluate spiritual well-being. The study findings show that as spiritual well-being increased, health related quality of life also improved. Spirituality was associated with higher levels of life satisfaction. Men who had lower levels of spiritual well-being also had lower levels of psychological well-being including increased anxiety and more symptom distress (Krupski, et al., 2005).

A study of 298 adult cancer patients receiving radiation therapy was conducted in Japan by Noguchi, et al (2005). This study examined the possibilities of providing spiritual care based on Frankl’s existential analytical therapy. All participants completed the Japanese versions of the Functional Assessment of Chronic Illness Therapy-Spiritual, the Purpose in Life test, the WHO subjective inventory, and the Hospital Anxiety and Depression Scale. The study confirmed that high levels of spiritual well-being correlated with lower levels of anxiety and negative thinking (Noguchi, et al., 2005).

Summary

Numerous studies indicate that patients on chemotherapy experience high levels of anxiety (Iconomou, et al., 2004; Schreier & Williams, 2004; Tchekmedyian, et al., 2003; Andersen, et al., 2004). Psychological interventions are of benefit in reducing anxiety (Andersen, et al., 2004). High levels of anxiety in cancer patients have been associated with fatigue (Tchekmedyian, et al., 2003) and reduced quality of life (Schreier & Williams, 2004). Unfortunately, health care professionals often fail to properly assess patients for anxiety and seldom make appropriate referrals for psychological treatment (Keller, et al).

Two studies have concluded that high levels of spiritual well-being correlate with less anxiety and negative thinking in cancer patients (Noguchi, et al., 2005; Krupski, et al.
2005). Neither of these studies examined the relationship between anxiety and spiritual well-being in patients receiving chemotherapy. Current research supports the idea that spiritual well-being results in decreased death anxiety among the terminally ill (Chibnall, et al., 2002). Knowing whether a relationship between anxiety and spiritual well-being in cancer patients receiving chemotherapy exists is essential to the development of nursing interventions aimed at decreasing anxiety and increasing quality of life in this population.
Chapter III

Methods

The purpose of this study was to determine whether there was a significant relationship between anxiety and spiritual well-being in cancer patients receiving chemotherapy. This chapter outlines the research methods. First the sample and setting are described. The instruments included in the study are then discussed. Third, data collection procedures are outlined, and finally, data analysis information is provided.

Setting and Sample

The sample consisted of 30 patients from an outpatient facility currently undergoing chemotherapy treatments. Sample size was estimated using power analytic techniques. With alpha set at .05 and power set at .80, a sample size of 30 would be needed to detect a moderate effect size. For inclusion in the study, patients had to be receiving chemotherapy for a known type of malignancy, be at least 18 years of age, and be able to speak, read, and write English. Those who had a history of psychiatric illness were excluded.

Instruments

State-Trait Anxiety Inventory

The State-Trait Anxiety Inventory (STAI) assesses both personal tendency toward anxiety, also known as trait anxiety, and current level of anxiety, referred to as state anxiety (Spielberger, 1983). This instrument was chosen because it allows for comparison between anxious personality characteristics and level of current anxiety.
There are a total of 40 multiple-choice questions, 20 assessing trait anxiety and 20 assessing state anxiety. It is a four point Likert-type scale, and possible answers to anxiety related questions include: 1 (not at all), 2 (somewhat), 3 (moderately so), and 4 (very much so). Scores range from 20 to 80 and higher scores correspond with higher anxiety levels. The questionnaire is written on a sixth grade reading level, is self-administered, and takes less than 10 minutes to complete.

Reliability

Alpha coefficients range from 0.83 to 0.94 for the state anxiety subscale and are higher under stressful circumstances. The median alpha coefficient for trait anxiety is 0.90 (Spielberger, 1983).

Validity

Construct validity of the trait anxiety scale was determined by comparing scores of neuropsychiatric patients, who tend to have high levels anxiety, to the scores of normal subjects. Of the 461 neuropsychiatric patients in the study, only one had trait anxiety scores within the normal range. The rest had elevated scores on the trait anxiety subscale (Spielberger, 1983). Validity of the trait anxiety scale was also confirmed by comparing scores of people with character disorder, for whom the absence of anxiety is a defining characteristic, to normal scores. The character disorder patients had significantly lower levels of trait anxiety.

Construct validity of the state anxiety subscale was determined by comparing the scores of military recruits (N=1,964) entering highly stressful training programs to those of people in the same age group under non-stressful conditions. Scores on the state anxiety scale were much higher for the military recruits than for those under non-stressful conditions.
conditions. Further validity of the state anxiety scale was determined by comparing scores of 977 college students during regular class periods, during an exam, and after relaxation training. Scores were highest during the exam and lowest during the relaxation training (Spielberger, 1983).

**The Functional Assessment of Chronic Illness Therapy-Spiritual Well-Being Scale**

The Functional Assessment of Chronic Illness Therapy-Spiritual Well-Being Scale (FACIT-Sp-12) is a Likert-type scale consisting of 12 multiple-choice questions (Cella, n.d.). This instrument was chosen because it was specifically designed for use in oncology patients. The instrument is comprised of two subscales; one measures the role of faith in illness, and the other assesses peace and meaning in life (Peterman, Fitchett, Brady, Hernandez, & Cella, 2002). Possible responses to the 12 questions assessing spiritual well-being include 0= not at all, 1= a little bit, 2= somewhat, 3= quite a bit, 4= very much. Higher scores indicate a higher degree of spiritual well-being.

**Reliability**

Reliability was evaluated with internal consistency coefficients. The alpha coefficients were 0.87 for the entire scale, 0.81 for the meaning/peace subscale and 0.88 for the faith subscale (Peterman, Fitchett, Brady, Hernandez, & Cella, 2002).

**Validity**

Positive correlations between FACIT-Sp and the Functional Assessment of Cancer Therapy General, and the Profile of Mood States have evaluated validity of this instrument. The correlation between the role of faith in illness subscale and the peace and meaning in life subscale was 0.54 (p=0.0001) (Peterman, Fitchett, Brady, Hernandez, & Cella, 2002).
Demographic data form

A demographic tool was developed for this study. The demographic tool included age, gender, cancer type, goal of chemotherapy, how many chemotherapy treatments the patient has received, marital status, who the patient lives with, income level, educational level, religion, and degree of involvement in organized religious activities assessed on a 0 to 10 scale.

Procedures

Approval for the study was obtained from the physicians who own the practices where the study was conducted, Ron D. Schiff, M.D., Ph.D. and Egberto Zayas, M.D. and from the University of South Florida Institutional Review Board. Expedited status was granted. The investigator was the nurse caring for the patients and thus identified patients meeting inclusion criteria when they came into the office to receive chemotherapy. The purpose of the study and requirements for the study were explained to patients coming into the office for chemotherapy, and their questions were answered. If they chose to participate in the study, informed consent was obtained and each patient was given a copy of the consent form to keep. The questionnaires were completed by the patients while they were receiving their chemotherapy or while they were waiting. All data was confidential and stored in a locked closet.

Data Analysis

Descriptive statistics were used to analyze the demographic data including frequencies and percentages, means, and standard deviations. Relationships between variables were assessed using the Pearson product-moment correlation coefficient. Data were analyzed using the Statistical Package for the Social Sciences. Levels of state and
trait anxiety were correlated with levels of spiritual well-being to determine whether a relationship existed between the two. Levels of state and trait anxiety were correlated with demographic characteristics to determine whether a relationship exists between any of the demographic variables and increased levels of anxiety. Levels of spiritual well-being were correlated with demographic characteristics to determine whether a relationship exists between any of the demographic variables and overall levels of spiritual well-being. Data were analyzed with the goal of shedding light on the following research questions:

1. Is there a significant relationship between spiritual well-being and severity of state and trait anxiety in persons with cancer receiving chemotherapy?

2. Are there significant relationships between anxiety in chemotherapy patients and their age, gender, marital status, education, involvement in organized religion, and what the patient believes the goal of treatment to be?

3. Are there significant relationships between spiritual well-being in chemotherapy patients and their age, gender, marital status, education, involvement in organized religion, and what the patient believes the goal of treatment to be?
Chapter IV
Results, Discussion and Conclusions

This chapter presents the findings of the study. The results, discussion of the results and limitations, conclusions, and suggestions for future research are discussed.

Results

Demographic data

The sample consisted of 30 patients, 15 male and 15 female, ranging in age from 31 to 88 with a mean age of 59.7 (SD=13.4). Years of formal education ranged from 9 to 21 years with a mean of 14 years. Two-thirds of the patients were married and lived with a spouse (n=20) (Table 1) and one-third were unmarried (n=10) (Table 2). Number of previous chemotherapy treatments ranged from 0 to 50 with a mean of 15.63 (SD=15.0). The majority of patients had an annual household income of $50,000 or more per year (n=18) (Table 2).

Table 1. Frequency and Percent of Participants’ Living Conditions

<table>
<thead>
<tr>
<th>Living Conditions</th>
<th>Frequency a</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>lives alone</td>
<td>5</td>
<td>16.7</td>
</tr>
<tr>
<td>lives with spouse</td>
<td>20</td>
<td>66.7</td>
</tr>
<tr>
<td>lives with family member</td>
<td>5</td>
<td>16.7</td>
</tr>
<tr>
<td>lives with friend</td>
<td>2</td>
<td>6.7</td>
</tr>
</tbody>
</table>

a Participants could choose multiple answers
Table 2. Frequency and Percent of Participants’ Demographic Characteristics

<table>
<thead>
<tr>
<th>Demographic Variable</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>15</td>
<td>50.0</td>
</tr>
<tr>
<td>Female</td>
<td>15</td>
<td>50.0</td>
</tr>
<tr>
<td><strong>Marital status</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single</td>
<td>1</td>
<td>3.3</td>
</tr>
<tr>
<td>Married</td>
<td>20</td>
<td>66.7</td>
</tr>
<tr>
<td>Divorced</td>
<td>3</td>
<td>10.0</td>
</tr>
<tr>
<td>Separated</td>
<td>1</td>
<td>3.3</td>
</tr>
<tr>
<td>Widowed</td>
<td>5</td>
<td>16.7</td>
</tr>
<tr>
<td><strong>Income</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Less than $25,000</td>
<td>5</td>
<td>16.7</td>
</tr>
<tr>
<td>$25,000-$49,999</td>
<td>6</td>
<td>20.7</td>
</tr>
<tr>
<td>$50,000-$74,999</td>
<td>9</td>
<td>30.0</td>
</tr>
<tr>
<td>More than $75,000</td>
<td>9</td>
<td>30.0</td>
</tr>
<tr>
<td>Missing Data</td>
<td>1</td>
<td>3.3</td>
</tr>
</tbody>
</table>

Most of the participants were Caucasian (n=27) and non-Catholic Christian (n=18) or Catholic (n=9). Ten percent of patients did not identify with any religion. Sixty percent rated their degree of involvement in organized religion on a scale of one to ten as a zero
(n=8), one (n=3), or two (n=7). Only 16.7% (n=5) were highly involved in organized
religion, responding with a score between 8 and 10 (Table 3).

Table 3. Frequency and Percent of Participants’ Religion and Religious Involvement

<table>
<thead>
<tr>
<th>Religion</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-Catholic Christian</td>
<td>18</td>
<td>60.0</td>
</tr>
<tr>
<td>Catholic</td>
<td>9</td>
<td>30.0</td>
</tr>
<tr>
<td>None</td>
<td>3</td>
<td>10.0</td>
</tr>
</tbody>
</table>

Involvement in organized religion on a scale of 0 to 10\(^a\)

<table>
<thead>
<tr>
<th>Score</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>8</td>
<td>26.7</td>
</tr>
<tr>
<td>1</td>
<td>3</td>
<td>10.0</td>
</tr>
<tr>
<td>2</td>
<td>7</td>
<td>23.3</td>
</tr>
<tr>
<td>3</td>
<td>4</td>
<td>13.3</td>
</tr>
<tr>
<td>4</td>
<td>1</td>
<td>3.3</td>
</tr>
<tr>
<td>5</td>
<td>0</td>
<td>0.0</td>
</tr>
<tr>
<td>6</td>
<td>2</td>
<td>6.7</td>
</tr>
<tr>
<td>7</td>
<td>0</td>
<td>0.0</td>
</tr>
<tr>
<td>8</td>
<td>2</td>
<td>6.7</td>
</tr>
<tr>
<td>9</td>
<td>1</td>
<td>3.3</td>
</tr>
<tr>
<td>10</td>
<td>2</td>
<td>6.7</td>
</tr>
</tbody>
</table>

\(^a\) Assessed on a 0 (no involvement) to 10 (highly involved) scale

Most patients were unaware of the stage of their malignancy (n=19). Forty percent
(n=12) believed that the goal of chemotherapy was cure or prevention of recurrence.
Almost sixty percent of the patients who responded to the question (n=17) believed the goal of chemotherapy was slowing down cancer growth (n=15) or relief of symptoms (n=2) (Table 4). Seven patients had lung cancer, six had colorectal cancer, six had breast cancer, three had prostate cancer, three had non-Hodgkin’s lymphoma, two had multiple myeloma, and four had other solid tumors.

Table 4. Frequency and Percent of Subjects by Their Perceived Goal of Chemotherapy

<table>
<thead>
<tr>
<th>Goal</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cure</td>
<td>5</td>
<td>16.7</td>
</tr>
<tr>
<td>Prevention of recurrence</td>
<td>7</td>
<td>23.3</td>
</tr>
<tr>
<td>Slowing down growth</td>
<td>15</td>
<td>50.0</td>
</tr>
<tr>
<td>Relief of symptoms</td>
<td>2</td>
<td>6.7</td>
</tr>
<tr>
<td>Missing</td>
<td>1</td>
<td>3.3</td>
</tr>
</tbody>
</table>

Table 5. Frequency and Percent of Site of Original Disease

<table>
<thead>
<tr>
<th>Type of Cancer</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lung</td>
<td>7</td>
<td>23.3</td>
</tr>
<tr>
<td>Colorectal</td>
<td>6</td>
<td>20.0</td>
</tr>
<tr>
<td>Breast</td>
<td>6</td>
<td>20.0</td>
</tr>
<tr>
<td>Non-Hodgkin’s Lymphoma</td>
<td>3</td>
<td>10.0</td>
</tr>
<tr>
<td>Multiple Myeloma</td>
<td>2</td>
<td>6.7</td>
</tr>
<tr>
<td>Anal Cancer</td>
<td>1</td>
<td>3.3</td>
</tr>
<tr>
<td>Bladder Cancer</td>
<td>1</td>
<td>3.3</td>
</tr>
<tr>
<td>Ovarian Cancer</td>
<td>1</td>
<td>3.3</td>
</tr>
</tbody>
</table>
State-trait anxiety

State and trait anxiety were assessed using the State-Trait Anxiety Inventory. There were no significant differences in scores between men and women. The mean score on the state anxiety inventory was 35.5 for males (SD=13.9) and 35.3 for females (SD=11.4). The mean score on the trait anxiety inventory was 35.6 for males (SD=11.3) and 36.9 for females (SD=9.7). No relationships were found between anxiety and age, marital status, level of education, or goal of treatment. Trait anxiety was significantly higher in people with a low degree of involvement in organized religion (r = -0.38, p =.037). State anxiety was also negatively associated with the degree of religious involvement (r = -0.35, p = 0.061), although the relationship was not considered statistically significant. Levels of state and trait anxiety were inversely related to levels of spiritual well-being.

Spiritual well-being

Spiritual well-being was measured using the Functional Assessment of Chronic Illness Therapy-Spiritual Well-Being Scale (FACIT-Sp-12). No significant correlation was found between spiritual well-being and age, marital status, level of education, or goal of treatment. The mean score on the FACIT-Sp-12 was 35.1 for males (SD=6.9) and 38.0 for females (SD=7.3). Levels of spiritual well-being were associated with involvement in organized religion (r=0.545, p=0.002). Level of spiritual well-being was negatively related to levels of both state and trait anxiety (Table 6).
Table 6. Correlations of Spiritual Well-Being and State and Trait Anxiety, and Religious Involvement

<table>
<thead>
<tr>
<th></th>
<th>r</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>State Anxiety</td>
<td>-0.463</td>
<td>0.010</td>
</tr>
<tr>
<td>Trait Anxiety</td>
<td>-0.524</td>
<td>0.003</td>
</tr>
<tr>
<td>Involvement in organized religion</td>
<td>0.545</td>
<td>0.002</td>
</tr>
</tbody>
</table>

Discussion

Demographic data

Participants were recruited from a two-physician private practice using a convenience sample. Data for the study were collected during the months of December 2005 through February 2006.

The sample largely consisted of middle-class, white, non-Hispanic participants. All of the participants who professed a religion were of the Christian faith and so the results cannot be generalized to people of other races, economic classes or faiths.

The majority of participants had received numerous chemotherapy treatments and cure was no longer the goal of treatment. Anxiety levels in this population may differ from those who are new to chemotherapy or are in early stages of cancer treatment. Treatment-related anxiety, disease-related anxiety, and facing their own mortality are major sources of anxiety for cancer patients. These issues that cancer patients must face, contribute to decreased feelings of well being and overall quality of life (Holland & Gooen-Piels, 2000).
State-trait anxiety

The results of this study confirm that trait anxiety levels are lower among cancer patients receiving chemotherapy who have higher levels of spiritual well-being. This means that the patients’ general tendency to be anxious was related to both their level of spiritual well-being and their degree of religious involvement. Similar findings related to spiritual well-being among radiation therapy patients (Noguchi, et al., 2005) and prostate cancer patients (Krupski, et al 2005) have been previously reported.

Mean levels of state and trait anxiety were higher among unmarried people, but the differences were statistically insignificant. Only five of the 30 participants lived alone. This small sample size may account for why this study failed to confirm the findings of previous studies that support the idea that people who live alone have higher levels of anxiety. No relationships were found between anxiety and age, gender, education, or what the patient believes the goal of treatment to be.

The study found that anxiety levels were lower among participants who were more active in organized religion. Current research literature does not address this topic. Increased social support and feelings of connectedness with God and others found through group worship would be expected to help alleviate anxiety, and contribute to a better sense of spiritual well-being and better quality of life.

Trait anxiety and spiritual well-being were inversely correlated, and although a negative correlation between state anxiety and religious involvement was found, again, it was a statistically insignificant finding. A larger sample size may have resulted in a statistically significant finding.
Spiritual well-being

There was no correlation between spiritual well-being and age, education, or what the patient thought the goal of treatment was. Again, more significant findings may have resulted from a larger sample size. Patients who were involved in organized religion had higher levels of spiritual well-being than did those who were not involved in organized religion. Religious involvement and spiritual well-being, while different, are related concepts. The affirmation of one's spiritual beliefs and values, the focus on a relationship with God, and the opportunity to interact with others who share the same beliefs is a positive experience for many.

Implications for nursing

The findings of this study have several implications for nursing. Holistic care should be emphasized in oncology nursing education. Assessment of spiritual and psychological health and interventions to help support spiritual and psychological well-being need to be incorporated into nursing curriculum. Nursing research focusing on the development of specific interventions to alleviate anxiety and support spiritual health are needed.

Because the primary role of nurses is that of patient advocate and because nurses tend to have a holistic approach to care, nurses are ideally suited to address the complex physical, emotional, and spiritual needs of patients facing an illness that is potentially life limiting. Health care professionals from other disciplines have been slow to address the emotional and spiritual aspects of cancer treatment believing that it is outside of their realm. Many health care professionals are reticent to discuss issues such as fear of loss of control, fear of pain and suffering, and fear of death and dying with patients because of their own personal fears and discomfort with the subject matter. These are areas where
nurses have expertise and where their input should be valued by other members of the health care team, who may not understand the complex needs of these patients including the need to be understood and to have their feelings and experiences validated.

Conclusions

Anxiety levels are higher among people with lower degrees of spiritual well being. Those who are involved in organized religion have higher levels of spiritual well-being and lower levels of anxiety. No relationships between anxiety or spirituality and age, marital status, level of education, or goal of treatment were significant. Findings suggest the need for evidence-based studies focusing on designing appropriate assessment and pertinent interventions.

Recommendations for future research

Future studies should include a larger sample size and a more ethnically, economically and religiously diverse sample. More studies looking at nursing interventions that help support spiritual and psychological well-being are needed. Studies are also needed to determine whether interventions designed to support spiritual well-being would be useful in helping to alleviate anxiety and increase quality of life in this population.
References


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Appendice
Appendix A: State Anxiety Inventory

SELF-EVALUATION QUESTIONNAIRE

Developed by Charles D. Spielberger
in collaboration with

STATE Form Y-1

Name ____________________________ Date __________ S __________
Age ____________ Sex: M ______ F ______

DIRECTIONS: A number of statements which people have used to describe themselves are given below. Read each statement and then blacken in the appropriate circle 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.

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

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Appendix B: Trait Anxiety Inventory

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 blacken in the appropriate circle to the right of the statement to indicate how you generally feel. 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 how you generally feel.

21. I feel pleasant .............................................. 0 2 3 4
22. I feel nervous and restless .................................. 0 2 3 4
23. I feel satisfied with myself .................................. 0 2 3 4
24. I wish I could be as happy as others seem to be ........ 0 2 3 4
25. I feel like a failure ............................................ 0 2 3 4
26. I feel rested ...................................................... 0 2 3 4
27. I am "calm, cool, and collected" ......................... 0 2 3 4
28. I feel that difficulties are piling up so that I cannot overcome them 0 2 3 4
29. I worry too much over something that really doesn't matter .... 0 2 3 4
30. I am happy ...................................................... 0 2 3 4
31. I have disturbing thoughts ................................... 0 2 3 4
32. I lack self-confidence ....................................... 0 2 3 4
33. I feel secure .................................................... 0 2 3 4
34. I make decisions easily ..................................... 0 2 3 4
35. I feel inadequate .............................................. 0 2 3 4
36. I am content .................................................. 0 2 3 4
37. Some unimportant thought runs through my mind and bothers me 0 2 3 4
38. I take disappointments so keenly that I can't put them out of my mind .............................................. 0 2 3 4
39. I am a steady person ......................................... 0 2 3 4
40. I get in a state of tension or turmoil as I think over my recent concerns and interests ...................................... 0 2 3 4

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Appendix C: FACIT-Sp-12 (Version 4)

Below is a list of statements that other people with your illness have said are important. By circling only (1) number per line, please indicate how true each statement has been for you during the past 7 days:

<table>
<thead>
<tr>
<th>Statement</th>
<th>Not at all</th>
<th>A little bit</th>
<th>Somewhat</th>
<th>Quite a bit</th>
<th>Very much</th>
</tr>
</thead>
<tbody>
<tr>
<td>I feel peaceful</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I have a reason for living</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>My life has been productive</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I have trouble feeling peace of mind</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I feel a sense of purpose in my life</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I am able to reach down deep into myself for comfort</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I feel a sense of harmony within myself</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>My life lacks meaning and purpose</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I find comfort in my faith or spiritual beliefs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I find strength in my faith or spiritual beliefs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>My illness has strengthened my faith or spiritual beliefs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I know that whatever happens with my illness, things will be okay</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix  D: Demographic Data Form

1. What is your current age? ______

2. Which gender are you? (circle one) male/female

3. What type of cancer are you being treated for (breast, colon, lymphoma, etc.)? 
   __________________________

4. What do you understand the goal of the chemotherapy is (check one answer below)?
   ___ cure
   ___ prevention of recurrence
   ___ slowing down the growth of the cancer
   ___ relief of symptoms
   ___ not sure

5. How many chemotherapy treatments have you had, not including today? ______

6. Who lives with you (check one or more answers below)?
   ___ I live alone.
   ___ I live with my spouse.
   ___ I live with at least one family member who is not my spouse.
   ___ I live with a friend.
   ___ I live in a nursing home or assisted living facility.

7. Marital status (check one).
   ___ single
   ___ married
   ___ divorced
   ___ separated
   ___ widowed

8. What is your annual household income (check one)
   ___ less than 25,000 dollars per year
   ___ 25,000-49,999 dollars per year
   ___ 50,000-74,999 dollars per year
   ___ more than 75,000 dollars per year

9. How many years of formal education have you completed? ________
example:
12 = high school graduate, 14 = associate degree or technical school 16=baccalaureate degree

10. What is your race or ethnicity (check all that apply)
___American Indian/Alaskan Native
___Asian
___Black/African American
___Hispanic/Latino
___Native Hawaiian/Pacific Islander
___White/Caucasian
___Other or Unknown

11. What is your religion (check as many as apply)?
___none
___Jewish
___Islamic
___Buddhist
___Catholic
___Christian (non – Catholic) denomination______________________
___other, please describe______________________

12. On the scale below circle the number that corresponds with your degree of involvement in organized religious activities.

no 0 1 2 3 4 5 6 7 8 9 10 very involved
Appendix D: Letter of Approval from Physician #1

August 18, 2005

To Whom It May Concern,

I have reviewed the research proposal by Cindy Toftinger entitled "Anxiety and Spirituality in Cancer Patients Undergoing Chemotherapy." I finds this research appropriate for my oncology patients on chemotherapy and give the investigator permission to conduct research in my office. Appropriate resources are available for interviews to be conducted, including a private room. A locked room where data can be stored is also available. Based on the risks associated with this research, there are adequate provisions to handle any unanticipated events. Thank you for your time and attention to this matter.

Ron D. Schiff, M.D., Ph.D.
Appendix E: Letter of Approval from Physician #2

August 16, 2005

To Whom It May Concern,

I have reviewed the research proposal by Cindy Turndano entitled Anxiety and Spirituality in Cancer Patients Undergoing Chemotherapy. I find this research appropriate for my oncology patients on chemotherapy and give the investigator permission to conduct research in my office. Appropriate resources are available for interviews to be conducted, including a private room. A locked room where data can be stored is also available. Based on the risks associated with this research, there are adequate provisions to handle any unanticipated events. Thank you for your time and attention to this matter.

Egberto Zayas, M.D.

Bethesda Cancer & Blood Institute
Appendix F: Informed Consent

Informed Consent

Social and Behavioral Sciences
University of South Florida
Information for People Who Take Part in Research Studies
IRB #104173

The following information is being presented to help you decide whether or not you want to take part in a minimal risk research study. Please read this carefully. If you do not understand anything, ask the person in charge of the study.

Title of Study: Anxiety and Spirituality in Cancer Patients Undergoing Chemotherapy

Principal Investigator: Cindy Tothagen

Study Location(s): office of Ron D. Schiff, M.D., Ph.D. and Eiberto Zayas, M.D.

You are being asked to participate because you are being treated with chemotherapy for a diagnosis of cancer.

General Information about the Research Study

The purpose of this research study is to determine whether or not a relationship exists between anxiety and spiritual well-being in cancer patients receiving chemotherapy. The study will also examine relationships between anxiety and spirituality and certain characteristics of individuals being treated for cancer with chemotherapy.

Plan of Study

While you are at the office where you receive your chemotherapy, you will be asked to complete four brief written questionnaires. The time it will take to complete these questionnaires should be less than 15 minutes.

Payment for Participation

You will not be paid for your participation in this study, nor will it cost you anything.
Benefits of Being a Part of this Research Study

You may help to increase our knowledge of anxiety in cancer patients on chemotherapy.

Risks of Being a Part of this Research Study

There are no known risks involved in participation in this study.

Confidentiality of Your Records

Your privacy and research records will be kept confidential to the extent of the law. Authorized research personnel, employees of the Department of Health and Human Services, and the USF Institutional Review Board, and others acting on its behalf, may inspect the records from this research project.

The results of this study may be published. However, the data obtained from you will be combined with data from others in the publication. The published results will not include your name or any other information that would personally identify you in any way. Only those directly involved in the research will have access to the data, which will be stored in a locked closet. Numbers will be assigned to each participant and used for identification purposes.

Volunteering to Be Part of this Research Study

Your decision to participate in this research study is completely voluntary. You are free to participate in this research study or to withdraw at any time. There will be no penalty or loss of benefits you are entitled to receive, if you stop taking part in the study. The alternative to this research study is not to participate. You will still receive your chemotherapy and all other planned treatments today, even if you do not participate in this study.

What other choices do you have if you decide not to take part?

If you decide not to take part in this study, that is okay. The other choice you have is to get your chemotherapy and other planned treatments today as planned, without participating in this study.

Questions and Contacts

If you have any questions about this research study, contact Cindy Tofthagen at 948-0286. If you have questions about your rights as a person who is taking part in a research study, you may contact the Division of Research Compliance of the University of South Florida at (813) 974-5638.
Consent to Take Part in This Research Study.

By signing this form I agree that:

- I have fully read or have had read and explained to me this informed consent form describing this research project.
- I have had the opportunity to question one of the persons in charge of this research and have received satisfactory answers.
- I understand that I am being asked to participate in research. I understand the risks and benefits, and I freely give my consent to participate in the research project outlined in this form, under the conditions indicated in it.
- I have been given a signed copy of this informed consent form, which is mine to keep.

Signature of Participant ___________________________ Date ____________

Printed Name of Participant ___________________________ Investigator Statement

I have carefully explained to the subject the nature of the above research study. I hereby certify that to the best of my knowledge the subject signing this consent form understands the nature, demands, risks, and benefits involved in participating in this study.

Signature of Investigator ___________________________ Date ____________

Printed Name of Investigator ___________________________