DEVELOPING & EVALUATING THE EFFICACY AND FEASIBILITY OF DELIVERING A PSYCHOEDUCATIONAL INDIVIDUAL INTERVENTION TO WOMEN WITH ADVANCED STAGE OVARIAN CANCER: A TWO PHASE STUDY

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DEDICATION

For Janie

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women with ovarian cancer. She is a rare and truly gifted instructor, sincerely invested in the development of her students. The very model by which the intervention was designed is attributable to Dr. Diane Myers' influence on my clinical development. It is truly a gift to have had the benefit of her expertise from the very beginning of my training. I've always said that learning therapy skills from Dr. Myers is like learning to scuba dive in Maui. Once you see that, nothing else really ever measures up. I consider myself extremely fortunate to have had the privilege of working with a committee who modeled professional and personal integrity and character in every interaction. That, in and of itself, is a gift.

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"If I have seen further, it is because I have stood on the shoulders of giants."

- Sir Isaac Newton

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by

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DISSERTATION

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The University of Texas Southwestern Medical Center at Dallas, 2007

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Purpose:

The purpose of this study was to assess the psychosocial needs of women with ovarian cancer treated at Baylor University Medical Center Sammons Cancer Center, and to design and evaluate the feasibility and efficacy of an individual psychoeducational intervention on reported symptoms of depression, anxiety, and psychosocial adjustment to illness. Secondary aims included identifying the barriers to accessing group support services as well as identifying a mechanism to address those barriers.

Method:

This study was conducted in two phases. Phase I consisted of a psychosocial needs assessment (n = 15) to determine the appropriate elements necessary for inclusion in an individual intervention. Perceived barriers to participation in psychosocial services, including group support, were also assessed. The outcome of the needs assessment combined with an extensive literature review was used to develop the Phase II intervention. In Phase II, participants (n = 30) were recruited from the gynecologic oncology practice at Baylor Sammons Cancer Center. Participants were randomized to intervention (n = 15) vs. control (n=15) groups. Intervention sessions lasted 60 minutes and were conducted weekly over a period of 8 weeks. Sessions consisted of a combination of education and psychosocial support. Growth modeling was used to evaluate variation in within-individual rate of change in outcome measures during the treatment (weeks 1-8) and follow-up (weeks 16-48) periods of the study. Repeated measures ANOVA was used to evaluate average group differences in outcome measures during the treatment and follow-up periods of the study.

Results:

No main effects of time, group, age, or education were observed with regard to rate of change of psychosocial adjustment to illness during the treatment period of the study using growth modeling. However, during the follow-up period of the study, time and group were significant predictors of within-individual variation in

rate of change in psychosocial adjustment to illness. Similarly, repeated measures ANOVA yielded no main effects of time or group in psychosocial adjustment to illness during the treatment period of the study; however, a main effect of group ($p<.05$) and an interaction between group and time ($p<.05$) were noted during the follow-up period of the study with the most significant differences in group means occurring at week 48 (effect size = .70). Although not stable across all models created, time was the only significant predictor of within-individual variation in rate of change in depression symptoms during the treatment and follow-up periods. A main effect of time without consideration of group ($p<.01$) and an interaction between group and time ($p<.01$) with regard to depression symptoms was noted in the treatment phase of the study, most significantly at week 8. A main effect of group ($p<.05$), most significantly at week 48, was observed during the follow-up phase (effect size = .69). Similar to depression scores, within-individual variation in anxiety symptom scores was significantly predicted by time during the treatment period of the study. Although no main effects of predictors were observed with regard to anxiety symptoms during the follow-up period of the study, the model with the greatest goodness of fit included the predictors education, group, and time. Repeated measures ANOVA suggest a main effect of time ($p<.05$) with regard to anxiety symptoms during the treatment period of the study but no main effect of group. However, during the follow-up period of the study, a main effect of time ($p<.05$) and group ($p<.05$) were noted

with regard to differences in the average state anxiety symptom score between groups, with the most significant difference occurring at week 48 (effect size = .43).

Cost analyses suggest minimal differences in the number of medical office visits and phone calls between groups and a moderate difference in usage of psychiatric and pain medication between groups.

Treatment satisfaction was high across all intervention topics, with participants rating sessions 1 and 8 the most helpful.

Research and Clinical Implications:

Concordant with the literature, the results of this study suggest that individual interventions with women with advanced stage ovarian cancer may help improve neurocognitive-related mood symptoms and anxiety during the initial phase of treatment and diagnosis. Decline in depression symptoms in intervention participants was primarily related to decline in neurocognitive complaints. A reduction in neurocognitive mood symptoms and anxiety likely contributed to the improvement in psychosocial adjustment to illness noted in the treatment group during the follow-up period of the study. The impact of psychosocial sequelae on cognitive functioning warrants attention by clinicians.

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LIST OF ABBREVIATIONS

BDI-II	Beck Depression Inventory II
BUMC	Baylor University Medical Center
LES	Life Experiences Survey
PAIS-SR	Psychosocial Adjustment to Illness Survey-Self Report
STAI	Spielberger State and Trait Inventory
TOPA	Texas Oncology Physician Associates
UTSW	The University of Texas Southwestern Medical Center

CHAPTER ONE
Introduction

The American Cancer Society estimates that there were 25,580 new cases of and 16,090 deaths due to ovarian cancer in 2004 (American Cancer Society, 2004). Approximately 1 woman in 55, or 2%, will develop ovarian cancer in her lifetime, and 1 in 100 will die of this disease (Connor and Langford, 2004). It is the fifth leading cause of cancer deaths among women (American Cancer Society, 2004). Because early stages of the disease may present few or mild symptoms, ovarian cancer is often diagnosed after it has progressed to an advanced stage. Connor and Langford (2004) attribute delayed diagnosis of ovarian cancer to the lack of a reliable screening test and the tendency to attribute symptoms to other causes ranging from a urinary tract infection or gastrointestinal problems to menopause.

The stigma of a historically poor prognosis may bring intense feelings of loneliness and isolation. Connor and Langford (2004) report that newly diagnosed ovarian cancer patients frequently present for clinic visits reporting decreased appetite, insomnia, difficulty concentrating, difficulty making decisions, anxiety, and feelings of emptiness and isolation. Unlike women newly diagnosed with breast cancer, a woman newly diagnosed with ovarian cancer may

know no other woman who has been treated, except those she may meet in a treatment setting.

Historically, as with many medical illnesses, the management of ovarian cancer has been primarily biologically based, with little attention given to the psychological, social, and spiritual aspects of the illness. However, with the advent of improved surgical and chemotherapeutic regimens and resulting improved prognosis, oncologists are now increasingly interested in the psychosocial, sexual, and quality of life issues surrounding the disease. The complex psychosocial impact of ovarian cancer can be addressed more comprehensively from the integrative perspective of the biopsychosocial model (Auchincloss and McCartney, 1998). Within this model, the field of psycho-oncology has emerged as a subspecialty. Research and clinical work in psycho-oncology have made great strides in the understanding of the psychosocial issues that contribute to the overall outcome of oncology patients as well as the development of appropriate programs and interventions to begin to address those issues for some oncology patient populations, most notably, breast cancer.

While there are many programs currently in place, significant gaps in psychosocial treatment of oncology patients, specifically women with ovarian cancer, remain. Despite the improvements in treatment and prognosis, ovarian cancer retains an aura of danger and lethality in the eyes of the general public, in

part as a result of a shortage of research. Auchincloss and McCartney (1998) report

> any woman diagnosed with ovarian cancer faces both a true medical challenge and a clear awareness that when she shares her diagnosis with anyone, she changes dramatically how she is perceived… women describe being treated as if they were heroines or written off as if they were already dead (pg 366-367).

In the sections that follow, the biopsychosocial model will be briefly discussed as an introduction to the development and history of the field of psycho-oncology. The body of literature encompassing the psychological and social factors surrounding a cancer diagnosis, regardless of type, will be presented in detail, followed by issues specific to gynecologic oncology patients to illustrate the significant impact such a diagnosis has on the patient as well as the patient's entire support system. Next, a description of the current modes of delivering psychosocial services to oncology patients will be discussed. Finally, rationale for the current study will be presented.

Biopsychosocial Approach

The biomedical model of disease emphasizes the disease process and the body's physiological response. In contrast, the biopsychosocial model focuses on illness, where illness is the complex interaction of biological, psychological, and social variables. This concept of illness includes the severity, duration, and

consequences for the individual. The expression of illness is accounted for by the interrelationships among biological changes, psychological status, and the social and cultural contexts that shape the individual's perception of, and response to his or her illness (Turk, 1996).

The diagnosis of a life threatening illness, such as ovarian cancer, can be devastating to the patient and her family. The acute psychological stress of facing one's own mortality can be overwhelming (Mortimer et al., 1999). Multiple studies suggest that up to one-third of cancer patients suffer psychiatric morbidity relating to diagnosis and treatment. For many patients, this may become disabling and prolonged. Grassi and Rosti (1996) found that over one-third of long-term cancer survivors continued to suffer symptoms of maladjustment up to six years following diagnosis and medical treatment. Furthermore, a significant proportion of cancer patients suffer sufficient emotional distress to qualify for a psychiatric diagnosis, most commonly anxiety or depression (Derogatis et al., 1983; Omne-Ponten et al., 1994; Vinokur et al., 1989). The rate of depression in oncology patients has been found to be up to four times higher than in the general population (Mortimer et al., 1999). Wong-Kim and Bloom (2004) found that physical pain, decreased self-esteem linked to feelings of inadequate body image following mastectomy or lumpectomy, and poor emotional support independently contributed to the progression from minor mood disturbance to major depression in young women newly diagnosed with breast cancer.

As physicians and researchers alike began to take note of the significant impact of the psychological and social issues related to cancer on their patients' well-being and adjustment, a subspecialty rooted in the biopsychosocial school of behavioral medicine emerged within the broader field of oncology. Although slow to develop, psycho-oncology-that is, the psychosocial aspect of oncology, has gained increased attention in the literature over the past 20 years. Oncologists have begun to realize that patients must learn to cope with the side effects and new problems, such as hair loss, nausea, and infertility, which accompany each advance made in treatment methods (Holland, 1998). Particularly poignant is the dynamic relationship between advances in treatment and diagnosis on one hand, and the psychosocial problems that are emerging with the advent of DNA testing of healthy individuals for cancer risk and biomarkers.

Psycho-Oncology

Psycho-oncology has brought attention to psychosocial sequelae of cancer through multiple mechanisms including: (a) training of oncology professionals in counseling and communication skills; (b) developing behavioral and psychosocial interventions; and (c) developing valid, standardized instruments to quantitatively measure subjective symptoms and states such as pain, nausea, dyspnea, anxiety, depression, delirium, and quality of life (Holland, 1998). Psycho-oncology plays a significant role in understanding and reducing stress related to cancer risk and

mortality by contributing to the understanding of behavioral components in cancer control and prevention (Holland, 1992).

Holland (1998) suggests that the experience of an individual cancer patient is greatly influenced by the historical epoch in which that diagnosis occurs, the nature of the cancer treatment, and how cancer is viewed in the individual's culture at that given time. Holland (1998) further outlines the three primary factors that influence psychological adaptation to a cancer diagnosis, outlined in Table 1.1. Clearly, any conceptualization of an individual's response to a cancer diagnosis is complex and must include awareness of the powerful social forces derived from myths and negative attitudes that are decades old. Table 1.2 traces the changes in treatment of cancer and social attitudes toward medicine and death, and the evolving role of psychiatrists and health psychologists as members of the treatment team.

Psycho-oncologists are beginning to fill a need in overall cancer care by developing and studying interventions to act on the variables that mediate disease and treatment effects. There are four primary categories of mediating variables addressed by psycho-oncology: personal characteristics, medical issues, social support, and concurrent life stressors (Holland, 1998).

Table 1.1

Factors that Primarily Influence Psychological Adaptation to Cancer Diagnosis

Factor Type	Components
Society-related	Knowledge of treatment options and prognosis Patient participation as a partner in treatment Popular beliefs • Stress causes cancer
Patient-related	Personal attributes of the individual Intrapersonal component • Emotional maturity at the time of diagnosis • Philosophic, religious, or spiritual beliefs which influence coping • Meaning of the diagnosis with respect to individual's life goals Interpersonal component • Social support (i.e. spouse, children, extended family, friends)
Cancer-related	Site Stage Symptoms Prognosis Treatment required • Degree of altered body structure or function • Availability of restorative procedures or rehabilitation Psychological management by treatment staff

Note: From "Societal Views of Cancer and the Emergence of Psycho-oncology" by J.C. Holland, 1998, Psycho-Oncology p. 4.

Table 1.2

Historical Review of the Development of the Psychosocial Component of Oncology

Era	Advances in Cancer Treatment	Attitudes Toward Cancer	Attitudes Toward Death	Psychiatry & Psychology
1900-1920s	Successful surgical removal of some early cancers; Radiation used for palliation	Era of home remedies and quack cures for cancer	Doctors assumed authoritarian and paternalistic role; Dx not revealed to patient	First Psychiatric Unit in general hospital (NY 1902); Psychobiological approach by Adolf Meyer
1930s	National Cancer Institute and International Union Against Cancer formed (1937)	Volunteer visitor programs for cancer patients with functional deficits initiated by ACS	Deaths in hospitals; Person "only sleeping" euphemism used for death	Beginning psyche consultation in general hospitals; Psychosomatic theory emerged
1940s	Nitrogen Mustards developed in WWII & found to have anti-tumor action; First remission of acute leukemia by use of drug	Pervasive pessimism of public and doctors about outcome of cancer treatment	Expression of grief encouraged; Funeral industry born	Search for cancer personality & life events as cause of cancer; First scientific study of acute grief

1950s	Beginning of cancer chemotherapy	Debates about practice of not revealing dx to patients	Post WWII concerns about informed consent	First papers on psyche reaction to cancer; First psyche unit established at Memorial Sloan-Kettering
1960s	Combined modalities lead to first survivors of childhood leukemia & Hodgkin's disease; Hospice movement started	More optimism; Survivors concerns are heard; Public concern grows for prevention research in cancer	U.S. Federal guidelines for patient participation in research	Kubler-Rosss' influence key in U.S.; Behavioral studies in lifestyle and habits which increase cancer risk
1970s	National Cancer Plan (1972), with rehab and cancer control; Psychosocial included	Dx usually revealed in U.S. & several other countries	Prognosis more likely not revealed; First Hospice	First support for psychosocial studies; Psychosocial Collaborative Oncology group began
1980s	Better analgesics and antiemetics developed; FDA mandates quality of life in cancer trials	More cancer survivors; Pain initiatives for public and professional education	U.S. physicians required to discuss wishes about resuscitation (DNR)	International Psycho-Oncology Society formed; Development of psychobiological research
1990s	First reported overall reduction in cancer mortality in U.S.	Increased public concern about cigarettes and cancer	Public and professional debate about physician assisted suicide	Third World Congress of Psycho-Oncology

Note: From "Societal Views of Cancer and the Emergence of Psycho-oncology" by J.C. Holland, 1998, Psycho-Oncology, p. 5.

By successfully addressing these mediating variables, psycho-oncologists are beginning to make a positive impact on physical, psychological, social, vocational, and sexual domains of functioning of cancer patients (Holland, 1998). Continued success of these efforts depends primarily on the future development of a cohort of individuals who are skilled in this area, are able to lead psycho-oncology units in cancer centers, interact well with other disciplines, and develop research studies that address the major issues that arise out of new oncologic discoveries and treatments (Holland, 1998).

Although the odds of recovery from many forms of cancer have greatly improved in recent years, especially when discovered in the early stages, cancer patients continue to be faced with a sense of uncertainty about the future. This uncertainty is not necessarily limited to long-term survival, but also includes concerns about possible side effects of treatment, financial burden, educational or career goals, family, and feelings of isolation (Spencer, Carver, and Price, 1998).

Psychological and Social Factors in Adaptation to Cancer Diagnosis

Psycho-oncology research has attempted to determine the point at which distress is the most intense, when it begins, and how it changes over time. In 1978, Jamison et al. established that distress arises with the first suspicion of cancer. Northouse (1989) and Stanton (1993) report that the diagnostic period

before surgery is widely seen as the most emotional phase of the treatment process. There seems to be less distress reported in the post-operative period, perhaps because the degree of disease involvement and prognosis is known with greater certainty. While distress seems to decrease post-operatively, completion of surgery and adjuvant chemotherapy and/ or radiation does not mark the end of the adaptation process. Adaptation continues long after the diagnosis and treatment process begins, and remains a long-term and dynamic journey for patients and families alike (Cassileth et al., 1985; Ell et al., 1988).

Hobfoll (1989) suggests considering adaptation in terms of an individual's ability to access a variety of resources. Although paramount, such resources are not limited to financial means or skilled medical personnel but extend to resources that are personal and social in nature. Furthermore, the psychological situation is influenced not only by the presence of a potentially life-threatening illness, the degree treatment disrupts life activities, and an individual's social support system, but also influenced by the way in which an individual perceives or experiences that external reality. An event that is deeply threatening to one person may be far less so to another (Spencer, Carver, and Price, 1998).

Spencer, Carver, and Price (1998) discuss adaptation within the framework of the self-regulation model proposed by Carver, Sheier, and Pozo (1992). Carver and colleagues assume that coping comprises behavior and cognitive activity aimed at responding to and overcoming adversity. Such

responses may be multidimensional with energy invested in: ensuring complete elimination of the cancer; minimizing the disruption to the other aspects of their lives; and dealing with feelings of distress elicited by the diagnosis and treatment process, including concerns about death. Well-cited work by Lazarus (1966) and Lazarus and Folkman (1984) supports the notion that all of the above are potential focuses of a person's coping efforts. Spencer, Carver, and Price (1998) add that, regardless of the specific focus, coping efforts serve the ultimate function of placing the person back into their normal life activities. However, for some, the severity of the perceived stress causes them to doubt their ability to return to the ordinary pursuits of life. When strong enough, this doubt may lead an individual to disengage, to withdraw from the pursuit of the goal, or even to entirely give up on the goal (Kirsch, 1990). Spencer and colleagues (1998) suggest that, with a serious illness like cancer, the goals that are threatened by the disease are literally the goals that define the person's very life. The combination of distress and an inability to motivate oneself to try to recover as much as possible may manifest itself as helplessness or hopelessness, leading to disengagement.

Disengagement may take several forms, which may include the avoidance tactics that individuals may employ when wanting to postpone dealing with real life problems. Miller (1990) and Repetti (1992) argue that avoidance coping is useful because it gives the individual a psychological breather by creating an opportunity to escape the constant pressure of the situation. Suls and Fletcher

(1985) and Levine et al. (1987) agree that denial is useful in the early period of diagnosis and treatment because it allows an individual to deal with the implications of the diagnosis and all of the treatment options in manageable chunks. Denial becomes maladaptive when an individual's desire to postpone treatment culminates in a more negative physical or psychological outcome.

Consistent with an individual's willingness to focus on returning to the ordinary pursuits of life, is the idea that multiple aspects of personality play an important role in contributing to psychological adjustment to a cancer diagnosis. Among such aspects, research suggests that having an optimistic outlook on life is related to positive psychosocial outcomes in cancer patients. Reports that optimists and pessimists differ in the manner in which they experience and cope with various stresses come as no surprise. (Carver et al., 1989; Scheier et al., 1986; and Scheier et al., 1992).

Fighting spirit, a quality within optimism, is a personality variable that is beginning to gain increasing attention in the health psychology literature. Spencer et al. (1998) define fighting spirit as an engagement in active efforts to overcome the adversity posed by the diagnosis of cancer. It represents a determined struggle to regain one's strength and remain fully involved in the process of living life. Nelson et al. (1989) suggest that fighting spirit is linked to the disposition to be optimistic about life in general. The consensus seems to be that people who are more negative about their lives, more prone to distress in response to adversity,

and who are more likely to feel helpless or hopeless when confronting adversity generally find it more difficult to successfully and effectively adapt and move forward with their lives.

Psychiatric Disorders in Oncology Patients

In a group of 215 randomly selected hospitalized ambulatory adult oncology patients in three cancer centers, Massie and Popkin (1998) found 47% have clinically apparent psychiatric diagnoses, and that over two-thirds (68%) of oncology patients have reactive or situational anxiety and depression, qualifying for a diagnosis of Adjustment Disorder with Depressed or Anxious Mood. Thirteen percent of Massie and Popkin's cohort met criteria for major depression, 8% had an organic mental disorder, 7% had a personality disorder, and 4% had a pre-existing anxiety disorder. Nearly 90% of the psychiatric disorders observed were reactions to or manifestations of cancer treatment. Only 11% represented prior psychiatric problems (i.e., personality disorder and anxiety disorder).

Depression in oncology patients is challenging to characterize because depressive symptoms occur on a spectrum that ranges from sadness to major affective disorder. Furthermore, assessing depression in cancer patients is often complicated by the many side effects of treatment and the disease process. As such, many of the somatic indicators, such as fatigue, insomnia, and weight loss, are of little value. Psychological symptoms, such as dysphoric mood, feelings of

helplessness or hopelessness, loss of self-esteem, feelings of worthlessness or guilt, anhedonia, and suicidal thoughts, weigh much more heavily in the diagnosis of depression in cancer patients (Massie, 1989).

The issue of suicide in a cancer patient is a dilemma that confronts professionals in the oncology setting. From a professional perspective, suicidal ideation is a symptom of psychiatric disturbance. However, from a philosophical perspective, suicide in those who face the distress of fatal illness is often described as a rational means to regain control and maintain a dignified death (Breitbart & Krivo, 1998). The danger of framing suicide in the cancer patient as a "rational act" is that it presupposes a lack of psychiatric comorbidity. Breitbart and Krivo (1998) acknowledge that a small minority of cancer patients commit suicide as an expression of personal autonomy but report that the vast majority of cancer patients, particularly those with advanced disease who express suicidal ideation or request hastened death, do so while suffering with unrecognized or untreated psychiatric disturbances, most commonly depression or delirium, combined with poorly controlled physical pain.

Campbell (1996) notes that, although relatively few cancer patients overtly commit suicide, the risk of suicide in cancer patients is twice that of the general population. Campbell (1996) suggests that the true incidence of suicide in cancer patients is underestimated because the frequency of passive suicide and the degree

to which noncompliance and treatment refusal represent a deliberate decision to end life is unknown.

A number of factors increase a cancer patient's vulnerability to suicide (summarized in Table 1.3). Among these factors are advanced stage of illness and poor prognosis. Campbell (1996) reports that cancer patients commit suicide most frequently in the advanced stages of disease. Hietenan et al. (1994) found that for 62% of cancer patients at any stage who committed suicide, cancer was the fundamental reason for the suicide, yet for 100% of those who committed suicide in the advanced stages of disease, cancer was the fundamental reason. Ovarian cancer patients are not only most commonly diagnosed at advanced stages (3 or 4), but they also have a relatively poor long-term prognosis, making them especially vulnerable. Breitbart and Krivo (1998) report that among those diagnosed with or those who have progressed to advanced stages of the illness, depression rates rise to 77%. Depression is a factor in 50% of suicides, with or without terminal illness. Clearly, the role that depression plays in cancer suicide is equally significant.

Table 1.3

Cancer Suicide Vulnerability Variables

Advanced illness and poor prognosis
Depression and hopelessness
Delirium
Control and helplessness
Exhaustion and fatigue
Pain
Pre-existing psychopathology
Prior suicide history – personal or family

Cohen-Cole et al. (1993) evaluate four approaches to assessing depression in oncology patients. An *inclusive approach* takes into account all symptoms of depression irrespective of whether or not they are secondary to an illness process. This method offers high sensitivity, low specificity, and does not include a consideration for etiology. In contrast, an *etiologic approach* gives credence to a depressive symptom only if it is not presumed to be secondary to the illness process. Spitzer et al. (1978) used the etiologic approach when developing the Structured Clinical Interview for DSM-IIIR. The *substitutive approach* replaces indeterminate symptoms, such as fatigue, with cognitive symptoms such as indecisiveness, brooding, and hopelessness (Endicott, 1984). The fourth

approach, called the *exclusive approach*, was used by Cohen-Cole et al. (1993). This approach eliminates symptoms such as anorexia and fatigue, which are presumed to be secondary to cancer treatment, as well as the disease process itself, and employs other depression criteria. The exclusive approach increases specificity, which is important for research purposes, but lowers sensitivity, which has the clinical consequence of increasing the number of overlooked cases of depression.

Although major depression is commonly seen in cancer patients, it should not be regarded as an unavoidable consequence of cancer. Massie (1989) recommends that oncologists screen their patients regularly for psychological symptoms of depression and promptly make referrals for pharmacologic or psychosocial interventions, when warranted.

Because the diagnosis of a serious illness, such as cancer, poses the threat of death, anxiety may be considered a normal reaction. However, some patients develop an exaggerated anxiety response, presenting with symptoms that overwhelm them and impair their functioning. In cancer patients, symptoms of anxiety often co-exist with depression. Noyes, Holt, and Massie (1998) report that mixed states are more common than anxiety alone. Cassileth et al. (1984) report a high correlation ($r = 0.81$) between scores on the State-Trait Inventory and the Beck Depression Inventory in cancer patients.

Derogatis et al. (1983), considered the most widely quoted study of prevalence of psychiatric disorders in cancer patients, used DSM-III criteria in a large sample of cancer patients, finding 44% of patients met criteria for current Axis I disorders. Approximately 21% had prominent anxiety symptoms including: anxiety disorders, adjustment disorder with anxious mood, and adjustment disorder with mixed emotional features. Pinder et al. (1993) estimated the prevalence of anxiety disorders in cancer patients between 9% and 19%.

Sharer et al. (1993) characterize the cancer patient presenting with pathologic anxiety, which is anxiety causing significant distress or functional impairment, as being troubled by uneasiness, anxious foreboding, or a sense of impending doom. They are irritable, unable to relax, and have difficulty falling asleep. Their thoughts are often catastrophic and over generalized, viewing unlikely dangers as probable and unfortunate consequences as devastating. Typically, they view their situation as uncontrollable and see themselves as helpless victims (Sharer et al., 1993). Unfortunately, anxiety symptoms may contribute to physical disability by increasing the symptoms associated with cancer treatment, such as loss of appetite, poor sleep, shortness of breath, fatigue, and pain.

Regardless of the diagnostic or treatment phase of cancer, anticipation, diagnosis, assessment, or treatment, patients and their significant others are confronted with enormous stresses. The literature has established that patients

may experience a frank psychiatric disorder for which explicit treatment is needed in response to the fear or knowledge that they have cancer. Even with this knowledge well established in the literature, a significant majority of cancer patients suffer from untreated depression and anxiety, which have the potential to contribute to negative emotional as well as physical consequences for patients and families alike.

Psychosocial Adaptation of Cancer Survivors

As the number of cancer survivors has begun to increase owing to the extraordinary successes in treatment advancement within the past 30 years, scientific attention is turning to assessments of the long-term medical, psychological, vocational, social, and sexual consequences of cancer treatment. While there is a tremendous difference in cancer treatment depending on the type of cancer diagnosis, there is also a common experience of survival that is shared by all cancer patients. According to Kornblith (1998), the foundation of the cancer experience is built on the life-threatening character of cancer, ranging from the possible toxicity of its treatments to the uncertainty of knowing when one is truly cured.

Although only 4%-10% of cancer survivors are likely to meet criteria for a diagnosis of Post-Traumatic Stress Disorder (PTSD), approximately 48% of cancer patients report a range of cancer-related PTSD symptoms such as re-

experiencing the event, avoidance of painful reminders of cancer, and re-experiencing emotional states associated with cancer (Alter et al., 1996; Cordova et al., 1995). A number of studies report PTSD symptoms involving intrusive thoughts about cancer uncontrollably appearing in one's mind, oscillating with avoidant attempts to deny or block cancer-related thoughts, in Hodgkin's disease and leukemia survivors (Cella and Tross, 1986; Kornblith et al., 1992; Greenberg et al., 1995; and Lesko et al., 1992). Greenberg et al. (1995) and Lesko et al. (1992) note that patients, for whom treatment was most recently completed, reported significantly more intrusive and avoidant cancer-related thoughts than those farther out from treatment completion. Cella and Tross (1986) found that the combined effect of late-stage disease with more recent completion of treatment in Hodgkin's disease survivors resulted in significantly greater intrusive thoughts than in those with early-stage disease with greater time from treatment completion. Lesko et al. (1992) suggests that an increase in intrusive thoughts and avoidant behavior reports in leukemia patients is related to significantly worse adjustment.

The fear of recurrence is a psychological entity unique to the experience of surviving cancer (Kornblith, 1998). Koocher and O'Malley (1981) refer to this phenomenon as the "sword of Damocles" that hangs over a survivor's head, threatening to fall at any point. This very vivid image explains the significant prevalence of this fear, with some studies reporting 42% - 89% of breast cancer

patients and 39% - 76% in bone marrow transplant patients (Polinsky, 1994; Sneeuw et al., 1992; Meyer et al., 1989; Bush et al., 1995; and Belec, 1992). Greenberg et al. (1995) found a significant correlation between fear of recurrence and psychosocial adjustment in leukemia patients using the Psychosocial Adjustment to Illness Scale (PAIS) ($p < 0.0001$) suggesting that fear of recurrence may serve as an indicator of overall adjustment.

As there is considerable evidence that the wide range of surgical, chemotherapeutic, and radiation therapies can leave permanent damage to organs and physiological functioning as well as disfigurement across all forms of cancer, body image is frequently included in many studies of survivors in an effort to assess long-term psychological impact of treatment (Loescher, 1989; Kornblith, 1998). Such studies have been most prominent in breast cancer patients and head and neck cancer patients. A number of studies found that breast cancer patients who had undergone mastectomy continued to report significant distress with respect to body image extending from 3.4 years to 8 years post-treatment (Lasry et al., 1987; Meyer and Aspergen, 1989). Adding insult to injury, Wingard (1992) suggests that as body image worsens, sexual activity and functioning significantly decrease. Superimposed on sexual functioning problems due to body image are medical and psychiatric sequelae specific to the type of cancer diagnosis and treatment. In contrast, Baker (1992) found that impairments in long-term adjustment with respect to body image in head and neck cancer patients were

significantly related to resultant physical dysfunction, like swallowing, talking, and eating, rather than the degree of facial disfigurement.

One often overlooked area of recovery for cancer survivors is vocational functioning. For many cancer patients, the fundamental need to earn a living and obtain important employee-related benefits, such as health insurance, strongly motivates those who were employed at the time of diagnosis to return to work as soon as physically able (Kornblith, 1998). Haberman (1993) reports survivors most vulnerable to becoming unemployed or working at a reduced level are those with significant cancer and treatment-related physical problems who become disabled or who had highly strenuous occupations. The significant financial strain cancer treatment puts on blue collar workers has long been documented (Feldman, 1978).

Feldman (1984) and Hoffman (1989) document cancer survivor reports of gross discrimination in which individuals were fired or laid off because of having cancer. Bloom et al. (1988) note 4% of testicular cancer survivors, 5% - 6% of Hodgkin's disease survivors, and 7% of leukemia survivors report such discrimination. Table 1.4 represents additional forms of vocational discrimination reported by cancer survivors.

Table 1.4

Vocational Discrimination Reported by Cancer Survivors

Type of Discrimination	%	Reference
Encouraged to leave	4 – 6	Kornblith et al. (1992); Greenberg et al. (1995)
Transferred to less desirable job	n/a	Feldman (1984)
Denied a deserved salary increase	n/a	Feldman (1984)
Denied a promotion	2	Greenberg et al. (1995)
Not offered a job	10 – 12	Fobair et al. (1986); Greenberg et al. (1995)
Had difficulty finding a new job due to cancer history	25	Schag et al. (1994)
Demoted	0 – 2	Kornblith et al. (1992); Greenberg et al. (1995)
Responsibilities unnecessarily limited	4	Greenberg et al. (1995)

The Rehabilitation Act of 1973 was designed to prohibit employment discrimination based on medical conditions that did not affect an employee's qualification for the position but only applied to employers who receive federal financial assistance. Two landmark cases, *Arline v. School Board of Nassau County* and *Ritchie v. City of Houston*, explicitly extended the Rehabilitation Act to healthy cancer survivors by clarifying the

"definition of handicapped individual to include not only those who are actually impaired, but also those who are regarded as impaired, and who, as a result are substantially limited in major life activity…" (pg. 282-283, *Arline v. School Board of Nassau County*, 1987).

Survivors who are not covered under the Federal Rehabilitation Act must look to state laws. Hoffman (1989) suggests that cancer survivors may need to rely on state laws prohibiting employment discrimination based on disabilities because state laws vary widely in their application of cancer-related discrimination.

Social functioning, as it pertains to relationships with spouse, family, friends, and social activities, is an area of concern for many cancer survivors. Kornblith (1998) reviewed a number of studies finding that the majority of cancer survivors' marriages are extraordinarily resilient in the face of considerable stress as a consequence of their disease. While a minority of survivors' marriages appear to end in separation and divorce due to cancer, Kornblith (1998) found that subtle changes in the marital relationship are more common, as indicated by survivors' reports of communication problems with their spouses. Polinsky (1994) reports 21% of breast cancer survivors report their husbands do not understand what they have been through. Kornblith (1998) suggests that this is a feeling commonly expressed by cancer survivors as they relate to the non-cancer world.

The literature gives mixed reviews of the long-term adjustment of family functioning for cancer survivors. Wolcott (1986) found that 73% of survivors in their study report high satisfaction with the family as a whole. Belec (1992) found that 19% of survivors in their study report the development of stronger

family bonds. Curbow et al. (1993) note that 53% of the cohort they studied reported positive changes in relationships with siblings, 49% reported positive changes in relationships with their parents, and 17% reported positive changes in their relationships with their children. However, there are a number of studies reporting a negative impact on family functioning. Polinsky (1994) relates that 43% of breast cancer survivors in their cohort feel that family members do not understand their situation, resulting in the experience of significant disruption in family and extended family relationships. Rapoport et al. (1993) found that family functioning is one of the three most problem-laden areas for head and neck cancer survivors, with the worst functioning occurring for those diagnosed 6 months to 1 ½ years prior to enrollment in the study. They found another spike in family dysfunction 5 or more years post-diagnosis, with the best family functioning occurring between 1 ½ years and 5 years post-diagnosis. Rapoport (1993) explains the second spike in family dysfunction as a byproduct of the chronic stress produced by having the disease, coping with health difficulties and limitations, and experiencing the overall emotional strain.

The extent of the impact on social and leisure activities reflects the idiographic pattern of adjustment across all previously discussed areas of functioning. Among the factors affecting social participation is the withdrawal of family and friends from cancer survivors. Bush et al. (1995) found that 96% of the bone marrow transplant survivors in their cohort report that people in their

social networks had been less supportive over time and that this was the single most distressing hardship of long-term survival. Haberman (1993) suggests that the phenomenon of social network withdrawal may reflect friends not understanding what survivors have experienced, fear that discussing cancer with the patient will lead to increased distress, or the individual's own fear of the disease and the specter of death.

One of the most difficult adjustment issues for male and female cancer survivors of child-bearing age is the prospect of infertility. Rieker et al. (1990) believe that the intrinsic association of reproduction with the sexual self-image and overall self-worth has considerable potential to create emotional distress and marital discord, particularly in survivors of child-bearing age. Kornblith (1998) suggests that the loss of the ability to have children is often a long-term grief process.

As described in the previous pages, the long-term psychological, social, and sexual consequences of cancer treatment have the potential to disrupt patients' lives beyond the inconvenience and discomfort of the actual medical treatment. As such, a consensus of clinical recommendations is needed to address these issues.

Clinical Recommendations

Andersen (1994) strongly suggests that programs created to address the many psychosocial issues of cancer patients need to be comprehensive in nature, with the core of the program consisting of educational and counseling programs with both group and individual components. Andersen (1994) notes that problems with sexual functioning encountered by cancer patients are often sidestepped, owing to their highly private nature, and need to be more frequently included as part of a comprehensive program. Reliance on either group support or education alone, without the individual component, may not be enough (Andersen, 1994).

Fawzy et al. (1995) suggest that psychosocial interventions applied earlier in the treatment process, or immediately after treatment completion, would be beneficial. Worden and Weisman (1984) advocate a preventive mental health approach of offering psychological assistance to cancer patients before they present with serious emotional distress. Kornblith (1998) agrees with Worden and Weisman's preventative approach and stresses that as the range and magnitude of the problems experienced by cancer survivors continue to come to light, this advice increasingly makes sense.

Leigh (1994) suggests implementing programs that more closely and systematically monitor psychological distress between infrequently scheduled office visits for cancer survivors who are farther along in the treatment process

and less enmeshed in the medical system. Kornblith et al. (1995) suggests telephone monitoring for psychological distress with follow-up for those in need. Oncologists can serve as a fulcrum for change by identifying those in distress at the time of office visits and referring them for the appropriate mental health treatment (Kornblith, 1995). Spitzer et al. (1994) believe that cancer patients have an enduring emotional bond with their oncologists, which may increase the likelihood of the patient seriously considering complying with a mental health consultation recommendation.

With regard to the under-treatment of psychological distress in oncology patients, Kornblith (1998) describes a multi-determined phenomenon, which is most likely a factor of: (1) survivors wanting to be viewed as the "good patient" and under-reporting their emotional distress to members of their treatment team; (2) physicians not recognizing signs and symptoms of distress due to a lack of time to assess for psychological distress or discomfort with addressing the emotional difficulties of their patients; and (3) financial limitations that make accessing mental health treatment financially prohibitive. Psychosocial intervention programs should include not only education pertaining to psychological distress and management options for oncology patients, but also oncology professionals. In order to be truly comprehensive in care, comprehensive cancer treatment centers should include a mental health

professional to offer psychosocial interventions as a standard component of treatment.

Finally, Kornblith (1998) recommends that psychosocial interventions need to focus on reducing cancer survivors' emotional and social isolation. One way to accomplish this goal is to create educational and counseling programs involving both cancer survivors and their family members and friends. Such programs would center on cancer-related problems told from the vantage point of survivors as well as family and friends and may help reduce communication barriers that lead to feelings of emotional and social isolation.

Standard Interventions

As allopathic medicine has moved to a more holistic treatment approach, many multidisciplinary treatment facilities have begun to realize the benefits of integrating behaviorally based treatment approaches. Fawzy et al. (1995) report that patients receiving behaviorally based treatment approaches, whether group or individual, experience improvement in psychosocial functioning irrespective of the content. Psychoeducational support groups have been found to have the potential to be a potent and cost-effective form of behaviorally based treatment for cancer patients with regard to (Classen et al., 2001) adjustment (Spiegel, Bloom, and Yalom, 1981; Johnson, 1982; Cain et al., 1986; Telch & Telch, 1986; Cunningham & Tocco, 1989; Berglund et al., 1994; Fawzy et al., 1990; Samarel

et al., 1999; and Edmonds et al., 1999), physical status (Speigel, Bloom, and Yalom, 1981; Berglund et al., 1994; Fawzy et al., 1990; and Fawzy et al., 1993), and survival (Fawzy et al., 1993; Spiegel et al., 1989; and Cunningham et al., 1998).

According to recent review articles, many types of group interventions have been employed, with the number of sessions ranging from 4 to 52, targeted at various types and stages of cancer (Speigel et al., 2000; Hosaka et al., 2001). The most commonly employed format is the psychoeducational group ranging from six to eight weekly sessions usually lasting 90 minutes per session (Cunningham et al., 1995; Fawzy et al., 1990; Fawzy et al., 1993; and Mortimer et al., 1999). Psychoeducational groups generally are theoretically based in Cognitive Behavioral Therapy (CBT) techniques but most commonly employ an eclectic theoretical orientation, integrating elements of multiple schools of therapy.

The CBT group model is highly structured, employing a combination of the following components: psychoeducation, stress management, problem-solving and coping skills, and social support. The psychoeducation component provides information to patients regarding any number of aspects related to the diagnosis, including, nutrition, exercise, self-care, depression, anxiety, and others. Stress management skills are taught by increasing the awareness of an individual's particular body signals. Awareness is increased by teaching participants to

identify emotions as they develop and then analyze their emotional response. A correlation is then made between the emotional response and the physical manifestation of stress. Relaxation, biofeedback, body scans, and meditation are a few of the techniques employed to assist patients with decreasing stress once they are familiar with their body's response to stress (Spiegel et al., 1991; Spiegel & Bloom, 1983; Hilgard & Hilgard, 1975; Zeltzer & Lebaron, 1982; Morrow & Morrell, 1982; Burish & Lyles, 1981; and Burish, 1991). The problem-solving component of CBT teaches patients to confront potential problems relating to situations of loneliness, isolation, fear, anxiety, doctor-patient communication, family communication, changes in body image and sexuality, and depression. The group venue also serves as a safe environment for testing newly-acquired problem-solving skills (Mortimer, 1999). The social support component integrates microcounseling skills and patient self-disclosure regarding concerns and experiences pertaining to disease-related issues, family issues, and general coping concerns. Self-disclosure, the concept of providing information about personal experiences or emotions, is a key component in group and/ or individual interventions, warranting a more detailed discussion.

Benefits of Self-Disclosure

Since the 1980s, self-disclosure's role in alleviating psychological distress and improving physical health has been explored in numerous subject groups and

in various settings. Pennebaker and Susman (1988) proposed a theory of psychosomatics in which inhibition of thoughts, feelings, or behaviors is associated with physiological work. Pennebaker and Susman (1988) found that (a) childhood traumatic experiences, particularly those that are never discussed, are highly correlated with current health problems; (b) recent traumas not discussed by subjects are linked to increased health problems; (c) asking individuals to discuss earlier traumas through self-disclosure in writing improves health and immune system function; and (d) using self-disclosure by actively talking about upsetting experiences is also associated with immediate reductions in selected autonomic activity.

Pennebaker et al. (1989) asked 33 Holocaust survivors to talk for one to two hours about their experiences during World War II. While the subjects talked, skin conductance and heart rates were continuously monitored. The interviews were videotaped and later rated by independent judges to determine the degree to which the subjects' experiences were traumatic. The researchers collected self reports of subjects' health approximately 14 months after the interview. Controlling for pre-interview health problems, the degree of disclosure by the subjects during the interview was found to be positively correlated with long-term health after the interview. The results of this study suggested that the more an individual disclosed personally upsetting or traumatic experiences, the better their long-term health following disclosure.

Berry and Pennebaker (1993) explored the correlation between verbal and nonverbal expression of emotion and its relation to physiological activity. The results suggested that when individuals must actively inhibit or restrain emotional expression, they are at an increased risk for a variety of health problems. Berry and Pennebaker (1993) conducted several experiments indicating that verbally expressing traumatic experiences by writing or talking improved physical health, improved or enhanced the immune system, and was also associated with fewer medical visits.

Petrie et al. (1995) investigated whether emotional expression of traumatic experiences influenced the immune response to a hepatitis B vaccination. Forty medical students who tested negative for hepatitis B antibodies at a baseline assay served as subjects. The students were randomly assigned to write about personal traumatic events or neutral topics over a period of four consecutive sessions. The day after the final session, all subjects were given the first hepatitis B injection. Booster injections were given at one month and four months. Blood for antibody analyses was collected after each injection and at a six-month follow-up. Compared with the control group, the experimental group showed significantly higher antibody levels against hepatitis B at the four and six month follow-up assessments, providing support for a link between emotional disclosure and improved health.

Finally, Davison and Pennebaker (1996) suggest that health improvements are most likely to be seen if an individual is able to acknowledge, organize, and ultimately integrate their emotional events into a larger framework of self-understanding and identity. Psychoeducational interventions used in oncology settings are excellent conduits for assisting patients with organizing and integrating their diagnosis and treatment experience in an effort to facilitate improved immune functioning and better overall emotional outcomes.

In addition to helping clients acknowledge, organize, and integrate their emotional experiences, as in self-disclosure, interpersonal counseling skills help support the client emotionally as well as promote rapport between client and therapist. Ivey (1994) developed a conceptual framework for the hierarchy of interpersonal counseling skills. The hierarchy represents the stages of intervention that client and therapist progress through when they enter into a therapeutic relationship. It begins with the interview or intake process and proceeds through intervention and change. The Basic Listening Sequence (BLS), employed in Ivey's hierarchy, facilitates rapport building between patient and therapist, establishes a qualitative therapeutic environment, allows the therapist to gather information, invites clarification of both content and feelings in communication, and allows the therapist to observe patient reactions.

When working with oncology patients, the use of interpersonal counseling skills may provide an opportunity for patients to have their distress validated and

heard in such a way that facilitates a climate of confidence in their treatment team. Additionally, interpersonal counseling skills may assist the therapist with detecting concerns or distress in the patient that may otherwise go unnoticed. These concerns can then be addressed, which may improve the patient's overall treatment experience and emotional outcome.

Therapeutic Implications for Ovarian Cancer Patients

While the efficacy of group interventions is well-established for breast cancer patients (Spiegel et al., 1981), little research has accumulated in the literature regarding the efficacy of psychosocial interventions, group or individual, for ovarian cancer patients. This may be due, in part, to difficulties in accruing a sufficient number of ovarian cancer patients to power a study assessing psychosocial interventions, as ovarian cancer accounts for only four percent of cancer diagnosed in women (American Cancer Society, 2004). However, approximately 70% of women with the epithelial ovarian cancer type are not diagnosed until the disease is in an advanced stage, making the five-year survival rate for these women only 15 to 20% (National Ovarian Cancer Coalition). The National Institutes of Health (NIH) (1994) speculated that the poor prognosis of patients with ovarian cancer contributes to the lack of appropriate psychosocial support for this population. Interestingly, women with ovarian cancer report that the lack of psychosocial support services specific to ovarian cancer increases their

anxiety regarding their chances of survival. Ferrell et al. (2003) found that women shared fears that their inability to find ovarian-specific psychosocial services led them to believe that no one survived this disease.

Kornblith (1998) notes that survivors of gynecologic cancers have gone almost completely unstudied and additional investigation is needed to better understand the issues unique to this group. A diagnosis of ovarian cancer requires a woman to reevaluate all of the roles she plays in her interactions with family, friends, and coworkers. It changes her relationship with the world around her, bringing with it, a host of new concerns. Ovarian cancer patients must cope with unwanted changes in areas spanning from financial stability to sexuality and fertility (Ferrell et al., 2003). Quality of life issues include physical changes, psychological changes, and spiritual crises (Ferrell, 1996). Houck et al. (1999) and Ersek et al. (1997) reported that the primary quality of life concern for advanced ovarian cancer patients was the welfare of family and friends. Specifically, women report being terrified of what their own diagnosis might mean to the futures of their daughters (Weitzel & MacDonald, 1998). Ferrell et al. (1997 & 1998) reported that the fear of risk to children was of greater concern to women with ovarian cancer than was the risk of losing their own lives to cancer.

The literature is clear that developing psychosocial interventions that adequately address the emotional needs of these women is paramount.

Psychosocial interventions with this group may not serve to extend life; however, precedent has been set that such interventions may improve the patient's overall quality of life, and that of their families, while they are undergoing standard treatment (Ferrell et al., 2003).

Rationale for the Present Study

Developing group interventions for ovarian cancer patients has been met with a number of challenges. Recruiting an appropriate number of patients to optimally power a study involving psychosocial research using an ongoing group service is difficult as the prevalence of ovarian cancer is relatively small. Additionally, patients are seen on multiple clinic days and often live in areas that are not geographically convenient for attending services in addition to necessary medical treatment visits. Individual interventions can be designed similarly to group interventions with the following advantages: (1) intervention sessions can be scheduled to coordinate with routine clinic or treatment visits; (2) patients receive one-on-one, intensive psychosocial support; (3) issues such as sexuality, that may be embarrassing for a patient to discuss in group, can be comfortably discussed individually; and (4) any possible concerns regarding "asking silly questions" in front of others will be minimized, potentially resulting in better understanding of the physical, psychological, and spiritual aspects of the disease.

The primary disadvantage of individual interventions compared to group interventions is the lack of peer support.

Components of psychoeducational supportive therapy with ovarian cancer patients integrate crisis intervention and exploration of emotion, maintaining a primary focus on the illness and its implications. Although issues from a patient's past may be introduced when appropriate, the focus is maintained on present concerns using a brief crisis intervention model. Patients often consider their feelings of fear about the illness and its outcome to be too painful or burdensome to reveal to family and friends. The supportive psychotherapeutic relationship plays a useful role by encouraging the exploration of feelings, which may otherwise go unexpressed. Such exploration often facilitates the patient's awareness that the majority of her fears are universal in cancer patients, thus alleviating the anxiety related to the stigma of feeling afraid (Sourkes, Massie, and Holland, 1998).

Major Comprehensive Cancer Centers (CCC) in the United States have taken note of the positive impact on quality of life promoted by psychoeducational interventions and have integrated them into their standard care protocols. In 1988, Memorial Sloan-Kettering Hospital established a unique, comprehensive program for cancer survivors known as the Post-Treatment Resource Program (PTRP). PTRP is offered to patients upon treatment completion and combines cancer support groups, individual counseling,

educational seminars, and consultation on insurance problems (Zampini and Ostroff, 1993). Because of its breadth of services and understanding of survivorship issues, PTRP continues to serve as a model to the field of psycho-oncology (Kornblith, 1998).

The oncology treatment service at Baylor University Medical Center (BUMC) currently offers ongoing group support for patients with any type of cancer as well as supportive and educational groups for breast cancer, prostate cancer, and ovarian cancer through the Virginia R. Cvetko Center. Located on the BUMC Dallas Campus, the Cvetko Center was developed to assist cancer patients and their families with understanding and managing the challenges of cancer and currently offers spiritual and emotional support as well as pastoral care. The Cvetko Center is guided by a gynecologic oncologist with a staff consisting of a nurse, multiple chaplains, a social worker, an office assistant, and trained volunteers who are cancer survivors.

The ovarian cancer support group offered at BUMC was developed using a three-armed approach consisting of an educational component, which repeats every nine weeks, coping skills training, and emotional support. The Cvetko Center also offers a closed, nine-week, educational and supportive self-help cancer group, open to all oncology patients regardless of cancer type.

Although the group intervention currently used in the Cvetko Center has met the needs of a number of women, this service has met with the same

recruiting challenges as many other group support programs in cancer centers across the country. As a result, a gap remains in the availability of a service to meet the needs of women who are in need of psychosocial support but who may not be able to attend or may not choose to attend the established group program. In an effort to respond to the requests of evidence-based medicine and to provide the type of service to ovarian cancer patients recommended by the current literature, a service approach offering more flexibility with individual needs is recommended in addition to the well-established group support program.

The purpose of this study was to create an individual psychosocial intervention service to compliment group support and bridge the gap in meeting the needs of ovarian cancer patients treated at Baylor University Medical Center. A two-phase approach was used. In Phase I of this study, a needs assessment was conducted to determine the level of patient interest in adding an individual intervention for women newly-diagnosed with ovarian cancer to the services currently in place within the Cvetko Center, and to compare the psychosocial adjustment needs of our cohort with those reflected in the literature. Perceived barriers and benefits to group participation were also assessed. The intervention used the comprehensive literature review above as well as the results of the needs assessment conducted during Phase I. Phase II of this study evaluates the feasibility and efficacy of implementing an individual psychoeducational intervention designed to target the specific psychosocial needs of ovarian cancer

patients. The intervention employed combines the well-established educational and crisis management components of CBT with a supportive psychotherapy component.

As highlighted in the literature review, most of the longitudinal studies of psychological adaptation in cancer survivors have been done with breast, lung, and head and neck cancer patients. In order to better understand the dynamics of psychosocial adjustment in ovarian cancer patients, additional longitudinal studies are needed, making this prospective, longitudinal pilot study a valuable contribution to the psycho-oncology literature.

Research Questions

This pilot study will address the following research questions:

1. Psychosocial Functioning
    a. Is within-individual variation in the weekly rate of change of psychosocial functioning, during the treatment portion of this study, related to group membership?
    b. Does the within-individual weekly rate of change in psychosocial functioning, during the treatment portion of this study, differ by participant age or number of years of education?

c. Is variation in the weekly rate of change of psychosocial functioning, during the follow-up portion of this study, related to group membership?

d. Does the within-individual weekly rate of change in psychosocial functioning, during the follow-up portion of this study, differ by an individual's psychosocial functioning at the beginning of the study, age, or number of years of education?

e. Are there differences in mean scores for psychosocial adjustment to illness between groups during the treatment or follow-up periods of the study?

2. Depression

a. Is variation in the weekly rate of change in depressive symptoms, during the treatment portion of this study, related to group membership?

b. Does the within-individual weekly rate of change in depressive symptoms, during the treatment portion of this study, differ by participant age or number of years of education?

c. Is variation in the weekly rate of change in depressive symptoms, during the follow-up portion of this study, related to group membership?

d. Does the within-individual weekly rate of change in depressive symptoms, during the follow-up portion of this study, differ by an individual's degree of depression at the beginning of the study, age, or number of years of education?

e. Are there differences in mean scores in depression symptoms between groups during the treatment or follow-up periods of the study?

3. Anxiety

a. Is variation in the within-individual weekly rate of change of state anxiety, during the treatment portion of this study, related to group membership?

b. Does the within-individual weekly rate of change in state anxiety, during the treatment portion of this study, differ by participant age or number of years of education?

c. Is variation in the weekly rate of change of anxiety, during the follow-up portion of this study, related to group membership?

d. Does the within-individual weekly rate of change in state anxiety during the follow-up portion of this study, differ by an individual's level of state anxiety at the beginning of the study, participant age, or number of years of education?

e. Are there differences in mean anxiety symptom scores between groups in the treatment or follow-up periods of the study?

4. Cost-Reduction
    a. Does participation in the individual intervention reduce participant requests for pain and/ or psychiatric medications (anxiety, depression, antipsychotic)?
        i. Are there differences in the amount of money spent on medication by group?
    b. Does participation in the individual intervention reduce the number of non-routine medical office visits?
        i. Are there differences in the amount of money spent on medical office visits by group?
    c. Does participation in the individual intervention reduce the number of participant phone calls to medical office nurses?
        i. Are there differences in nursing time spent on participant phone calls by group?

CHAPTER TWO
Method – Phase I

Subjects

Approximately 50 newly diagnosed ovarian cancer patients have been seen by gynecological oncologists at Baylor each year. These patients ranged in age from 15 to 85 years. Following Institutional Review Board (IRB) approval, patients between the ages of 18 and 80, diagnosed with ovarian cancer, were invited to participate in Phase I of this pilot study. Ovarian cancer patients of all stages and at all points in treatment were invited to participate in this phase of the study in an effort to gain a broad perspective of the psychosocial needs of this patient population. A clinical research coordinator made personal contact with patients during their clinic visits to introduce the study. Information describing the study was given to patients at the initial contact. The information provided to patients included contact information for the clinical research coordinator. Patients were asked to contact the clinical research coordinator by telephone to answer any questions and/ or to arrange an appointment to discuss the study in detail. Informed consent was completed at enrollment. A total of 15 patients were recruited between August 2004 and September 2004 to gather feasibility and program development information.

Inclusion/ Exclusion Criteria

Women between the ages of 18 and 80 who were: (1) diagnosed with ovarian cancer; (2) under the care of the gynecologic oncologists at Baylor or referred by a community oncologist; and (3) English-speaking were eligible for participation in Phase I of this study. Women were excluded from this study if: (1) they were unable to communicate verbally in English; or (2) were known to have an IQ <70 (mental retardation). Every effort was made to include as many minority women as possible.

Instruments of Measure

Demographic Information

The following demographic data were collected at the time of the interview for the purpose of describing the study sample and is included as Appendix A:

Table 2.1

Demographic Information Collected at Enrollment

Current age	Age at diagnosis	Stage of ovarian cancer
Time since diagnosis	Treatments completed	Marital status
Education	Ethnicity	Number of children
Ovarian/ breast cancer family history	Household income	Previous/ current psychiatric medications
Previous/ current psychiatric diagnosis		

The total time needed to administer this questionnaire is two-five minutes.

Needs Assessment

The needs assessment was conducted using a 20-minute semi-structured interview developed for the purpose of this study, which is included as Appendix B. This interview asked participants to rate their interest in discussing topics related to social support, genetics, sexuality, physical changes, infertility, depression, communication, and financial concerns. Topics were rated on a scale from 1 to 11, with 1 being the topic of most importance and 11 being the topic of least importance. Participants were also given the opportunity to provide information on topics that are not mentioned in the topics presented. Participants were asked to rate their willingness to attend individual sessions and to provide feedback on the optimal setting in which to provide an individual intervention (i.e. along with routine clinic visit, coordinated with chemotherapy or radiation visit, etc.). Finally, participants were asked if they were afforded the opportunity to participate in the support group currently offered to ovarian cancer patients in the Cvetko Center. They were asked to comment on the following: (1) if they chose to participate in the support group, what appealed to them the most about that opportunity; and (2) if they chose not to participate in the support group, what were the barriers to their participation.

Procedure

Attending gynecologic oncology physicians with the Texas Oncology Physician Associates (TOPA) group identified potential study participants using the eligibility criteria above. The physicians briefly explained the study to potential participants and facilitated the introduction of the study coordinator during clinic visits or inpatient treatment admissions. The study coordinator explained the purpose of the study in more detail. If patients were interested in participating, the study coordinator obtained informed consent and conducted a 20-30 minute interview using the demographic data form and the semi-structured interview discussed above.

Feasibility and intervention development data were collected using the information obtained from the semi-structured interview from this phase. All patients, whether or not they chose to participate in the study, were provided appropriate referrals for psychosocial support upon request. All patients received standard educational materials pertaining to diagnosis and treatment, which are referenced in Appendix C.

Statistical Considerations

Research Questions

1. What are the perceived barriers to psychoeducational group support participation held by women with ovarian cancer treated at BUMC?
2. Will ovarian cancer patients at BUMC be interested and willing to participate in an individual psychoeducational intervention designed for newly diagnosed women?
3. What are the perceived psychoeducational needs of newly diagnosed ovarian cancer patients at BUMC?

Data Analyses

Much of the data analyzed in Phase I of this study was qualitative in nature. For example, open-ended interview questions solicited participant opinion about why she did or did not attend group. However, standard nonparametric analyses were used to assess willingness to participate in an individual intervention and to determine the outcome of the needs assessment. All analyses were conducted using SPSS version 11.0, Graduate Pack statistical software.

CHAPTER THREE
Method – Phase II

Subjects

A total of 48 women, with stage 3 or 4 ovarian cancer (advanced stage), were invited to consider participation in Phase II of this study. A clinical research coordinator made personal contact with patients during their clinic visits to introduce the study. Information describing the study was given to patients at the initial contact. The information provided to patients included contact information for the clinical research coordinator. Patients were asked to telephone the clinical research coordinator to have questions answered and/ or arrange an appointment to discuss the study in detail, obtain informed consent, and enroll eligible patients. Three women were excluded based on having early (stage I or II), rather than late (stage III or IV) stage disease. Fifteen women declined participation. A total of 30 women were enrolled and randomized into treatment (n=15) or control (n=15) groups in Phase II of this study. Table 3.1 illustrates the demographic representation of the women who participated in Phase II of this study. Patients who participated in Phase I of this study were excluded from Phase II to prevent experimental bias. There were no significant differences between groups in any of the demographic variables assessed.

A total of 15 women were randomized into the control group of the treatment period of this study, and a total of 13 women in the control group completed the treatment period of this study. One participant was dropped from the study at week 4 secondary to acute psychological distress requiring psychiatric medication as well as psychotherapy intervention. One death occurred in the control group secondary to surgical complication during the treatment period of the study. Fifteen women were randomized into the treatment group of the treatment period of this study. Fifteen women in the treatment group completed the treatment period of this study.

The follow-up period began with 13 participants in the control group and 15 participants in the treatment group. During the follow-up period of the study, one participant was dropped from the control group following week 24 of data collection secondary to reporting that completing the questionnaires was "giving her a negative attitude." One death occurred in the control group during the follow-up period of the study. A total of 11 women completed the follow-up period of the study in the control group. Two deaths occurred during the follow-up period in the treatment group, one following week 8 and one following week 24. One participant in the treatment group was lost to follow-up after week 16. A total of 12 women completed the follow-up period of the study in the treatment group.

Inclusion/ Exclusion Criteria

Women between the ages of 18 and 80 who were: (1) diagnosed with advanced stage ovarian cancer (stage 3 or 4) within the prior 120 days; (2) under the care of the gynecologic oncologists practice at Baylor or were referred by community oncologists; and (3) English-speaking were eligible for participation in Phase II of this study. Women were excluded from this study if: (1) they were unable to communicate verbally in English; (2) were known to have an IQ <70 (mental retardation); (3) were in early stage ovarian cancer; (4) were not newly diagnosed, as defined above; (5) were receiving individual or group psychotherapy at the time of enrollment; or (6) participated in Phase I of this study.

Measures

Demographic information was collected upon enrollment in the study for the purpose of describing the study sample. All other measures comprise the study's protocol and were collected at the following time points: enrollment, 4, 8, 16, 24, and 48 weeks after enrollment.

Table 3.1

Demographic Variables for Phase II Participants

		Treatment Group n = 15	Control Group n = 15
Age	*M* (S.D.)	57.47 (8.21)	53.80 (16.20)
Number of Children	*M* (S.D.)	2.53 (2.26)	1.78 (1.62)
Education	*M* (S.D.)	13.79 (2.48)	14.33 (2.92)
Marital status	Married	10	12
	Single	2	1
	Divorced	1	2
	Widowed	2	0
Household Income	< $25,000	3	2
	$25,000 - $50,000	6	2
	$50,000 - $100,000	3	6
	> $100,000	3	5
Ethnicity	Caucasian	11	14
	African American	3	0
	Hispanic	1	0
	Asian	0	1
Breast/ Ovarian	Maternal Only	3	0
Cancer Family	Paternal Only	0	1
History	Maternal & Paternal	2	0
	None	9	12
	Unknown	1	2
Health Insurance	Percentage	100%	100%

Psychosocial Adjustment to Illness

Psychosocial adjustment was measured using the *Psychosocial Adjustment to Illness Survey – Self Report (PAIS-SR 30)* (Derogatis, 1986). The PAIS-SR-30 is a 46-item, self-report questionnaire developed to assess the quality of a patient's psychosocial adjustment to a current medical illness or to the sequelea of

a previous illness. It assesses seven domains of psychosocial adjustment to illness: Health Care Orientation (8 items); Vocational Environment (6 items); Domestic Environment (8 items); Sexual Relationships (6 items); Extended Family Relationships (5 items); Social Environment; and Psychological Distress (7 items). For the purposes of our analyses, we will use only the total score and the psychological distress score for our models.

Psychological Distress (7 items): The final section of the PAIS covers psychological distress, and is designed to measure dysphoric thoughts and feelings that accompany the patient's disorder, or are a direct result of the illness and its sequelae. Major indicators of psychological distress such as anxiety, depression, and hostility, as well as reduced self-esteem, body image problems, and inappropriate guilt are measured in this domain. This subdomain was used for comparison of the construct of depression with the Beck Depression Inventory II.

Each item is rated on a 4 point scale (0-3), with higher scores indicating poorer adjustment. Raw scores are converted to T-scores using normative tables provided in the scoring manual. Participants with a PAIS-SR Total Score equivalent to or greater than a T-score of 62 are positive for clinical levels of psychosocial maladjustment. A sample item from the PAIS-SR 30 is "To what degree has your illness interfered with your duties and tasks around the house?"

Response options are: 0 = no interference; 1 = slight interference; 2 = substantial impairment in some domestic tasks; 3 = marked impairment affecting all or nearly all tasks. Internal consistency estimates range of 0.63 to 0.87, making this a reliable instrument. The PAIS-SR 30 highly correlates (0.81) with the well-known Symptom Checklist 90 Revised (SCL-90-R). The PAIS-R-30 requires approximately 15-20 minutes to complete and was completed at all time points at which measures were taken during the study.

Depression

The construct of depression was measured using the *Beck Depression Inventory (BDI-II)* (Beck, Steer, and Brown, 1996). The BDI-II was developed to measure the behavioral manifestations of depression in adolescents and adults. It was designed to standardize the assessment of depression severity in order to monitor change over time. The BDI-II contains 21 items, each with a series of 4 statements. Statements describe symptom severity along an ordinal continuum from absent or mild (a score of 0) to severe (a score of 3). A sample item for sad mood is "0 = I do not feel sad; 1 = I feel sad; 2 = I am sad all of the time and can't snap out of it; 3 = I am so sad or unhappy that I can't stand it." Overall scores are interpreted as follows: 0-9 = minimal depression; 10-16 = mild depression; 17-29 = moderate depression; 30-63 = severe depression. The BDI-II shows high internal consistency (Cronbach's alpha ranged from 0.76 – 0.95). Validity

correlations with other standard measures range from 0.55-0.96, making the BDI-II a valid instrument for use in this study. The BDI-II requires approximately 5-10 minutes to complete and was completed at all time points at which measures were assessed during the study.

Anxiety

The construct of anxiety was measured using the *Spielberger Anxiety Inventory State and Trait (SAI)* (Spielberger et al., 1980). The SAI State and Trait Anxiety Scale is a self-report measure intended for patients to rate how they feel "now." The Trait scale asks patients to report how they feel in general. Internal consistency is uniformly high (alpha >0.90). This measure is widely used. Norm parameters have been established for adults. The trait scale was given at baseline only. As Trait is descriptive of a stable characteristic, we did not anticipate changes in this measure. However, the State scale was given at all time points as it is a situational-specific measure. The State and Trait scales required approximately 10 minutes each to complete, making the approximate time for completion of this measure at enrollment 20 minutes and the approximate time for completion at subsequent time points, where only the State scale is given, approximately 10 minutes.

Life Events

Information pertaining to positive and negative life events participants may be experiencing during the period of this study was obtained using the *Life Experiences Survey (LES)* (Sarason et al., 1978). The LES is a self-report questionnaire that includes 47 specified items and 3 additional open-ended items on which patients will indicate and rate other recent experiences that may have affected their lives (other than ovarian cancer). Respondents indicate their ratings on a 7 point scale that ranges from extremely negative (-3) through no impact (0), to extremely positive (+3). Patients also indicate whether each event occurred during the past 6 months or during the past 7-12 months. Three scores are derived from the LES: a positive sum scale is obtained by summing impact ratings for items respondents rate as having been slightly (+1), moderately (+2), or extremely (+3) positive, yielding total scores ranging from 1 to 150. A negative change score is obtained by summing items rated by the respondent as being slightly (-1), moderately (-2), or extremely (-3) negative, resulting in scores ranging from -1 to -150. Items rated as having no impact (0) do not contribute to either positive or negative change scores. A total change score can be obtained by adding the positive or negative change scores, yielding scores that range from -150 to +150. The LES yields moderate reliability scores (0.63). The LES requires approximately 10 minutes to complete and was completed at all data collection time points of the study. However, because there was considerable inconsistency

within subjects in completing the measure per instructions, only the baseline LES was used in analyses. Rather than using the scores derived from the LES, the total number of life events acknowledged by each participant was used for the purposes of our analyses.

Response to Treatment

Response to standard medical treatment was assessed using the Karnofsky Performance Rating Scale (Karnofsky and Burchenal, 1949). This scale is commonly used for assessing functional physical status in oncology patients. The Karnofsky Scale index allows patients to be classified as to their level of functional impairment. The Karnosky Scale consists of ratings from 0 – 100, with lower scores representing worse survival for most serious illnesses. Scores between 100 – 80 indicate the patient is able to carry on normal activity, including normal work activities, and no special care is needed. Scores between 70 – 50 indicate that the patient is unable to work but is able to live at home and care for most personal needs, with varying amounts of assistance needed. Scores in the range of 40 – 10 indicate that the patient is unable to care for herself and requires the equivalent of institutional or hospital care. Scores approaching 10 indicate rapid progression of disease. A score of 0 is equal to death. This classification system is often used to compare the effectiveness of different oncology treatment

modalities and to assess the prognosis in individual patients. The Karnofsky Scale score was assigned at enrollment, week 8, week 16, week 24, and week 48.

Table 3.2

Summary of the Study Protocol Corresponding to the Number of Weeks after Enrollment the Data were Collected

	Timeline						
	Treatment Phase			Follow-up Phase			
Measure	Enrollment	WK 4	WK 8	WK 16	WK 24	WK 48	Time[g]
Demographics	X						5 min
Psychosocial adjustment (PAIS-SR)[a]	X	X	X	X	X	X	20 min
Depression (BDI-II)[b]	X	X	X	X	X	X	10 min
Trait Anxiety (SAI-trait)[c]	X						10 min
State Anxiety (SAI-state)[d]	X	X	X	X	X	X	10 min
Life Events (LES)[e]	X	X	X	X	X	X	10 min
Response to Medical Treatment[f]	X		X	X	X	X	5 min

[a]Derogatis, 1986 [b]Beck et al., 1996 [c]Spielberger, 1980 [d]Spielberger, 1980 [e]Sarason, 1978
[f]Karnofsky, 1949
[g]Estimated time of administration

Procedure

Following obtaining informed consent, patients were randomized into the treatment group or a control group. A log was kept to track all of the patients approached about participating in this study, which is included as Appendix D. The log included: (1) if prospective participant met eligibility criteria; (2) if they did not meet eligibility criteria, why; (3) whether or not the patient chose to participate; (4) date of consent and enrollment; and (5) group status (treatment vs. control). All patients were assigned a study identification number. No patient names were used on study documents to preserve confidentiality. All study documents were kept in a locked file, behind a locked door.

Treatment Group

The treatment group received 8 individual psychoeducational intervention sessions. Sessions were conducted weekly for a period of 60 minutes (30 minutes education, 30 minutes psychotherapeutic support). Baseline measures were completed during the enrollment visit, which was prior to the beginning of treatment. Participants completed the study protocol (refer to Table 3.1) during both the treatment and follow-up portions of the study. Specifically, all measures, with the exception of demographic, trait anxiety, and response to treatment information, were completed at enrollment, 4 weeks, 8 weeks, 16 weeks, 24 weeks, and 48 weeks after enrollment. Demographic information and trait anxiety

were collected at enrollment. Response to treatment information was collected at enrollment, 8 weeks, and 48 weeks after enrollment. Baseline, week 4 and week 8 measures were completed immediately following intervention visits. Measures taken at additional time points were mailed to participants to complete. A self-addressed, postage paid envelope was included, in which participants were able to return the measures by mail at no cost to them. Follow-up phone calls were made to assist with assuring follow-up data was gathered in a timely manner.

Control Group

Participants in the control group did not receive individual psychoeducation intervention sessions. Instead, following obtaining informed consent and completing baseline measures, the control group participants were given educational materials pertaining to diagnosis and treatment as is standard of care (Appendix C). As with the treatment group, baseline measures were completed during the enrollment visit. Participants completed the study protocol measures (refer to Table 3.1) at 4 weeks, 8 weeks, 16 weeks, 24 weeks, and 48 weeks after enrollment. Baseline measures were completed in person at the time of enrollment. All subsequent measures were mailed to participants to complete. A self-addressed, postage paid envelope was included, in which participants were able to return the measures by mail. Follow-up phone calls were made to assist with assuring follow-up data was gathered in a timely manner.

Participants in the control group were asked to refrain from attending the Cvetko Center ovarian cancer support group or any other self-help group during the time they were enrolled in the study. If at any time point during the study period, a patient in the control group expressed the need to begin psychosocial interventions, she was dropped from the study and immediately provided a list of appropriate referral sources for individual or group therapy. Following the conclusion of the treatment phase for both groups, appropriate referrals were made upon request for additional psychosocial services.

Intervention

The psychoeducational intervention was conducted in individual sessions. Sessions were conducted once weekly for a period of 8 weeks. Each session consisted of an educational component, standard for each patient, lasting approximately 30 minutes, followed by approximately 30 minutes of psychosocial support. In an effort to preserve a high level of standardization, all intervention sessions were conducted by the same therapist, who is a licensed professional counselor. Intervention topics were determined by a combination of a thorough literature review (as detailed in Chapter I) and the outcome of Phase I of this study (detailed in Chapter IV), and are outlined in Table 3.3.

Table 3.3

Individual Intervention Session Topic Outline

Timeline	Intervention Topic
Session 1	Enrollment/ orientation & developing rapport/ opportunity for participant to tell her story
Session 2	Impact of the diagnosis
Session 3	Communication with treatment team
Session 4	Depression & anxiety
Session 5	Behavioral techniques for managing anxiety
Session 6	Spirituality & concerns about death
Session 7	Relationships with significant others
Session 8	End of treatment issues/ wrap up & closure

Session 1: Introduction

The primary objectives of the initial session were to: (1) establish rapport; (2) establish ground rules and explain the limits of confidentiality; and (3) allow the participant the opportunity to tell her story beginning with the first symptoms she experienced to the point she was then at in treatment.

Session 2: Impact of the Diagnosis

The primary objective of Session 2 were to: (1) guide the participant to label and normalize feelings and emotions experienced as a result of receiving the ovarian cancer diagnosis; (2) reduce physical and psychological distress by helping the participant link psychological distress with physical manifestations;

(3) assist the participant in accessing coping skills through real life examples of positive and negative coping styles; and (4) validate the participant's experience and the impact the diagnosis and treatment have had on her life.

Session 3: Communication with the Treatment Team

The primary objectives of Session 3 were to educate the participant on her rights and responsibilities as a patient and to provide instruction for the basic skills needed to actively participate in treatment decision-making. Potential barriers to effective communication were identified. Participants were also encouraged to seek information in the amount they felt they could comfortably process and at a pace that was comfortable for them.

Session 4: Depression

The focus of Session 4 was to demystify depression and attempt to remove some of the social stigmas associated with the disorder. Objectives included: (1) explain the possible origins of depression using situational examples as well as the biochemical premise behind the disorder; and (2) introduce and demonstrate life charting to provide the participant with a tool to improve insight into her mood changes as well as to provide her something tangible to help her explain her current symptoms to her treating physician should she seek intervention for depressed mood.

Session 5: Behavioral Techniques for Managing Anxiety

In Session 5, the participants were introduced to the use of behavioral techniques to manage anxiety and physical discomfort. The primary objectives of the session included: (1) familiarize the participant with behaviorally-based interventions to reduce stress, anxiety, and pain; (2) reinforce the link between emotions and physical symptoms; and (3) introduce relaxation techniques using a guided body scan.

Session 6: Spirituality

This session is placed late in the progression of sessions in order to allow ample time for therapist and participant to build an alliance of trust and for rapport to be well established. Session 6 was designed by Dr. Jann Aldredge-Clanton, a chaplain on staff at BUMC, included the following objectives: (1) discuss spiritual questions raised for the patient through her ovarian cancer experience; (2) explore sacred images and their impact on spiritual experience; (3) discuss feelings of guilt and forgiveness; (4) explore the spiritual dynamic of hope; and (5) identify spiritual resources.

Session 7: Relationships with Significant Others

The primary objectives of Session 7 were to: (1) discuss the impact of the participant's illness on her relationships with her primary support system; (2) discuss the difficulties experienced by individuals within her primary support system and how those difficulties have impacted the participant; and (3) through

an exercise using diagrams of the participant's life at three different time points: pre-diagnosis, current time, and ideal, discuss how priorities have shifted since the ovarian cancer diagnosis and begin to explore achieving desired balance in those priorities.

Session 8: Termination of Treatment Issues and Wrap-Up

The primary focus of this final session is to recap the previous sessions and provide the participant with the opportunity to continue to process any issues that have come up during the course of the previous seven sessions. A secondary objective of this session is to normalize the anxiety a participant may feel regarding the end of medical treatment. Participants were also given information about the group support program and encouraged to attend at least once to assess whether or not it they would feel comfortable in that setting. Additional psychosocial service referrals were provided if requested by the participant. Issues pertaining to terminating therapy were addressed, including a discussion of the remaining steps in the study and what the participant could expect during the follow-up phase of the study.

Statistical Considerations

Rationale for Growth Modeling

This study sought to characterize within-individual change over time with respect to the attributes of interest, psychosocial functioning for instance, and to evaluate whether treatment and demographic information had systematic impact on the individual rates of change of participants. Traditional repeated measures multivariate techniques were not the analyses of choice for several reasons enumerated below. Instead, a more flexible approach was adopted.

First, an important consideration for this data set is that the statistical method chosen for the analysis must allow for flexibility in the timing of data collection. Every attempt has been made to schedule intervention visits and data collection points as similarly as possible, but the flexibility of the individual intervention allows for intervention visits to be scheduled along with chemotherapy, laboratory, and physician office visits in order to make attending the sessions more convenient for study participants. As such, patient 201 may attend an intervention visit on Friday of one week and then attend a second visit on Wednesday of the next week, depending on the schedule of other treatment related appointments. A similar problem arises within the control group as participant measures are mailed at equally scheduled intervals; however, the measures may not actually be completed at equal intervals. For example, patient

205 may receive her measures on the scheduled date but may not complete and return those measures until several days later.

Traditional repeated measures multivariate approaches compare the means of different groups at specific time points in a given data set and require that there be no variability between study participants with respect to the spacing of data collection points as well as baseline scores. Repeated measures multivariate analysis also requires that there be equal numbers of participants in each group in the comparison. As Figure 3.1 illustrates, there is variability in the spacing of intervention sessions, which are also data collection points in this study.

Second, using traditional repeated measures multivariate analysis, we would be unable to use the data from this subject at the week 8 time point. Excluding that time point for that participant would result in unequal numbers between the treatment and control groups. Figure 3.1 also demonstrates the considerable variability in the level of state anxiety each participant in this study reports at the point at which they entered the study. Unlike other studies that measure change in symptoms of depression or anxiety in a sample of patients who enter the study with a similar degree of distress, the participants in this study are not homogenous with respect to baseline outcome measures. Neither are they homogenous in patterns of change over time. Notice that the four week time point shows anxiety ratings clustered in two separate groups, one group reporting low anxiety ratings and the second group reporting high anxiety ratings. For this

particular time point, a comparison of means would be meaningless as taking the mean of the reported scores would result in a mean anxiety rating that is not truly reflective of study participant report. Because the data set for this study does not meet the assumptions for repeated measures multivariate analysis of variance, the use of traditional repeated measures multivariate statistical approaches, such as repeated measures MANOVA, would provide little information with respect to individual change over time for participants in this study.

Figure 3.1

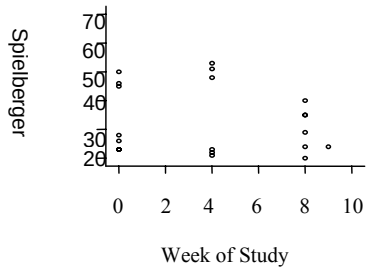


Figure 3.1. Illustrates variability between individual participants with respect to level of anxiety at enrollment, clustering of anxiety scores at week 4, and the variability in spacing of data collection points, where one participant completed the State anxiety measure at week 9 rather than week 8.

Finally, multivariate analyses are more robust with large patient samples. As this is a pilot study with a population of patients representing only 4% of all

cancer patients, obtaining a sufficient sample size from one treatment site would be quite difficult. Long (1997) recommends a minimum of 100 individuals and labels sample sizes of 500 as "adequate" with respect to multivariate analyses in cross-sectional work. However, Snijders and Bosker (1999) consider a sample size of 30 or more to be large for general hierarchical model analysis in longitudinal studies. As this is a longitudinal study with a sample size of 30, the more flexible approach of hierarchical linear modeling, discussed in detail below, is more likely to accurately represent individual change over time than would multivariate analyses.

A more flexible approach, such as growth modeling, is more suited to this study. Singer and Willet (2003) provide three basic criterion longitudinal data sets must meet in order to conduct hierarchical modeling analyses: (1) there must be three or more data collection points in the study; (2) there must be an outcome whose values change systematically over time; and (3) a sensible metric for clocking time must exist. Our study meets all three requirements with a minimum of three data collection points in the treatment phase (baseline, week 4, week 8) and the follow-up phase (week 16, week 24, week 48), the use of multiple outcome variables measured by standardized valid and reliable instruments, and enrollment weeks in the study as the clocking metric.

A two-level hierarchical model for change over time, known as growth modeling, was used. First an observed growth record for each participant in the

study for each variable of interest was assembled. The growth plots may be summarized by fitting a suitable individual growth model to the data for each participant. Since there were 3 waves of data in the treatment phase, each participant's growth plot was summarized with a linear model. Descriptive analyses were used to determine how well the linear model fits the data. The first level of analysis describes, for each participant, within-individual change over time. The second level describes the amount of variance in individual change that may be attributed to specific factors. For example, in this study, factors assessed included the variance in individual change attributable to the participant's group assignment (treatment versus control) and demographic information. Data collected at baseline, week 4, and week 8, were used to create growth models for the treatment phase of this study. A second growth model was created to represent change over time during the follow-up period, using data collected at weeks 16, 24, and 48.

Level One Model

The level one component of the growth model represents the individual change over time with respect to the attribute of interest. The level one model is also referred to as the within-person growth model. This level of the growth model describes the weekly rate of change for the attribute of interest for each individual study participant. For example, Figure 3.2 illustrates the degree of

variability in within-individual per week rate of change in psychosocial adjustment, which reinforces the perception that individual change over time in this population is idiographic. Note that one individual made no change over time, another had positive change, and yet another had negative change. In this study, it was hypothesized that psychosocial adjustment exhibited by individual study participants at a given time point can be expressed as a linear function of the week of the study and is represented by the equation below:

$$\text{Psychosocial Adjustment} = \{\pi_0 + \pi_1(\text{week})\} + \text{error}$$

where π_0 (intercept) represents functioning at time one, (baseline for the treatment phase growth model; week 16 for the follow-up phase growth model), and π_1 (slope) represents per weekly change in psychosocial functioning. Thus, the level one model yields two parameters, the intercept and the slope of the linear model. It was necessary to re-center initial status so that more substantive questions may be asked. For example, subtracting 8 weeks, the parameter estimate π_0 in the equation "Psychosocial Adjustment = $\{\pi_0 + \pi_1(\text{week} - 8)\}$ + error" represents the end of treatment rather than initial status. Similarly, subtracting 4 weeks, the parameter estimate π_0 in the equation "Psychosocial Adjustment = $\{\pi_0 + \pi_1(\text{week} - 4)\}$ + error" represents the participant's status at

week 4 rather than initial status. Re-centering was used as a valuable tool for the purposes of creating a growth model to evaluate the weekly rate of change for the attribute of interest for each individual study participant in the follow-up portion of this study (Table 3.4).

Table 3.4

Example of Re-centered Level One Growth Model Equations

Follow-up Time Point	Level One Growth Model Equation
Week 16	Psychosocial Adjustment = $\{\pi_0 + \pi_1(\text{week} - 16)\}$ + error
Week 24	Psychosocial Adjustment = $\{\pi_0 + \pi_1(\text{week} - 24)\}$ + error
Week 48	Psychosocial Adjustment = $\{\pi_0 + \pi_1(\text{week} - 48)\}$ + error

Figure 3.2

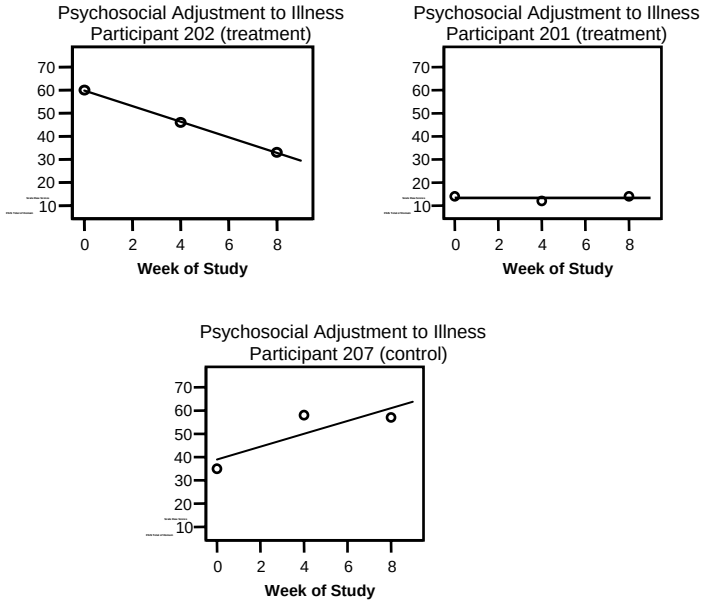


Figure 3.2. Illustrates the degree of variability in within-individual per weekly rate of change over time for psychosocial adjustment to illness.

Note: Higher scores on the PAIS-SR suggest poorer psychosocial adjustment.

Figure 3.3, below, illustrates what would be seen, looking only at between group differences without accounting for individual change over time. Whereas relying only on the comparison of means seen in Figure 3.3, one might assume that all participants of each group had similar rates of change in psychosocial adjustment at each data time point. Thus, the substantive individual participant information within each group (Figure 3.2) might be missed, indicating that individual participants entered the study at quite different levels of psychosocial adjustment, and that the rate of change over time was unique to each individual.

Without such information, it is more difficult to understand the characteristics that impact the efficacy of the intervention that is being evaluated.

Figure 3.3

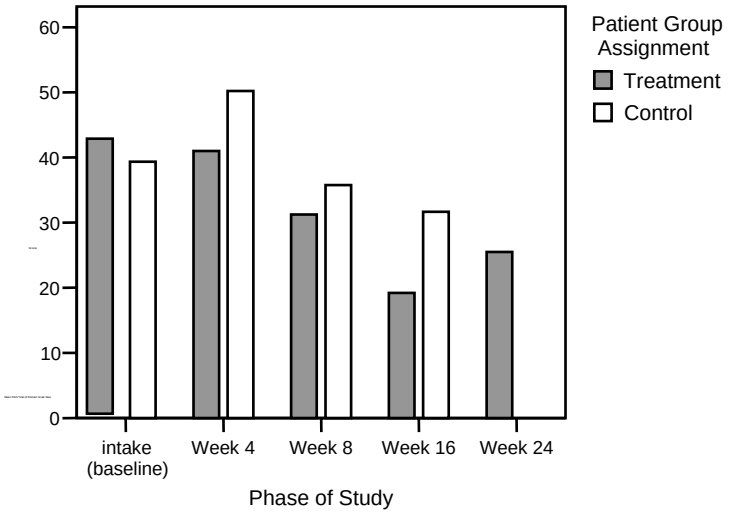


Figure 3.3. Comparison of means of overall psychosocial adjustment between treatment and control groups at enrollment, and weeks 4, 8, 16, and 24 of the study.

Note: Higher scores on the PAIS-SR suggest poorer psychosocial adjustment.

Level Two Model

A second level of investigation allowed examination of the degree to which individual effects for each person differ systematically across people. For example, the level two model allowed assessment of the degree to which

individual changes in psychosocial adjustment are related to group assignment (treatment versus control). The level two model is represented by the following equations:

$$\text{Psychosocial Adjustment } (\pi_{0i}) = \{\beta_{00} + \beta_{01}(\text{GROUP})\} + \text{error}$$

And

$$\text{Psychosocial Adjustment } (\pi_{1i}) = \{\beta_{10} + \beta_{11}(\text{GROUP})\} + \text{error}$$

Individually, the above two equations resemble regular regression models. Note that the outcome variables in the level two model, π_{0i} and π_{1i}, were the parameter estimates in the level one model. Thus, the level two models use the intercept from the level one model (π_{0i}), which is variation in initial status, and the slopes from the level one models (π_{1i}), which is the variation in the rate of change, as a factor of the outcomes variables that may be associated with the predictor, GROUP (treatment versus control). Furthermore, data collected during this study allowed assessment of outcome as a function of a number of predictors, for example: level of functioning at beginning of study, socio-demographics, and response to treatment. In this way, the differences in within-individual participant change, can be assessed, which may be important to address in order to make adjustments to our individual psychoeducational intervention for ovarian cancer

patients, that is flexible enough to meet the needs of a broad spectrum of individual patients.

Repeated Measures Analysis of Variance (ANOVA)

As discussed at length, repeated measures ANOVA is limited in its ability to address our research questions related to within-individual rate of change over time; however, it does allow us to address, on average, treatment differences between groups. For the purpose of comparing the data analyses with and without accounting for within-individual change, we conducted repeated measures ANOVA in two models, treatment and follow-up, outcome measures for psychosocial adjustment to illness, depression symptoms, and state anxiety symptoms. The treatment model ANOVA consisted of a between group comparison of outcome measure data collected at baseline, week 4, and week 8. The follow-up model ANOVA consisted of a between group comparison of outcome measure data collected at week 16, week 24, and week 48.

Cost Analyses

In order to most efficiently assess differences in the number of pain or psychiatric medication (anxiety, depression, antipsychotic) prescriptions provided to participants in the treatment versus control groups, participants were asked to report whether or not they used any medications for pain or psychiatric reasons

during the study period. The number of medications in each category (pain, anxiety, depression, antipsychotic) prescribed for each participant was documented via self-report by participants. The sum of all medications in each category prescribed for each group was tallied and used for comparison.

As this study was also interested in assessing any potential cost-reduction effects, pricing information for all of the prescribed medications was obtained from frequently used pharmacy internet websites. An average of the dollar amount obtained from the websites was used to assess differences in medication cost between groups.

A final interest of investigation in this study was assessing possible reduction in "non-routine" office visits and phone calls as a result of providing this individual intervention. Study participants were asked to report the number of medical office visits they scheduled and attended during their participation in the study. The cost of a physician office visit from the Texas Oncology Physician Associates (TOPA) accounts receivable was noted to be $82.00. TOPA nursing staff reported that patient phone calls take an average of 15 additional minutes of their time per phone call. Nursing time defined the cost-related outcome for participant phone calls. The cost of nursing time is defined as $25.00 per hour. The estimated cost of phone calls was calculated at $6.25 of nursing time per call, which is the equivalent of 15 minutes of nursing time.

Data Analyses

The data base for this study was designed at the beginning of data collection in 2004 using SPSS (11.0). All data analyses were conducted using the updated version, SPSS (14.0). Growth modeling analyses were conducted per Singer and Willet (2003). SPSS Syntax for the models was written by Lisa Fitzgibbons, Ph.D., Research Director at Green Oaks Center for Neuropsychiatric Study using Singer and Willet (2003) as a guide. Empirical growth graphs were created by Statistical Solutions, Inc.

CHAPTER FOUR
Results – Phase I

Description of Subjects

A total of fifteen women with a diagnosis of ovarian cancer, participated in Phase I of this study. The mean age of participants was 58.53 years, and the mean time since diagnosis was 32.40 months. The mean level of education was 15.0 years. On average, participants had 2.00 children. All participants in Phase I of this study were covered under health insurance.

Table 4.1

Phase I Demographic Data

			Range	
Demographic Variable	M	SD	Min	Max
Age at interview	58.53	10.80	39	72
Age at diagnosis	56.00	10.61	37	70
Time since diagnosis in months	32.40	27.60	2	108
Education level	15.00	2.50	12	20
Number of children	2.00	1.99	0	4

The participant sample is limited in terms of ethnicity and socioeconomic status as 14 of 15 participants in Phase I were Caucasian and 1 of 15 was American Indian. Six of fifteen participants reported a household income of

> $100,000 per year, 6 of 15 reported a household income of $50,000 - $100,000 per year, 2 of 15 reported a household income of $25,000 - $50,000 per year, and 1 of 15 reported an income of < $25,000 per year. Fourteen of 15 participants (93.3%) were married and 1 of 15 participants (6.7%) was divorced.

Stage of diagnosis was distributed as follows: stage "X" (pt reported being unaware of staging) = 2 of 15 participants; stage 1 = 2 of 15 participants; stage 3 = 8 of 15 participants; and stage 4 = 3 of 15 participants.

All participants underwent chemotherapy (15 of 15), 14 of 15 participants underwent surgery, 1 of 15 participants underwent radiation treatment, and 2 of 15 participants underwent a bone marrow stem cell transplant as part of treatment. Forty percent (6 of 15) of participants had a positive family history for breast cancer and 13.3% (2 of 15) of participants had a positive family history for ovarian cancer.

Current Service Participation and Awareness

Participants were asked a series of questions regarding participation in support services currently offered at Baylor University Medical Center (BUMC) and elsewhere in their communities. The sample was relatively evenly split with regard to participation in the group program offered at the Cvetko Center with 7 of 15 study participants currently participating in the ovarian cancer support group and 8 of 15 study participants not currently participating. The majority of

participants in Phase I endorsed awareness of the opportunity to participate in the support group at BUMC (13 aware; 2 unaware). This split in group participation is not unexpected as group participants were afforded the opportunity to participate in this phase of the study to further our understanding of individual perceptions of group participation. Upon query as to why 8 of 15 of study participants chose not to participate in group support, the following themes emerged: (1) inconvenient to personal schedule; (2) not ready to hear about the difficulties of others, especially with regard to recurrence; (3) feeling that the group environment is not confidential; (4) not wanting to appear to others (specifically family) as if not handling diagnosis well; (5) feeling of having adequate social support; and (6) equating participation in any kind of psychological service as a lack of faith in God to heal them. When asked to report participation in psychological support services outside of the support group, 1 of 15 study participants reported seeing a counselor or social worker in individual therapy, 2 of 15 reported seeing a psychiatrist for depression or anxiety medication and therapy, and 1 of 15 reported seeing a minister regularly for pastoral counseling.

Interest & Willingness to Participate in Individual Intervention

The individual intervention model was described to all participants in Phase I, and they were then asked if they would have been interested in

participating in such a service if it had been available to them at the time of diagnosis. The majority of participants (13 of 15) reported that they would have liked to have an individual service available at the time of diagnosis whereas 2 of 15 participants reported that they would have declined participation in such a service. Of those who affirmed willingness to participate in an individual intervention, 12 of 13 study participants listed privacy as the primary attractive component, and 1 of 13 listed avoiding the negative emotions of others as the primary attractive component.

Participants rated the content of the individual interventions on a scale of 1 to 11, with 1 being the most important and 11 being the least important topic to discuss. The topics shaded in Table 4.2 below represent the six topics rated as most important to include in the individual intervention. Cognitive dulling, listed at the bottom of Table 4.2, was offered spontaneously by participants and was the number one concern of all participants; however, given the limitations of the study design, this topic was not included but will be evaluated in a future investigation.

Table 4.2

Participant Ratings for Intervention Topics

Topic	M	SD
Spirituality	3.33	3.03
Depression/ Anxiety	5.40	2.74
Body Image	8.33	2.28
Sexuality	7.26	2.65
Communication w/team	4.33	2.66
Genetics & heritability	6.93	2.81
Impact on family	4.06	2.21
Concerns about death	6.26	3.63
Relaxation techniques	7.80	2.88
Relationships with significant others	3.80	1.69
Financial concerns	8.73	2.34
Cognitive dulling[a]	1.00	0

Note: Participants rated items on a scale from 1 to 11, with 1 being the most important. Shaded items indicate the 6 highest ratings, which were translated into intervention sessions.
[a]Cognitive dulling, also known as "chemo brain", was added spontaneously by all interviewees.

Eighty percent (12 of 15) of participants reported that they would find the flexibility of scheduling individual interventions around already scheduled office and treatment visits very appealing. Participants were asked to define the time period from diagnosis in which they would have been most receptive to participation in an individual service. The majority of participants (9 of 15)

reported they would have liked to have been offered this service immediately upon diagnosis, 3 of 15 participants reported believing they would have been more willing to participate approximately 30 days from the time of diagnosis, allowing them time to process the diagnosis, and 3 of 15 participants reported believing they would have liked to begin an individual intervention approximately six to eight weeks following diagnosis, allowing them time to begin treatment and adjust to the side effects. The majority of participants (13 of 15) reported the optimal length of the session to be one hour, 1 of 15 participants endorsed a 45 minute session, and 1 of 15 participants endorsed a 30 minute session. Therapist gender preference was relatively evenly split with 8 of 15 participants preferring a female therapist and 7 of 15 participants having no preference so long as the therapist was a licensed professional with appropriate experience in counseling oncology patients.

Finally, participants were asked what a reasonable fee would be to charge for an individual service if payment became crucial to the ability to provide this service to women beyond this study. The distribution is as follows: 1 of 15 participants endorsed a fee of $10.00 per session, 7 of 15 participants endorsed a fee of $25.00 per session, 4 of 15 participants endorsed a fee of $50.00 per session, and 3 of 15 participants endorsed a fee of $75.00 per session. All participants (100%) endorsed approval of billing their insurance companies for participation in an individual psychoeducational support service if possible.

Phase II sessions (Table 3.2) were designed using the combination of the literature review above and the outcome data from Phase I.

CHAPTER FIVE
Results – Phase II

Psychosocial Adjustment to Illness

Descriptive Statistics of Observed Data

The distribution of observed total scores for psychosocial adjustment to illness is presented in Figure 5.1. Psychosocial adjustment to illness varied both within and between groups at each wave of data collection. Figure 5.1 (a) illustrates both the central tendency and the dispersion of individual scores for total psychosocial adjustment to illness by group at each time point of the study. The shape of the distribution of scores for psychosocial adjustment to illness in the treatment group at baseline is slightly negatively skewed with more participants endorsing psychosocial adjustment above the mean of 59.16 than below compared to the more symmetrical nature of the reported scores in the control group, with a mean of 60.53. A T score of $\geq$62 is indicative of the "unhealthy" range of psychosocial adjustment to illness. The treatment group evidenced slightly more variability around than mean (SD=10.73; interquartile range = 19) than does the control group (SD=8.65; interquartile range = 12.0). At week 4 of the treatment period of the study, the control group's mean increased to

64.53 placing it in the "unhealthy" range of psychosocial adjustment to illness whereas the treatment group's mean of 59.20 remained relatively stable from baseline. The shape of the distribution for the treatment group was more symmetrical at week 4, and the control group's distribution shape was slightly negatively skewed. The treatment group continued to evidence greater variability around the mean (SD=10.63; interquartile range = 18.0) as compared to the control group (SD=7.34; interquartile range = 8.0). At the end of the treatment period of the study (week 8), the control group evidenced a slight decline in psychosocial adjustment to illness scores with a mean of 61.23, which placed the group slightly below the cutoff point into the "healthy" range of psychosocial adjustment to illness. The treatment group evidenced a slight increase in central tendency (mean = 56.60) but remained within the healthy range of psychosocial adjustment to illness. The shape of the distribution of scores for the treatment group continued to be relatively symmetrical whereas the shape of the distribution of scores for the control group at week 8 appeared positively skewed, with more control group participants endorsing psychosocial adjustment to illness below the mean of 61.23 than above. The treatment group continued to evidence slightly greater variability around the mean (SD=11.76; interquartile range = 24) as compared to the control group (SD=8.41; interquartile range = 8.0). At week 16, the beginning of the follow-up period, both groups evidenced a decline in mean scores for psychosocial adjustment to illness (treatment = 54.78; control = 53.30).

The shape of the distribution of scores for the treatment group was negatively skewed whereas that of the control group was relatively symmetrical. The variability in scores around the mean for both groups was similar (treatment SD=12.26; interquartile range = 20.5; control SD=10.72; interquartile range = 20.0). At week 24, the shape of the distributions of both groups was negatively skewed. Both groups evidenced a decline in mean psychosocial adjustment to illness scores (treatment = 38.30; control = 47.00), and the variability around the mean also remained similar in both groups (treatment SD=11.07; control SD= 12.30). At the final data collection point of the study (week 48), the treatment group evidenced a relatively symmetrical distribution of scores compared to the negatively skewed distribution of scores for the control group. Although, on average, both groups endorsed psychosocial adjustment within the healthy range of functioning, the treatment group evidenced a slight decline (improvement) from week 24 whereas the control group evidenced a slight increase (worsening) from week 24 (36.58 and 51.18, respectively). The treatment group evidenced less variability around the mean at week 48 (SD=8.63) than did the control group (SD=18.78). Figure 5.1 (b) further illustrates the individual variability in scores across all six time points of the study by representing individual scores within groups at each time point. Figure 5.1 (b) more clearly demonstrates that the majority of individuals within both groups endorsed total psychosocial adjustment to illness scores within the healthy range ($T < 62$) by the end of the follow-up

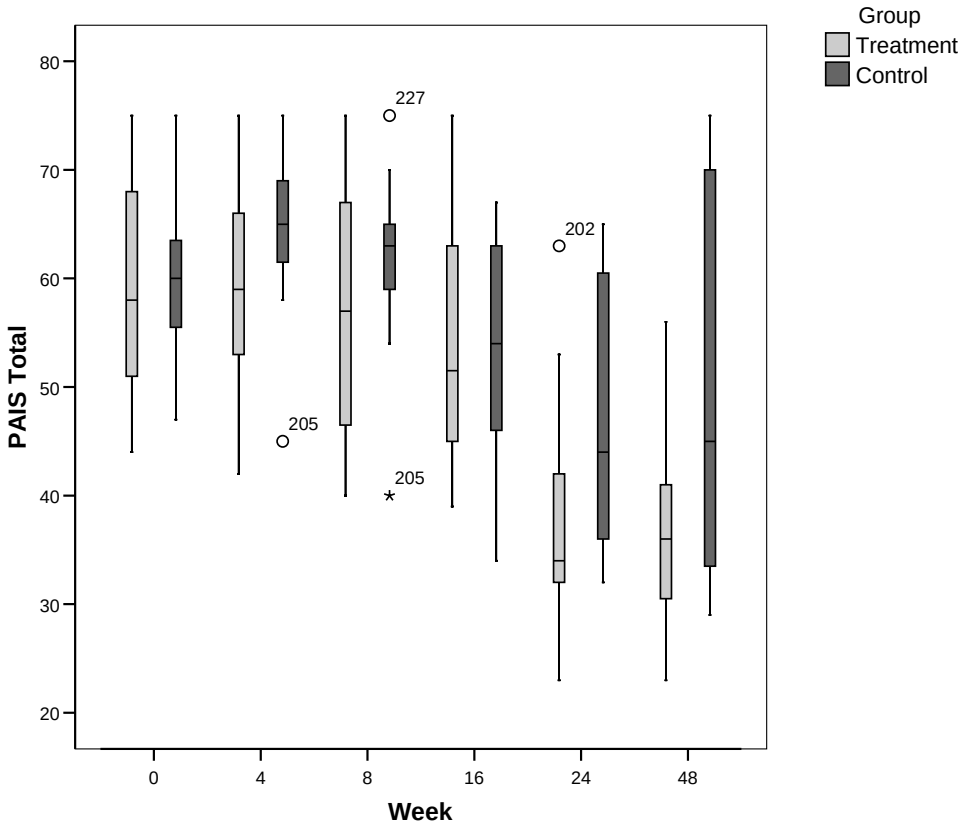
period. Figure 5.1 (c) represents the individual growth of all participants across the study and nicely illustrates the within-individual variability in patterns of change in psychosocial adjustment to illness.

Table 5.1

Descriptive Statistics for the Total Score of the Psychosocial Adjustment to Illness Scale- Self Report (PAIS-SR)

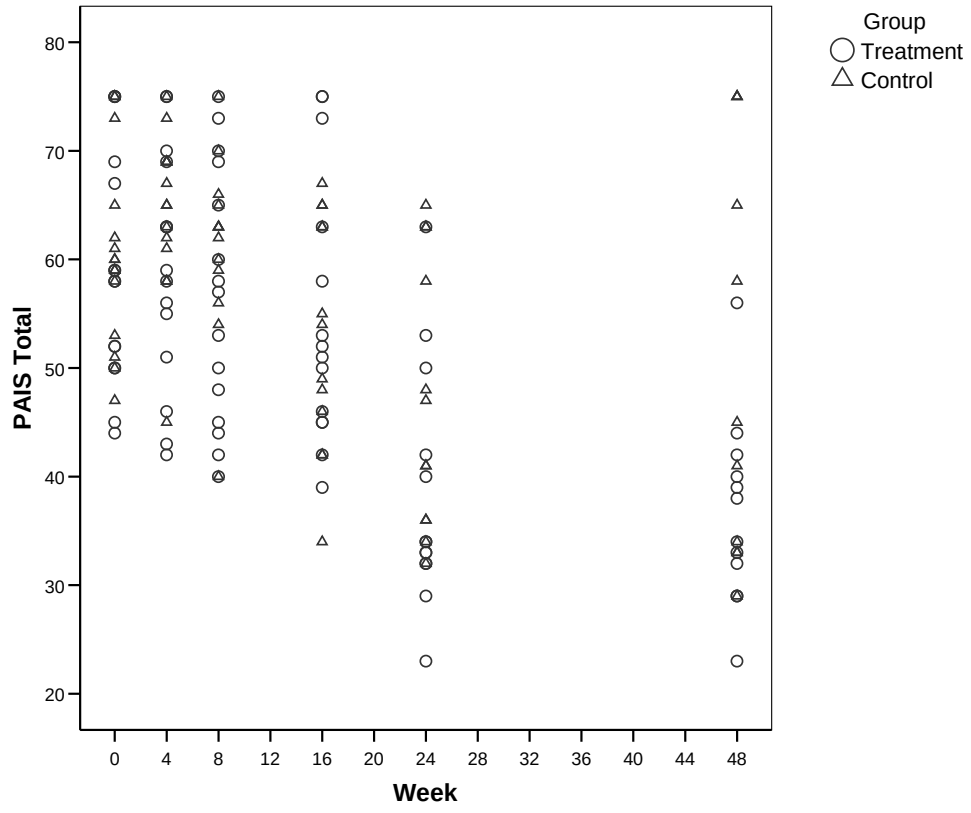
PAIS-SR Total Score	Group	Mean	Median	SD	Min	Max
Treatment Phase						
Baseline	Treatment	59.20	58.00	10.73	44	75
	Control	60.53	60.00	8.65	47	75
Week 4	Treatment	59.20	59.00	10.63	42	75
	Control	64.53	65.00	7.34	45	75
Week 8	Treatment	56.60	57.00	11.76	40	75
	Control	61.23	63.00	8.41	40	75
Follow-Up Phase						
Week 16	Treatment	54.78	51.50	12.26	39	75
	Control	53.30	54.00	10.72	34	67
Week 24	Treatment	38.30	34.00	11.07	23	63
	Control	47.00	44.00	12.30	32	65
Week 48	Treatment	36.58	36.00	8.63	23	56
	Control	51.18	45.00	18.78	29	75

Figure 5.1 (a)



Note: Distribution and central tendency of total scores for psychosocial adjustment to illness by group across all six waves of data collection. Outliers, or extreme scores, that may require special consideration are denoted by patient identification number.

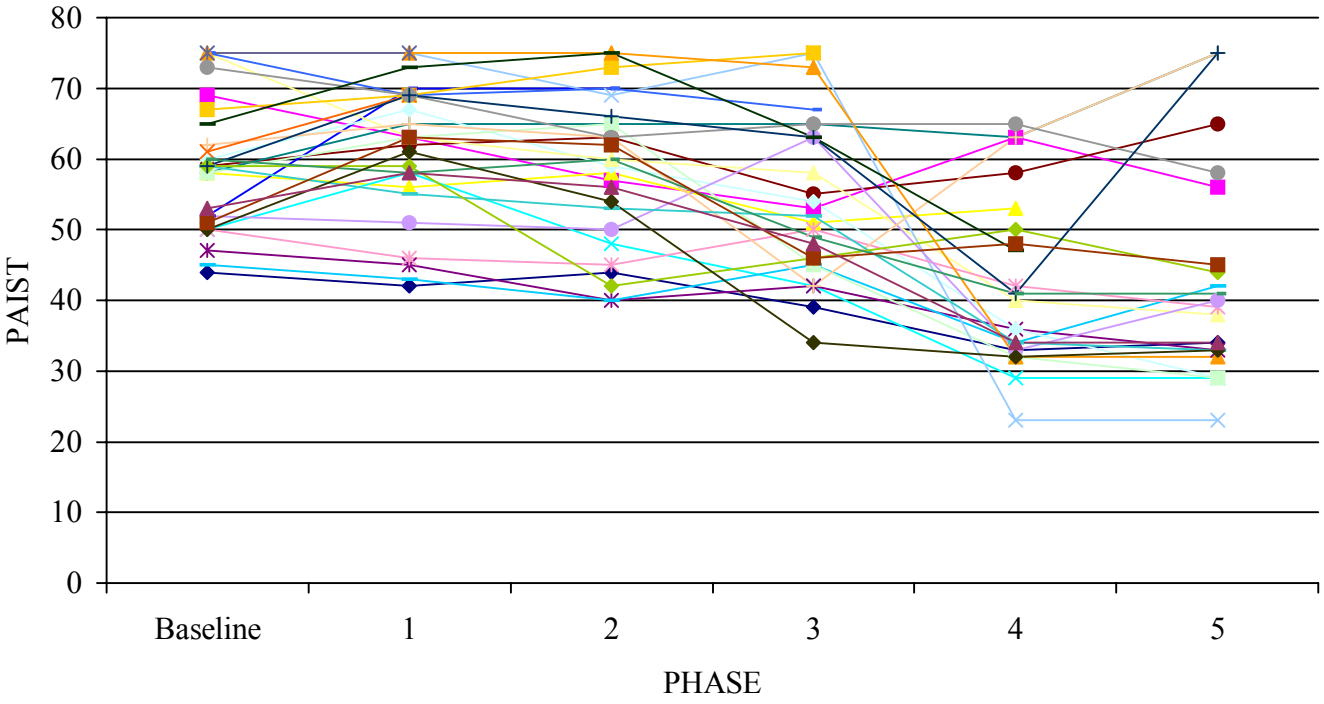
Figure 5.1 (b)



Note: Distribution of individual total scores for psychosocial adjustment to illness at each wave of data collection for treatment (circles) and control (triangles) group participants. This scatter plot highlights the variability in scores between individuals at each wave of data collection.

Figure 5.1 (c)

Empirical Growth Plots of the Total Score for Psychosocial Adjustment to Illness for Treatment and Control Groups



Note: Phase numbers correspond to the data collection points during the study: 1 = week 4; 2= week 8; 3 = week 16; 4 = week 24; 5 = week 48. The within and between group variability in change in psychosocial adjustment to illness is evident with this illustration of combined group individual change over time in psychosocial adjustment to illness total score. A T score of ≥62 denotes the "unhealthy" range of psychosocial adjustment to illness. PAIS total scores are presented as T scores, which were derived from transforming raw scores using the norms provided for oncology patients (Derogatis, 1986).

Statistical Models

As described in detail in the Methods section, empirical growth plots, nonparametric and parametric smoothing, and interindividual differences in change were examined to explore the overall pattern of change over time as recommended by Singer and Willet (2003). Each individual participant's data was summarized by fitting a linear model using object of least squares (OLS) regression. The linear model was chosen as each of the models (treatment phase and follow-up phase) contain only three time points. Appendix F represents the taxonomy used to construct the growth models while Appendix G contains an explanation of the interpretation of parameters in the growth models.

To answer the research question, is variation in the within-individual weekly rate of change in psychosocial functioning during the treatment portion of this study related to group membership, a two-level model was constructed beginning with an unconditional means model, that is, a model with no predictors, to partition out the total outcome variation across individuals without regard to time (Table 5.2). The intraclass coefficient correlation (Appendix G), that is, the proportion of the total outcome variation that lies between individuals, suggests that an estimated 77% of the total variation in psychosocial adjustment is attributable to differences among women in our sample.

Table 5.2

Growth Modeling for Psychosocial Adjustment to Illness Total Score: Treatment Phase (Weeks 1-8)

		Parameter	Model A	Model B	Model C	Model D	Model E
Fixed effects	Intercept	γ_{00}	60.38***	60.58***	57.73***	60.72***	65.52***
Initial status			(1.64)	(1.66)	(5.22)	(7.92)	(9.90)
	Group	γ_{01}			1.88	1.80	2.76
					(3.30)	(3.27)	(3.33)
	Age					-.050	
						(.101)	
	Education						-.665
							(.632)
Rate of change	Intercept	γ_{10}		-.038	-.909	-.829	-.612
				(.181)	(.543)	(1.05)	(1.03)
	Group	γ_{11}			.588	.557	.679
					(.348)	(.360)	(.353)
	Age					-.000	
						(.014)	
	Education						-.033
							(.066)
Variance Components							
Level 1	Within person	σ^2_ϵ	21.94****	13.37***	13.23***	13.28***	13.63***
			(4.07)	(3.55)	(3.49)	(3.51)	(3.65)
Level 2	In initial status	σ^2_0	73.13***	71.69***	70.72***	69.23***	68.39***
			(20.90)	(21.60)	(21.32)	(21.18)	(21.18)
	In rate of change	σ^2_1		.538	.463	.480	.433
				(.278)	(.257)	(.265)	(.258)
	Covariance	σ^2_{01}		-.453	-.673	-.874	-1.16
				(1.76)	(1.69)	(1.77)	(1.72)
R^2 Statistics & Goodness of Fit							
	R^2			.39	.014	.021	.012
	ρ		.77				
	Deviance		592.73	586.94	583.13	582.86	561.43***
	AIC		598.73	598.94	599.13	602.86	581.43
	BIC		606.16	613.83	618.95	627.63	605.86

*p < .05; **p < .01; ***p < .001

The second model we constructed introduced the predictor TIME (Model B) to assist with evaluating the baseline amount of change in psychosocial adjustment to illness. This model suggests that the average patient in this study is functioning within the healthy range of psychosocial adjustment to illness (60.58) and that psychosocial adjustment to illness is decreasing (improving) at a rate of -.038 points per week. As this rate is not statistically significantly different from zero, there is no main effect of time. However, comparing the variance components from the unconditional means model (Model A) to the unconditional growth model (Model B), the within-person variation in psychosocial adjustment associated with linear time is significant ($p<.001$), and an estimated 39% of the within-person variation is systematically associated with linear time (see R^2 in Appendix G).

The third model constructed introduced the predictor GROUP (treatment vs. control) as a substantive predictor. This model suggests that the average psychosocial adjustment to illness score for women in this study is 57.73 (healthy range). There was no main effect of group. The treatment group evidenced a rate of change of -1.49 points (improvement in psychosocial adjustment by 1.49 points per week) and the control group had a rate of change (γ_{10}) of -.909 points per week (improvement in psychosocial adjustment by .909 points per week); however, statistically speaking, neither group evidenced a rate of change significantly different from zero.

The variance components suggest that the introduction of the predictor group slightly reduced the scatter of observed scores in psychosocial adjustment to illness; however significant scatter remains ($\sigma^2_{\epsilon} = 13.23$, $p<.001$). The unpredicted variability in true initial status was also slightly, but not significantly, reduced with the introduction of Group ($\sigma^2_0 = 70.72$, $p<.001$). There is slightly less unpredicted variability in the true rate of change from Model B (time only) to Model C (addition of predictor "Group"). Finally, the introduction of group has no impact on the covariance, meaning that there does not appear to be a relationship between the direction of rate of change in psychosocial adjustment to illness and group membership. Pseudo R^2 estimated that the percentage of unexplained variance accounted for by the addition of GROUP to the model is ~1.4%.

Standard parametric analyses found that there were no significant differences between groups in the mean comparison of demographic variables that may account for the remaining variance. However, because growth modeling is designed to account for within-individual change as opposed to group averages and a significant amount of variability remains to be explained in the rate of change of psychosocial adjustment to illness in the treatment phase of the study, age and education were introduced as substantive predictors.

The fixed effects of Model D suggest that the average score for psychosocial adjustment to illness is 60.72 (healthy) and the variability between

groups is not significant. There was not a main effect of age and age did not significantly impact the rate of change in psychosocial adjustment to illness during the treatment phase. The introduction of age slightly increased the within-individual scatter of observed scores in psychosocial adjustment to illness (σ^2_{ϵ} = 13.28, p<.001) and the unpredicted variability in the true rate of change of psychosocial adjustment to illness (σ^2_1= .480); however, it resulted in a slight reduction in the unpredicted variability in the true initial status of psychosocial adjustment to illness (σ^2_0= 69.23***) as compared to the previous model. Pseudo R^2 suggests that the addition of group explains approximately 2.1% of the remaining variance in psychosocial adjustment to illness.

The number of years of education reported by study participants was introduced as a substantive predictor in Model E. The fixed effects of Model E suggest that the average participant endorsed psychosocial adjustment to illness in the unhealthy range (65.52, p<.001) and that there is not a significant difference in the variability in the initial level of psychosocial adjustment to illness between groups. No main effect of education was observed and the number of years of education reported by participants did not significantly impact the rate of change in psychosocial adjustment to illness. With respect to the variance components of Model E, the introduction of education as a substantive predictor increased the scatter of observed scores in psychosocial adjustment related to linear time but slightly decreased the unpredicted variability in true initial status and true rate of

change of psychosocial adjustment to illness. However, education accounted for only approximately 1.2% of the remaining variability in psychosocial adjustment to illness.

Models D and E served to answer our research question: Is variability in within-individual scores in psychosocial adjustment to illness related to age or education of participants? Neither age, nor education, significantly impacted the rate of change in psychosocial adjustment to illness in the treatment phase of this study.

The analysis of deviance statistics were examined, the method of quantifying how much better or worse the current model is in comparison to previous models (i.e. Model A vs. Model B, Model B vs. Model C). The deviance statistics were smaller from Model A to Model B and from Model B to Model C; however, when the differences between models were compared using χ^2, they were not significant. Next, we examined the deviance statistics in Models D and E. Model D was a slightly more parsimonious model than Model C; however, Model E, the model which includes time, group, and education as predictors, was significantly more parsimonious than Model C ($p<.001$).

We conclude that within-individual variation in psychosocial adjustment to illness is not significantly related to time, group membership, age, or number of years of education of a participant during the treatment phase of the study.

To answer the research question, is variation in the within-individual weekly rate of change in psychosocial functioning during the follow-up period related to group membership, we constructed a model consisting of only the three data points in the follow-up phase of the study (weeks 16, 24, and 48) (Table 5.3, pg. 108). In contrast to the treatment phase of the study, main effects of both time ($p<.01$, Model B) and group ($p<.05$, Model C) were found in the follow-up models.

Beginning with Model B, the model which introduces Time, the fixed effects suggest that the average participant endorsed psychosocial adjustment to illness in the healthy range (53.79) during the follow-up period of the study. Time significantly impacted the rate of change during the follow-up period ($p<.05$). A significant reduction in the scatter of observed scores is noted from Model A to Model B (137.05 to 106.63); however, significant scatter remained in the model ($p<.001$). In Model B, there is no longer significant unpredicted variability in true initial psychosocial adjustment to illness and true rate of change in psychosocial adjustment to illness. Time accounted for approximately 22% of the within-individual variability in psychosocial adjustment to illness.

The predictor group was introduced in Model C. The fixed effects suggest that the average participant endorsed psychosocial adjustment to illness in the unhealthy range (62.41) and that the difference in variability in psychosocial adjustment to illness scores between groups was not significant. Main effects of

both time ($p<.01$) and group ($p<.05$) were noted in Model C. Participants in the treatment group evidenced decreased psychosocial adjustment to illness scores of -1.31 points per week (improvement in psychosocial adjustment to illness) compared to control participants who evidenced a slower rate of improvement of -0.87 points per week.

The addition of group resulted in a slight decrease in the scatter of observed psychosocial adjustment to illness scores; however, significant scatter remained ($p<.001$). The addition of the predictor Group accounted for approximately 5.8% of the remaining within-individual variability in psychosocial adjustment to illness during the follow up period of the study.

To answer the research question: Is variability in within-individual psychosocial adjustment to illness during the follow-up period of the study related to age, education, or baseline psychosocial adjustment, three additional models were created. Model D introduced the predictor age, Model E introduced the predictor education, and Model F introduced psychosocial adjustment to illness endorsed by participants at the beginning of the study (baseline) as a substantive predictor.

The fixed effects of Model D suggest that the average participant endorsed psychosocial adjustment to illness in the unhealthy range (81.31) during the follow-up period of the study and significant differences in the variability of psychosocial adjustment to illness scores were not present between groups.

Significant variability in participant age was not noted between groups. Age did not significantly contribute to the within-individual variation in psychosocial adjustment to illness during the follow-up period of the study. However, both time ($p<.05$) and group ($p<.05$) remained significant contributors to the variation in within-individual psychosocial adjustment to illness during the follow-up period.

The variance components of Model D suggest that the addition of the predictor age to the model resulted in a slight decrease in the scatter of observed psychosocial adjustment to illness scores. Similar to previous models, significant scatter remained in the model ($p<.001$). A very slight reduction in the variability in the true rate of change in psychosocial adjustment to illness was also noted in Model D (.06 in Model C to .05 in Model D). Age accounted for approximately 2.4% of the variability in within-individual psychosocial adjustment to illness.

The number of years of education reported by participants was introduced as a predictor in Model E. Fixed effects suggest that the average participant endorsed psychosocial adjustment to illness in the unhealthy range (74.17) and no significant differences were noted in the variability of psychosocial adjustment to illness by group. Variability in education level was not significant. Time remained a significant predictor in the within-individual rate of change of psychosocial adjustment to illness ($p<.01$); however, neither group nor education

significantly contributed to the within-individual variation in rate of change in psychosocial adjustment to illness in Model E.

The addition of education as a predictor did, however, reduce the scatter in observed psychosocial adjustment to illness scores (105.09 to 95.56) and slightly reduced the variability in the true rate of change in psychosocial adjustment to illness (0.06 to 0.02). Education accounted for approximately 8.1% of the within-individual variability in psychosocial adjustment to illness during the follow-up phase of the study.

Finally, we were interested in evaluating whether or not the level of psychosocial adjustment to illness endorsed by participants at the beginning of the study would impact the within-individual rate of change in psychosocial adjustment to illness during the follow-up period of the study. To answer this question, we introduced the baseline score for psychosocial adjustment to illness as a substantive predictor in Model F. The fixed effects suggest that the average participant endorsed psychosocial adjustment to illness in the healthy range (61.92). Concordant with previous models, significant variability in psychosocial adjustment to illness scores was not noted between groups during the follow-up period of the study. However, as illustrated in Figure 5.1, significant variability ($p<.01$) is noted in baseline psychosocial adjustment to illness scores. However, this variability does not significantly contribute to the within-individual variation in rate of change of psychosocial adjustment to illness during the follow-up period

of the study. Only the predictor group remained significant ($p<.05$) in Model F. As with the previous models, a reduction in the scatter of scores for psychosocial adjustment to illness was noted in Model F (105.09 to 94.72). Significant scatter ($p<.001$) remained in the model. A slight reduction in the variation in the true rate of change of psychosocial adjustment to illness was also noted in Model F (0.06 to 0.04). The baseline level of psychosocial adjustment to illness accounted for approximately 9.8% of the remaining within-individual variability in rate of change in psychosocial adjustment to illness during the follow-up period of the study.

Goodness of fit deviance statistics suggest that Model B (time) is significantly more parsimonious ($p<.05$) than Model A (no predictors). While not significantly different, Model C (time + group) is a better fit than Model B (time). Model D (time + group + age) is a slightly better fit than Model C (time + group) and Model E (time + group + education) is a significantly better fit ($p<.01$) than Model C (time + group). However, Model F, which includes the substantive predictors group and baseline level of psychosocial adjustment to illness along with the predictor time, is significantly more parsimonious than any of the other models ($p<.001$).

Although age, education, and baseline level of psychosocial adjustment to illness account for a small proportion of the variability in psychosocial adjustment to illness during the follow-up period of the study, none are significant predictors

of within-individual variability in rate of change. However, both time and group significantly contribute to the within-individual variability in rate of change of psychosocial adjustment to illness during the follow up period of the study.

Similar to the method in which the growth models were constructed, repeated measures analysis of variance was conducted in two separate analyses using the total score on the PAIS-SR across the first 3 time points (baseline, week 4, week 8) to address the research question, on average, is variation is psychosocial functioning during the treatment phase of this study related to group membership. We then ran a separate analysis using the last three time points (week 24, and week 48) to assess the same question for the follow-up phase of the study. The more conservative Greenhouse-Geisser test of within subjects effects was used to minimize Type I error for these analyses. A T score of $\geq$62 is representative of the unhealthy range of psychosocial adjustment to illness as compared to the normative group (Derogatis, 1986). In Figure 5.2, we see that while the treatment group, in general, had lower mean T scores for psychosocial adjustment, scores for both groups were generally in the healthy range with the exception of the control group at week 4, with a mean T score greater than 62. There was no significant main effect of time or group for psychosocial adjustment to illness total scores during the treatment phase of the study. However, during the follow-up phase of the study, a main effect of group ($p<.05$) and an interaction between group and time ($p<.05$) were observed, with participants in the treatment

group evidencing lower (healthier) psychosocial adjustment to illness total scores as compared to participants in the control group. Post hoc analyses suggest that the significant difference between groups occurred at week 48, the final wave of data collection. Effect size from baseline to week 48 was .70 (large; Cohen, 1992). When looking at effect sizes in the treatment period (.22-small; Cohen, 1992) vs. the follow-up period (.85- large; Cohen, 1992), the data suggest that the greatest effect of the intervention occurred during the follow-up period.

Comparing mean T scores for total psychosocial adjustment to illness during the follow-up period of the study to the fixed effects of the growth models discussed above illustrates the primary difference between the methods of analyzing the data. When individual scores and variability in additional predictors are accounted for, the average level of psychosocial adjustment to illness during the follow-up period of the study reaches the unhealthy range (Models C, D, and E in Table 5.3). In contrast, when only the group averages are considered in the equation, psychosocial adjustment to illness during the follow-up phase appears to remain in the healthy range. While both methods address salient questions about the data, growth modeling provides a method to account for the within-individual variation in change. Such analyses are key to the understanding of the mechanism involved in improving psychosocial adjustment to illness using an individual intervention.

Table 5.3

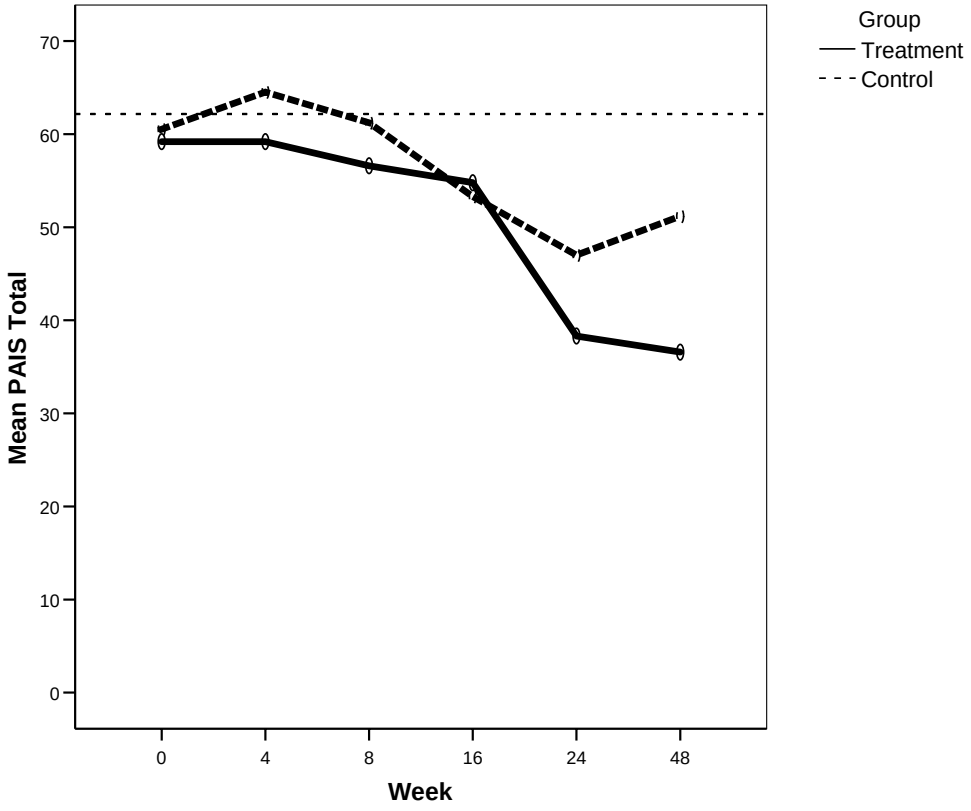
Psychosocial Adjustment to Illness Follow-Up Growth Model

		Parameter	Model A	Model B	Model C	Model D	Model E	Model F
Fixed effects Initial status	Intercept	γ_{00}	47.44*** (2.03)	53.79*** (2.84)	62.41*** (8.81)	81.31*** (17.41)	74.17*** (15.81)	61.92 (19.13)
	Group	γ_{01}			-5.82 (5.63)	-7.30 (5.67)	-2.78 (5.48)	-5.22 (5.35)
	Age					-.305 (.244)		
	Education						-1.18 (1.01)	
	BLPAIST							1.00** (.284)
Rate of change	Intercept	γ_{10}		-.22* (.10)	-0.87** (.32)	-1.34* (.656)	-1.46** (.515)	.074 (.686)
	Group	γ_{11}			0.44* (.21)	.471* (.204)	.350 (.183)	.428* (.190)
	Age					.007 (.009)		
	Education						.050 (.033)	
	BLPAIST							-.015 (.010)
Variance Components								
Level 1	Within person	σ^2_{ϵ}	137.05*** (28.38)	106.63*** (21.58)	105.09*** (21.60)	102.55*** (21.16)	96.56*** (19.47)	94.72*** (21.62)
Level 2	In initial status	σ^2_0	60.08 (33.12)	.00 (.00)	.00 (.00)	.00 (.00)	.00 (.00)	.00 (.00)
	In rate of change	σ^2_1		.06 (.00)	0.06 (.00)	0.05 (.00)	.02 (.00)	.04 (.00)
	Covariance	σ^2_{01}		-.40 (.42)	.51 (.43)	.12 (.38)	.56** (.18)	.18 (.36)
R^2 Statistics & Goodness of Fit								
	R^2			.22	.058	.024	.081	.098
	ρ							
	Deviance		603.16	592.72	587.15	585.56	577.72**	570.56***
	AIC		609.16	604.72	603.15	605.56	597.72	590.56
	BIC		616.11	618.63	621.69	628.74	620.76	613.73

***p<.001; **p<.01; *p<.05

Figure 5.2

Mean Psychosocial Adjustment to Illness Total Scores by Group



Note: Scores for psychosocial adjustment to illness are primarily in the "healthy" range of functioning (T < 62) with the exception of the control group at week 4, the second wave of data collection, with a mean T score of 62.

Depression Symptoms

Descriptive Statistics of Observed Data

Reported depression symptoms varied both within and between groups at each wave of data collection. The distribution of scores as well as the central tendency in reported depression symptoms by group at each wave of data collection is illustrated in Figure 5.3 (a) (pg. 114). The shape of the distribution of depression symptoms scores for the treatment group at baseline was negatively skewed whereas the shape of observed depression symptom scores for the control group appears more symmetric with only a slight negative skew. Along with the variability in the shape of the distribution of scores, the central tendencies of both groups are different, with the treatment group having a median of 8.00 compared to the control group's median of 12.00. The mean depression score for the groups at baseline was virtually the same, with the treatment group reporting a mean of 13.80 and the control group reporting a mean of 13.20, both within the mild range of depression symptoms (Table 5.4). The variation in reported depression scores around the median for the treatment and control groups was similar (SD=9.75, SD=7.11, respectively) with the treatment group evidencing slightly more variation. Figure 5.3 (b) (pg. 115) illustrates the variability within-individual scores by group at each point of data collection. This slight difference in variability is underscored by the minimal difference between groups in

interquartile ranges (Treatment = 15.0; Control = 13.0). At week 4, the shape of the observed distribution of depression symptom scores for the treatment group was more symmetrical with a slight positive skew whereas the shape of the distribution of scores for the control group was negatively skewed, with more control group participants endorsing depression symptom scores above the median of 21 than below. The treatment group continued to show similar variability around the mean (SD=10.03) as compared to the control group (SD=9.08). At week 8, the shape of the distribution of observed depression scores for the treatment group was positively skewed with more treatment group participants endorsing depression symptoms below the median of 11.0 than above compared to the control group's negatively skewed distribution with more control groups endorsing depression symptoms above the median of 21 than below. The variability in depression symptom scores was significantly reduced in the treatment group at week 8 (SD=6.28). The control group evidenced slightly more variability in distribution of depression symptom scores (SD=8.30) as compared to the treatment group; however, the variability in depression scores was a decrease from week 4. At week 16, the shape of the distribution of depression symptom scores was negatively skewed for both groups. There was a significant difference in central tendencies between groups with the control group evidencing higher depression symptom scores (mean = 13.07; median = 10.00) than the treatment group (mean = 9.57; median = 5.50). The variability in the distribution

of scores; however, was similar in treatment and control groups (SD=8.68 and 9.57, respectively). The interquartile ranges of both groups are also similar (treatment = 16.3; control = 17.5). At week 24 of the study, the shape of the distribution of observed depression symptom scores for the treatment group was more normally distributed with greater symmetry in the distribution of scores. The shape of the distribution of scores for the control group remained negatively skewed with a greater number of control group participants endorsing depression symptom scores above the median than below. Differences in central tendencies of the two groups began to converge at this point of data collection with the treatment group (mean = 4.46; median = 4.00) evidencing lower depression symptom scores than the control group (mean = 9.47; median = 6.00) although both were reporting depression symptoms scores within the normal range. The control group evidenced approximately twice as much variability in the distribution of scores at week 24 (SD=8.82; interquartile range = 16.8) as compared to the treatment group (SD=4.17; interquartile range = 5.5). At the last point of data collection, week 48, the shape of the distribution of observed scores for both groups was negatively skewed. The central tendencies of the groups continued to evidence a difference with the control group endorsing a greater number of depression symptoms as compared to the treatment group. Both groups, however, continued to endorse depression symptoms within the normal range. The control group evidenced significantly more variability in the

distribution of scores at week 48 than the treatment group (SD=11.23, SD=2.64, respectively. Figure 5.3 (c) summarizes the variability in change in observed depression symptoms over the course of the study both within and between groups.

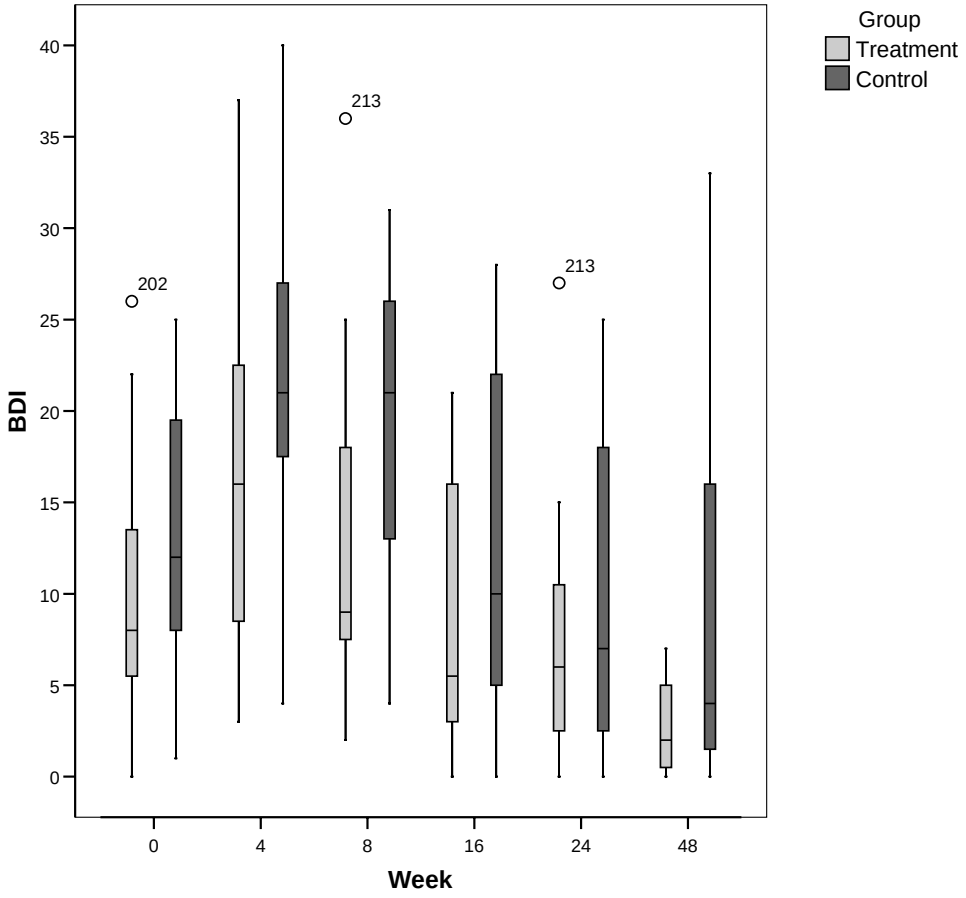
Table 5.4

Descriptive Statistics by Group for Depression Symptoms Across all Six Waves of Data Collection

BDI-II Depression Symptom Scores	Group	Mean	Median	SD	Min	Max
Treatment Phase						
Baseline	Treatment	13.80*	8.00	9.75	2	37
	Control	13.20*	12.00	7.11	1	25
Week 4	Treatment	15.33*	13.00	10.03	3	36
	Control	22.26**	21.00	9.08	4	40
Week 8	Treatment	11.93*	11.00	6.28	2	25
	Control	19.30**	21.00	8.30	4	31
Follow-Up Phase						
Week 16	Treatment	9.57	5.50	8.68	0	27
	Control	13.07*	10.00	9.57	0	28
Week 24	Treatment	4.46	4.00	4.17	0	15
	Control	9.41	6.00	8.82	0	25
Week 48	Treatment	2.33	1.00	2.64	0	7
	Control	9.54	4.00	11.23	0	33

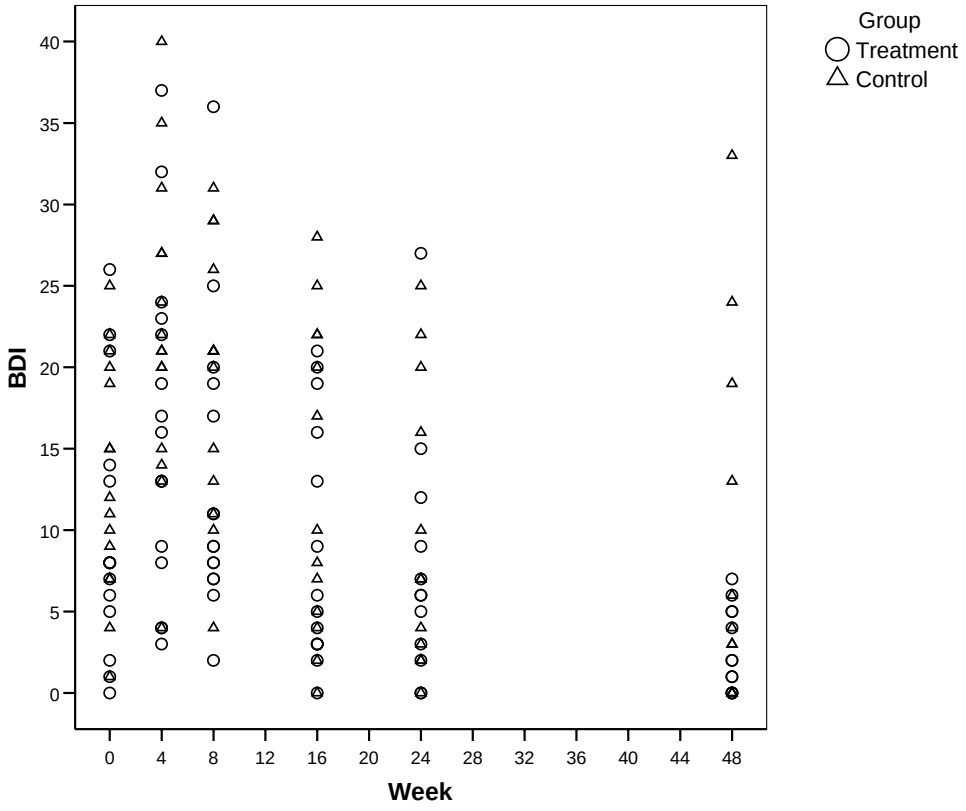
Note: 0-9 = within normal limits;* 10-16 = mild depression; **17-29 = moderate depression; ***30-63 = severe depression

Figure 5.3 (a)



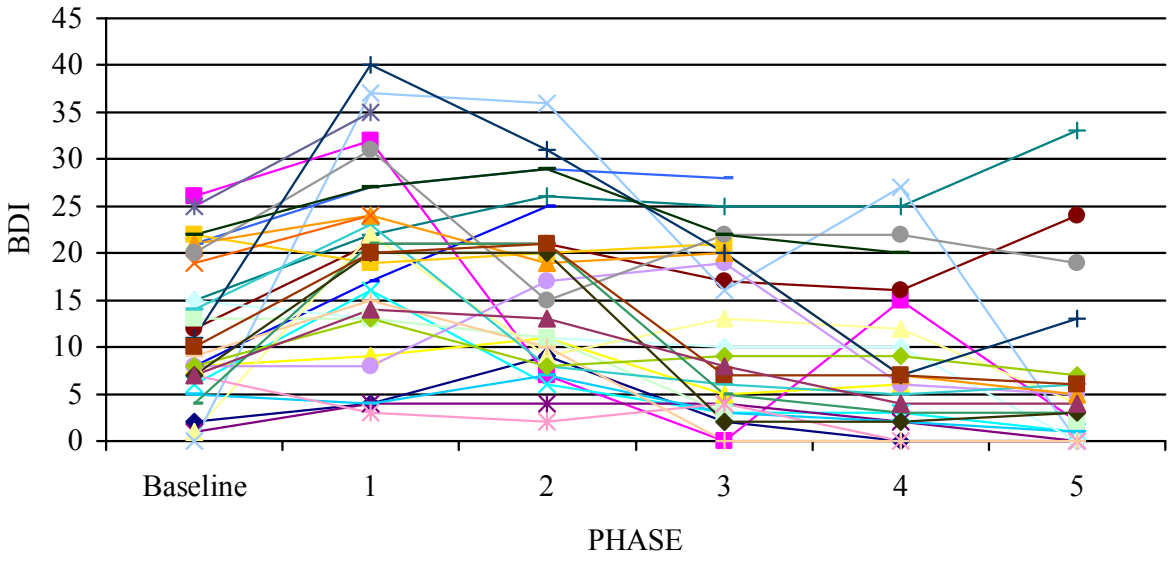
Note: Distribution and central tendency of depression symptom scores on the Beck Depression Inventory-II by group across all six waves of data collection. Outliers, or extreme scores, that may require special consideration are denoted by patient identification number. Higher scores denote increased presence of depression symptoms.

Figure 5.3 (b)



Note: Distribution of individual depression symptom scores on the Beck Depression Inventory-II at each wave of data collection for treatment (circles) and control (triangles) group participants. This scatter plot highlights the variability in scores between individuals at each wave of data collection. Higher scores denote increased presence of depression symptoms.

Figure 5.3 (c)



Note: Combined group (treatment + control) individual empirical growth plots of change in depression symptom scores across the six waves of data collection illustrates the within and between group variability in change over time with regard to endorsement of depression symptoms. Higher scores denote increased levels of depression symptoms. Depression scores are presented as raw scores derived from the BDI-II. Phases correspond to the points of data collection: 1= week 4; 2 = week 8; 3= week 16; 4= week 24; 5 = week 48.

Statistical Models of Depression Symptoms

To answer the research question, is variation in within-individual weekly rate of change in depression symptoms related to group membership, we constructed three models (Table 5.5). The fixed effects of the unconditional means model (Model A) suggest that the average participant in the study endorsed depression symptoms in the mild depression range (10-16) with an average depression score of 15.71. Analysis of the random effects of the unconditional means model for depression symptoms (Model A), suggests that the average level of depression symptoms varies over time and between women in our sample (σ^2_{ϵ} = 55.93, $p < .001$; $\sigma^2_0 = 31.75$, $p < .05$). The intraclass correlation coefficient estimated that ~ 43% of the total variation in depression symptoms is attributable to differences among women in our sample.

The predictor TIME was introduced in Model B and a main effect was observed. Model B suggests that the average participant in the study evidenced an average depression score in the mild range (13.26). Regardless of group, study participants evidenced an increase in depression scores of .65 points per week over time

Table 5.5

Growth Model for Depression Symptoms during the Treatment Phase

		Parameter	Model A	Model B	Model C	Model D	Model E
Fixed effects Initial status	Intercept	γ_{00}	15.71 (1.31)	13.26*** (1.40)	8.06 (4.30)	15.45* (7.43)	18.15* (7.62)
	Group	γ_{01}			3.47 (2.72)	3.21 (2.70)	4.61 (2.57)
	Age					-.124 (.102)	
	Education						-.865 (.486)
Rate of change	Intercept	γ_{10}		.65* (.240)	-0.14 (.74)	-.625 (1.36)	-.662 (1.39)
	Group	γ_{11}			0.53 (.47)	.534 (.465)	.477 (.478)
	Age					.008 (.018)	
	Education						.044 (.089)
Variance Components							
Level 1	Within person	σ^2_ϵ	55.93*** (10.52)	46.124** (12.05)	45.48*** (11.78)	44.38*** (11.65)	43.80*** (10.87)
Level 2	In initial status	σ^2_0	31.75* (13.85)	20.31 (18.15)	17.31 (17.23)	17.19 (17.13)	10.73 (15.14)
	In rate of change	σ^2_1		.17 (.56)	0.12 (.54)	.11 (.54)	.197 (.550)
	Covariance	σ^2_{01}		-1.85 (2.47)	-1.43 (2.39)	1.35 (2.41)	1.45 (2.27)
R^2 Statistics & Goodness of Fit							
	R^2			.18	.19	.024	.037
	ρ		.43				
	Deviance		626.11	616.140*	604.088**	616.711***	595.247**
	AIC		632.113	628.140	620.088	636.711	615.247
	BIC		639.511	643.004	639.906	661.484	639.674

***p < .001; **p < .01; *p < .05

With respect to the variance components of Model B, there was a reduction in the scatter of observed depression scores from Model A (55.93 to 46.12); however, significant ($p<.01$) scatter remained. There was also a reduction in the variability in true initial status from Model A to Model B such that this variability is no longer significant (31.75 to 20.31). Time accounted for approximately 18% of the variability in within-individual rate of change in depression symptoms during the treatment phase of the study.

The predictor group was added to Model C to assess whether or not variation in within-individual rate of change in depression symptoms during the treatment phase of the study was related to group membership. The fixed effects suggest that the average participant endorsed depression symptoms in the normal range (8.06) and that the variability in depression scores between groups was not significant. No main effect of group was observed in Model C, suggesting that group does not significantly contribute to the within-individual variation in rate of change in depression symptoms during the treatment phase of the study. Treatment group participants did evidence a slightly greater rate of change as compared to control group participants; however, this difference was not significant. Interestingly, the main effect of time observed in Model B is not stable, as time was not a significant contributor to the within-individual variation in rate of change in depression symptoms in Model C.

A slight reduction in the scatter of observed depression symptoms was noted from Model B (time) to Model C (time + group) (46.12 to 45.48); however, significant scatter remained ($p<.001$). Slight reductions were also noted in the variability in true initial status and true rate of change in observed depression symptoms with the addition of group to the model. The addition of group accounted for approximately 19% of the within-individual variation remaining in the model.

To answer the research question: Is variability in within-individual rate of change in depression symptoms during the treatment phase of the study related to demographic characteristics of the sample, age and education were added as substantive predictors. Model D (age + group + time) suggests that the average participant endorsed depression symptoms in the mildly depressed range (15.45) and no significant differences in the variability in scores were observed between groups. No main effect of age was observed in Model D suggesting that age was not a significant predictor of within-individual variation in rate of change in depression symptoms during the treatment phase of the study. Concordant with Model C, no main effect of time or group was noted in Model D, providing further support of the instability of the main effect of time with regard to rate of change in depression symptoms during the treatment phase of the study.

Looking to the variance components of Model D, there was a reduction in the scatter of observed depression scores from Model C to Model D; however,

significant scatter remained ($p<.001$). A slight reduction in the variability in true initial status of depression symptoms was observed with the addition of age to the model along with a very small reduction in the variability in true rate of change in depression symptoms. Participant age accounted for approximately 2.4% of the remaining variability in within-individual rate of change in depression scores during the treatment phase of the study.

Finally, Model E included the addition of the number of years of education reported by participants as a substantive predictor in rate of change in depression symptoms. The fixed effects suggest that the average participant endorsed a moderate level of depression symptoms (18.15) and that no significant differences in the variability of depression scores were noted between groups. No main effect of education was observed, suggesting that education does not significantly predict the within-individual variation in rate of change in depression scores during the treatment phase of the study. As with Models C and D, time and group remained insignificant as predictors of within-individual variation in rate of change in depression symptoms during the treatment phase of the study.

The variance components of Model E suggest a slight decrease in the scatter of observed depression scores as compared to Model C; however, significant scatter in observed depression scores remained ($p<.001$). A relatively large reduction in the variability in true initial status of depression scores was noted with the addition of education to the model (Model C=17.31; Model E =

10.73). However, a slight increase in the variability of the true rate of change in depression symptoms was noted in Model E (.12 in Model C to .19 in Model E). Education accounted for approximately 3.6% of the variability in depression symptoms remaining in the model.

We conclude that, although not stable across all models, time was the only significant predictor of within-individual variation in rate of change in depression symptoms during the treatment phase. Deviance statistics were compared across models to estimate the goodness of fit of each model. The addition of the introduction of the predictor TIME was significantly more parsimonious than the unconditional means model ($p<.05$). The introduction of the predictor GROUP makes Model C a significantly better fit ($p<.01$) than Model B (time). The difference in goodness of fit between Models C (time + group) and D (age + group + time) was also significant ($p<.001$); however, Model D was a significantly worse fit (significantly greater deviance score) than Model C. Finally, Model E (education + group + time) was compared to Model C (time + group) and found to be the most parsimonious of all of the models ($p<.01$).

To explore the variation in within-individual rate of change in depression symptoms related to group membership during the follow-up phase of this study, we constructed growth models using only the last three time points of the study (weeks 16, 24, and 48). The unconditional means model (Model A) suggests that significant within-individual variation exists ($p<.001$) that could be possibly

explained by additional predictors (Table 5.6). The fixed effects of Model B suggest that the average participant in the study endorsed a depression symptom rating in the mild depression range (12.46). We find that there is a main effect of time ($p<.01$) contributing to the variation in within-individual rate of change in depression symptoms during the follow-up phase of the study. In general, participants in the study are showing improvement in depression symptoms at a rate of -.11 points per week ($p<.01$).

With the introduction of time into Model B, a reduction in the scatter of observed depression scores was noted; however, significant scatter remained ($p<.01$). There was also a reduction in the variability in the true initial status of depression scores such that the variability was no longer significant. Virtually no variability in true rate of change was noted in Model B. Time accounted for approximately 5.8% of the remaining within-individual variation in rate of change in depression scores in the follow-up period of the study.

Table 5.6

Growth Modeling for Depression Symptoms: Follow- Up Model (Weeks 16 – 48)

		Parameter	Model A	Model B	Model C	Model D	Model E	Model F
Fixed effects Initial status	Intercept	γ_{00}	9.26 (1.52)	12.46*** (1.83)	11.07 (5.75)	25.85* (10.71)	13.30 (10.88)	7.10 (5.69)
	Group	γ_{01}			.987 (3.67)	-.239 (3.59)	2.23 (3.71)	-.003 (3.43)
	Age					-.238 (.148)		
	Education						-.320 (.688)	
	Baseline BDI-II							.488 (.242)
Rate of change	Intercept	γ_{10}		-.11** (.04)	-0.32* (.12)	-.539* (.248)	-.428 (.217)	-.332* (.127)
	Group	γ_{11}			0.13 (.08)	.152 (.077)	.114 (.077)	.135 (.075)
	Age					.003 (.003)		
	Education						.010 (.014)	
	Baseline BDI-II							.002 (.005)
Variance Components								
Level 1	Within person	σ^2_{ϵ}	23.64*** (4.96)	20.52** (6.00)	18.63*** (3.85)	18.65*** (3.91)	18.56*** (3.83)	18.40*** (3.79)
Level 2	In initial status	σ^2_0	53.10* (17.65)	49.04 (28.19)	53.27* (22.17)	45.60* (21.92)	51.47* (22.22)	41.01* (18.88)
	In rate of change	σ^2_1		.00 (.02)	0.00 (.00)	-.035 (.297)	-.163 (.275)	-.143 (.242)
	Covariance	σ^2_{01}		.05 (.02)	-.17 (.28)			
R^2 Statistics & Goodness of Fit								
	R^2			.13	.092	-.001	.003	.012
	ρ							
	Deviance		496.54	488.80	483.05	480.46	474.27**	474.24**
	AIC		502.54	500.80	499.05	500.46	494.27	494.24
	BIC		509.45	514.62	517.48	523.50	517.17	517.28

***p<.001; **p<.01; *p<.05

Model C presents the impact of the introduction of group as a substantive predictor. The model suggests that there was no main effect of group. The fixed effects of Model C suggest that participants endorsed a depression symptom rating in the mild depression range (11.07). Participants in the treatment group evidenced an improvement in depression symptom ratings of -0.45 points per week compared to participants in the control group who were showing improvement at a rate of -0.32 points per week. Figure 5.4 illustrates the similarity in slopes for both groups. Although groups differ at the intensity at which they endorse depression symptoms, both groups show a steady decline in reported depression symptoms from week 16 to week 24. Between weeks 24 and 48, the treatment group evidenced slight improvement (lower scores) while the control group evidenced a slight increase. The rate at which each changed, however, is similar regardless of the direction of change.

Examination of the variance components of Model C suggest that there was a reduction in the scatter of observed depression scores with the addition of the predictor group. Interestingly, there was an increase in the variability in the true initial status of depression symptoms such that the variability was again significant ($p<.05$). Virtually no variability in true rate of change was noted. Group accounted for approximately 9.2% of the remaining within-individual variation in rate of change of depression symptoms in the follow-up period of the study.

To answer the research question: Is variation in within-individual rate of change in depression scores during the follow-up phase of the study related to demographic characteristics of the participant sample or initial endorsement of depression symptoms at the beginning of the study, we introduced age, education, and baseline BDI-II scores as substantive predictors in the follow-up growth model.

Model D includes the substantive predictor age. The fixed effects suggest that the average participant endorsed depression symptoms in the moderate range (25.85) with no significant differences in the variability of depression scores noted between groups. No significant differences were noted in the variability of reported participant age. No main effect of age was noted in Model D suggesting that age did not significantly predict the within-individual variation in rate of change in depression symptoms during the follow-up period of the study. A main effect of time was observed in this model suggesting that time continued to significantly influence the within-individual rate of change in depression symptoms during the follow-up period of the study.

Interestingly, while there was a slight increase in the scatter of observed depression scores (18.63 to 18.65), there was a slight reduction in the variability in both true initial status and true rate of change of depression scores with the introduction of age as a predictor in the model. Participant age accounted for

approximately -0.1% of the within-individual variation in rate of change in depression symptoms during the follow-up period of the study.

Model E included the introduction of the substantive predictor education. The fixed effects suggest that the average participant endorsed depression symptoms within the mildly depressed range (13.30) and no significant differences were observed between groups with regard to the variation in depression scores. No significant differences were observed with regard to participant education levels. No main effects of time, group, or education were noted in Model E. Treatment group participants evidenced a negligibly faster rate of improvement in depression scores (.542 points per week) compared to control group participants' improvement of .428 points per week during the follow-up period of the study.

In contrast to Model D, the variance components of Model E suggest a reduction in the scatter of observed depression scores as well a decrease in the variability in true initial status of depression scores with the addition of education into the model. Education accounted for approximately 0.03% of the within-individual variation in rate of change in depression symptoms during the follow-up period of the study.

The final predictor introduced into the follow-up growth model was the baseline depression symptom score. Model F suggested that the average participant endorsed depression symptoms within the normal range (7.10) with no

significant differences noted between groups with regard to variability in depression scores. No significant differences were noted between groups with regard to variability in baseline depression scores. Baseline depression scores do not significantly predict the within-individual variation in rate of change in depression symptoms during the follow-up period of the study; however, there was a main effect of time observed in Model F ($p<.05$). Concordant with the treatment period growth model, time was an inconsistent but significant predictor of within-individual variation in rate of change in depression symptoms during the follow-up phase of the study.

The variance components of Model F suggest significant reductions in the scatter of observed depression scores as well as in the variability in true initial status of depression scores, although both continued to evidence significant variability ($p<.001$, $p<.05$, respectively).

Goodness of fit analyses across all of the models suggest that, although there was no main effect of baseline BDI-II scores or group, Model F does appear to be the most parsimonious of the five models ($p<.01$).

To evaluate average differences in depression scores based on group means, repeated measures analyses of variance (ANOVA) was conducted using scores on the Beck Depression Inventory-II across the first three time points (baseline, week 4, week 8) of the study. The more conservative Greenhouse-Geisser test of within-subjects effects was used to minimize Type I error for these

analyses. Results suggest a main effect of time without consideration of group ($p<.01$) as well as a significant interaction between group and time ($p<.01$). Patients in the treatment group evidenced lower mean scores of depression symptoms as compared to patients in the control group, most significantly at week 8 (effect size =.95). In Figure 5.4, the mean depression symptom score for the treatment group was on the border between the mild depression range and within normal limits. In contrast, the mean depression symptom score for the control group remained in the moderately depressed range.

To evaluate average differences in depression symptoms by group during the follow-up phase of the study, repeated measures ANOVA was conducted using the last three time points (weeks 16, 24, and 48) of the study. As with the treatment phase analyses, the more conservative Greenhouse-Geisser test of within subjects effects was used to minimize Type I error for these analyses. There is a main effect of group ($p<.05$), most significantly at week 48 of the study, with participants in the treatment group endorsing significantly fewer symptoms of depression than patients in the control group (effect size =.33). In Figure 5.4, we see that by week 16 of the study, the gap between groups with regard to depression symptoms has become much smaller with the treatment group now scoring, on average, just within the within normal limits range and the control group scoring a the low end of the mild depression range. The difference in depression scores becomes more prominent at week 24 and most significant at

week 48 as the treatment group continued to evidence decline in depression symptom scores, scoring well within the normal limits range, whereas the control group continued to endorse depression symptoms at the upper limit of the normal range. The effect size of the individual intervention from baseline to week 48 was .69, which is considered large (Cohen, 1992). When comparing effect sizes during the treatment vs. follow-up periods, the data suggest that the intervention had the greatest effect during the treatment period.

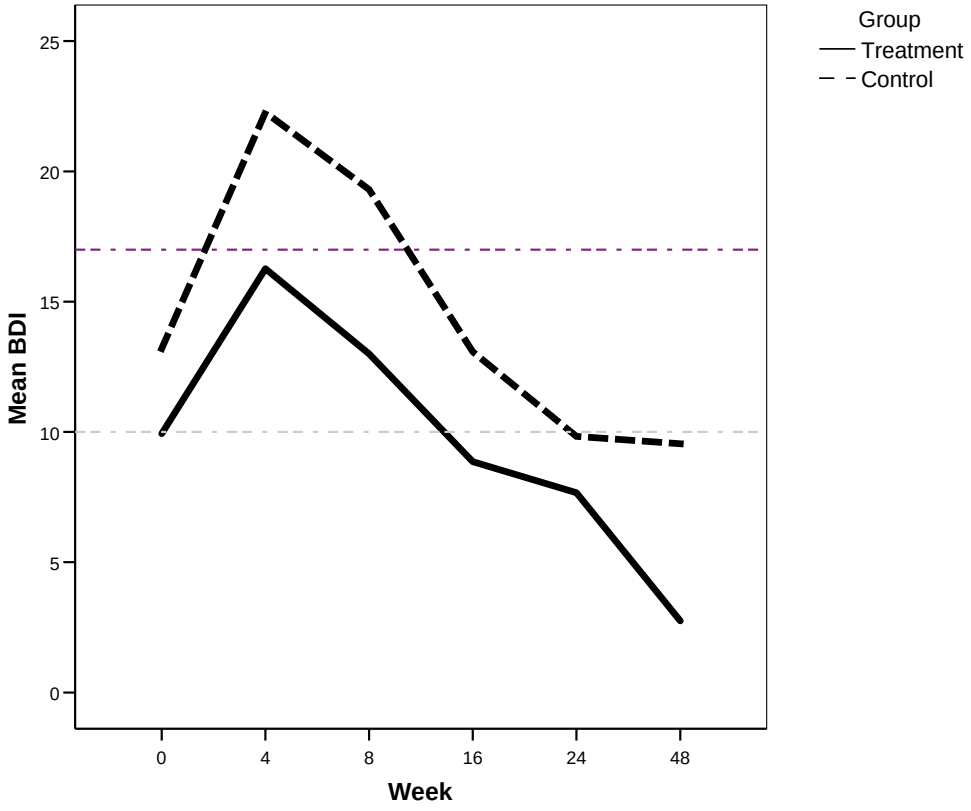
Differences in mean depression scores are primarily related to the greater frequency and intensity at which control group participants endorsed subjective neurocognitive symptoms of depression as compared to participants in the treatment group. Analysis of individual items on the BDI-II showed that the depression scores were primarily accounted for by endorsement of items related to concentration (Figure 5.6, pg. 136), decision-making ability (Figure 5.5, pg. 132), energy, sleep, and sexual interest (Figure 5.7, pg. 140). Differences between groups in the frequency at which more intense disruption in one or more of these domains was reported accounted for the differences in overall depression scores between groups. Participants in the control group more frequently and more intensely endorsed disruption in one or more of these domains as compared to participants in the treatment group.

The case for the subjective neurocognitive symptoms accounting for the differences in depression scores is underscored when mean T scores on the

Psychological Distress Subdomain of the PAIS-SR are compared to mean raw scores on the BDI-II. A T score of $\geq$62 represents psychological distress in the "unhealthy" range. Figure 5.8 (pg. 144) illustrates that mean T scores for the subdomain of Psychological Distress do not reach the unhealthy range at any time point during the study. In contrast, participants in both groups reached at least the mild depression range when measured by the BDI-II (Figure 5.4). Unlike the BDI-II, the Psychological Distress Subdomain of the PAIS-SR does not assess subjective neurocognitive symptoms.

Figure 5.4

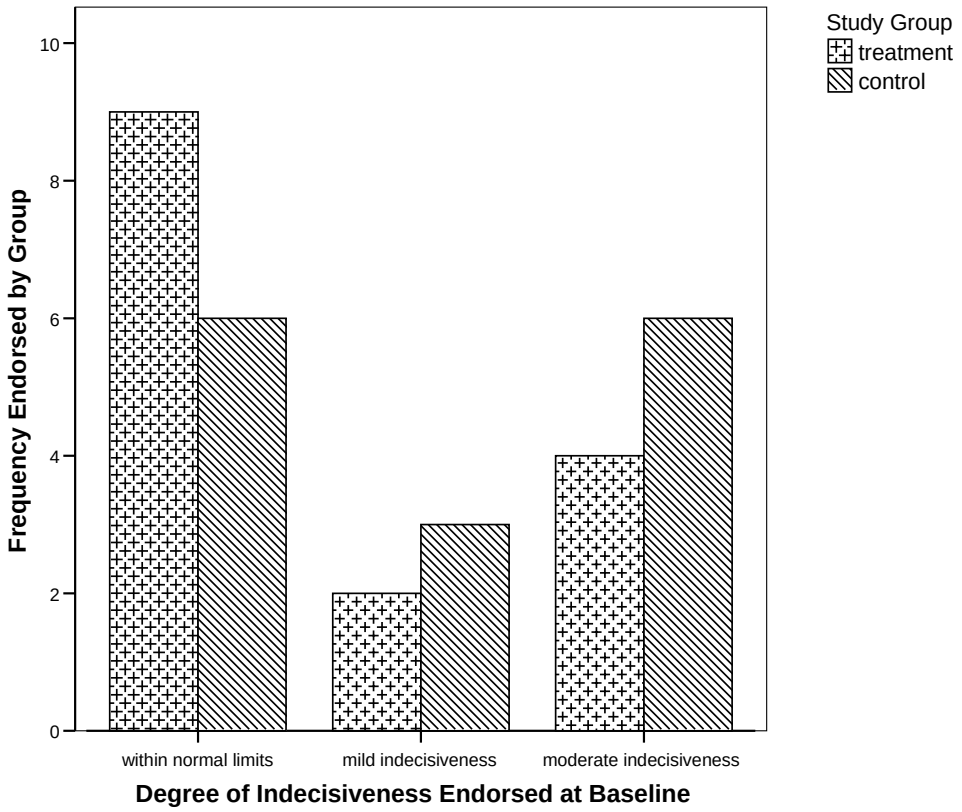
Differences in Mean Depression Scores in Treatment vs. Control Groups



Note: BDI-II scores of 0-9 = normal functioning; 10-16 = mild depression; 17-29 = moderate depression; 30-63 = severe depression. Differences in scores on the BDI-II between groups during the follow- up phase are primarily related to endorsement of the neurocognitive symptoms rather than mood symptoms.

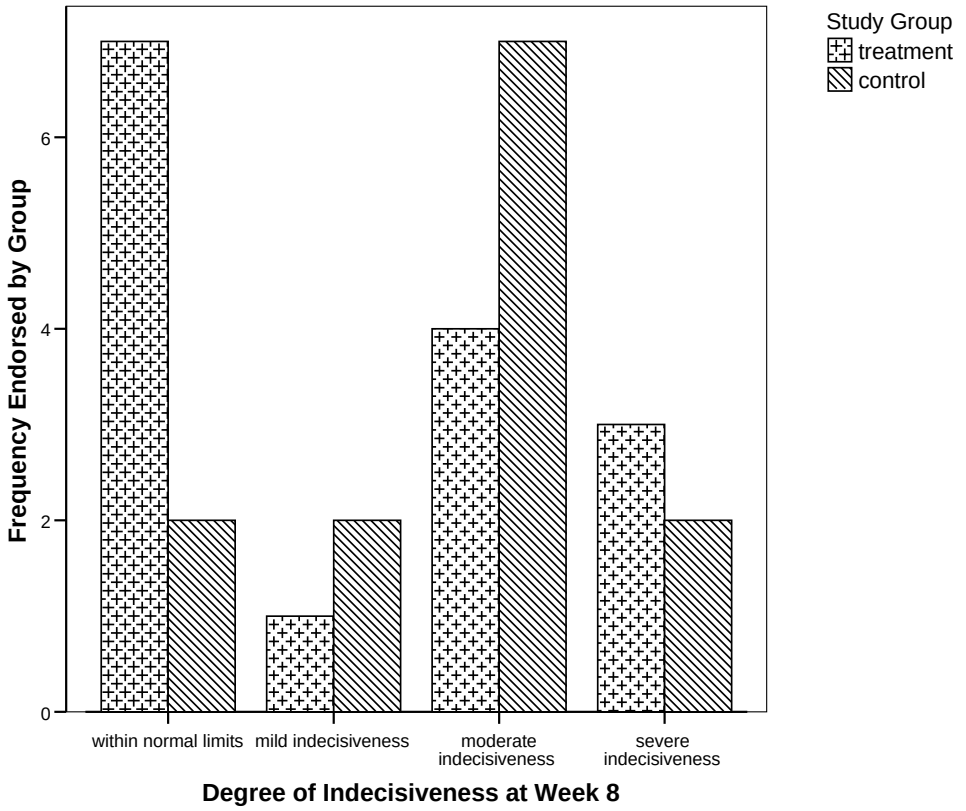
Figure 5.5 (a)

Frequency & Intensity of Endorsing Indecisiveness



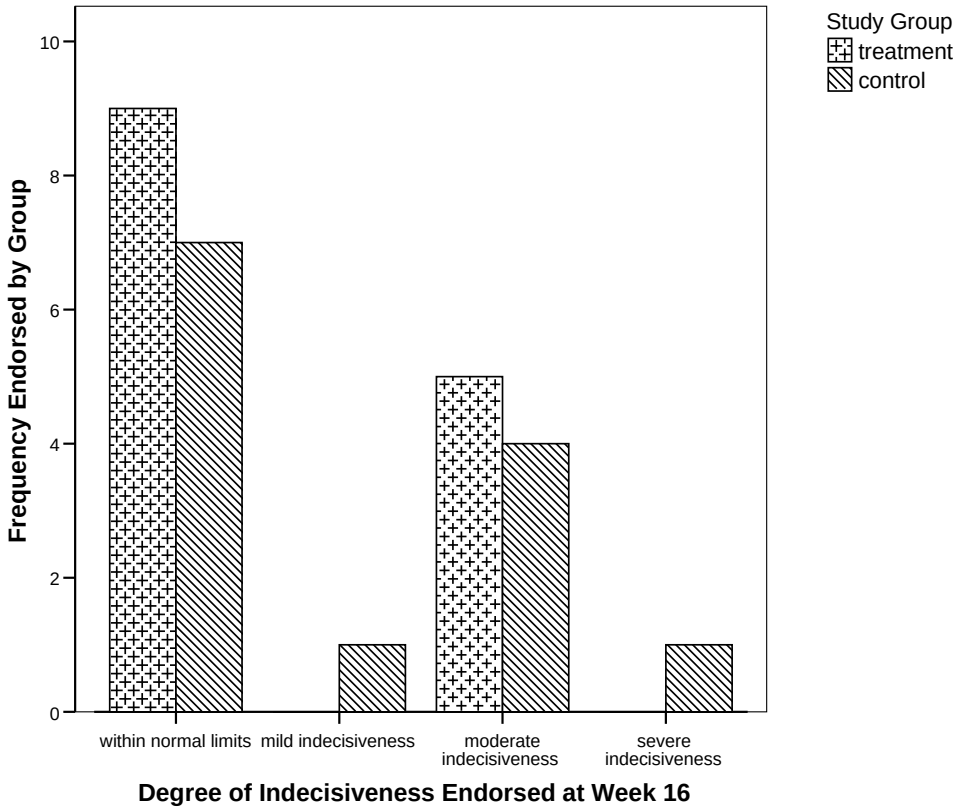
Note: Indecisiveness was endorsed at similar frequency and intensity at baseline within both groups.

Figure 5.5 (b)



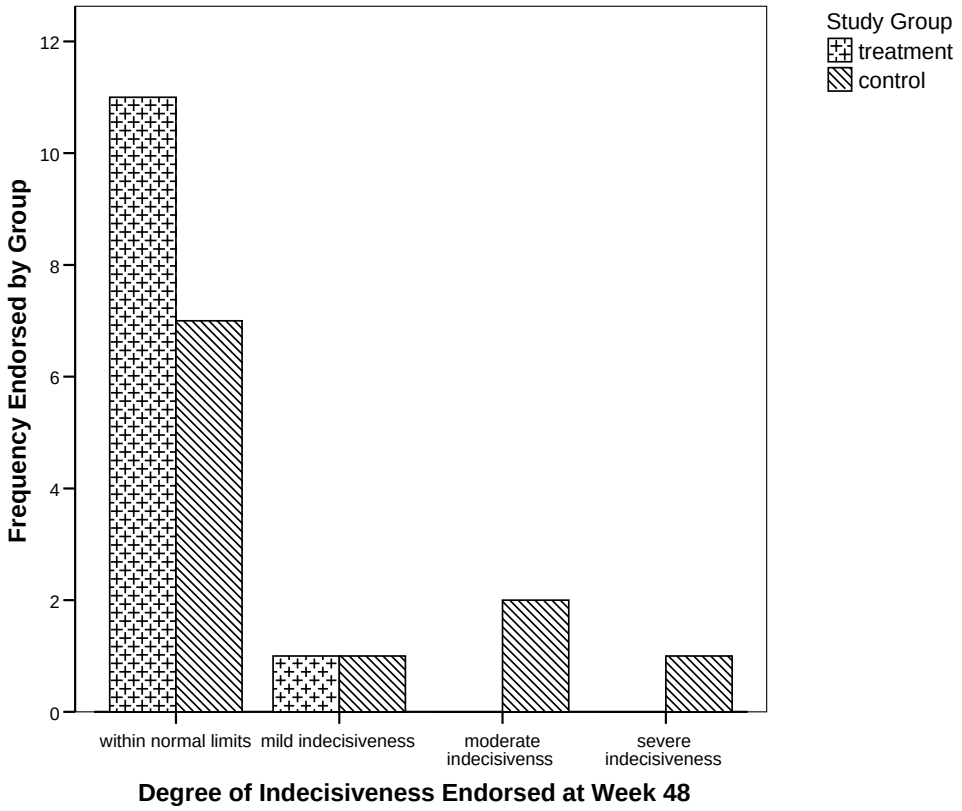
Note: Although some treatment group participants continue to endorse indecisiveness with a greater intensity, a greater number are endorsing a lesser degree of intensity as compared to controls at the end of the treatment period of the study.

Figure 5.5 (c)



Note: Differences between groups in frequency and intensity with which indecisiveness is endorsed begin to more clearly emerge.

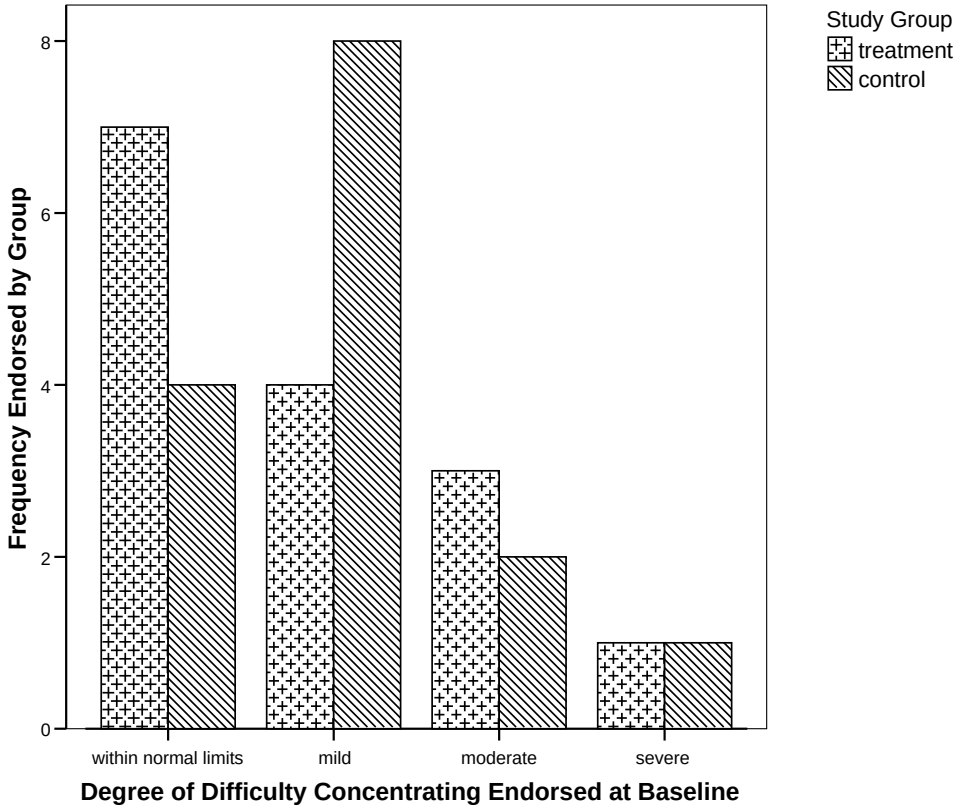
Figure 5.5 (d)



Note: By the end of the follow-up period of the study, treatment group participants endorse indecisiveness within normal limits or with mild intensity compared to control group participants' endorsement of moderate to severe intensity.

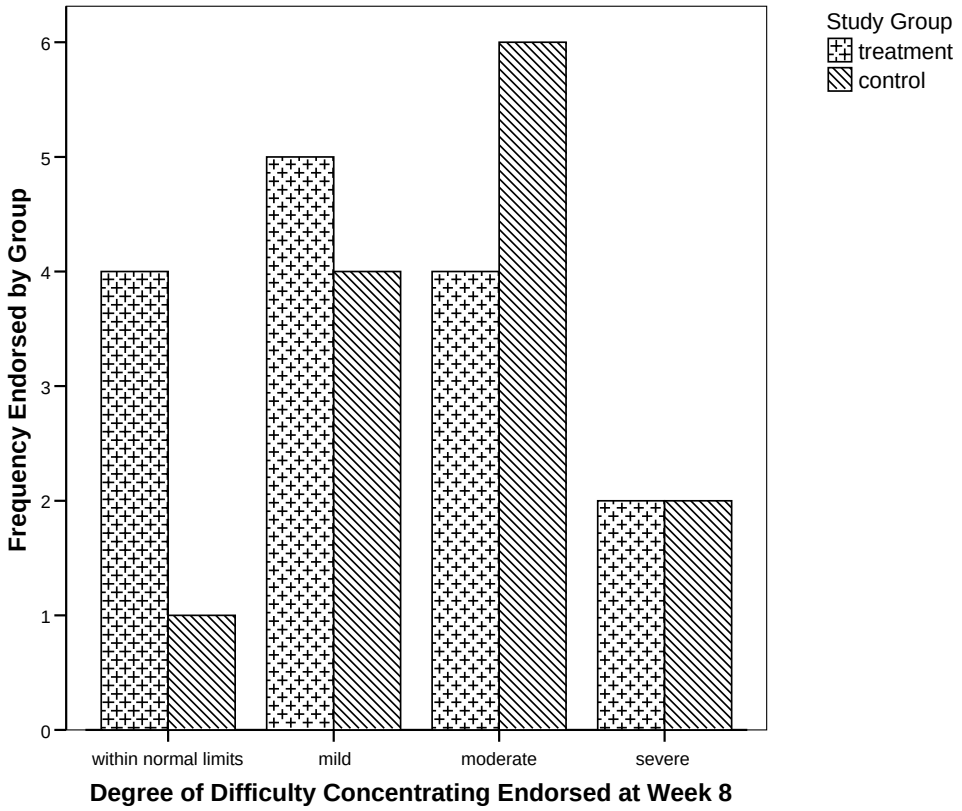
Figure 5.6 (a)

Frequency and Intensity of Endorsing Concentration Difficulty by Group



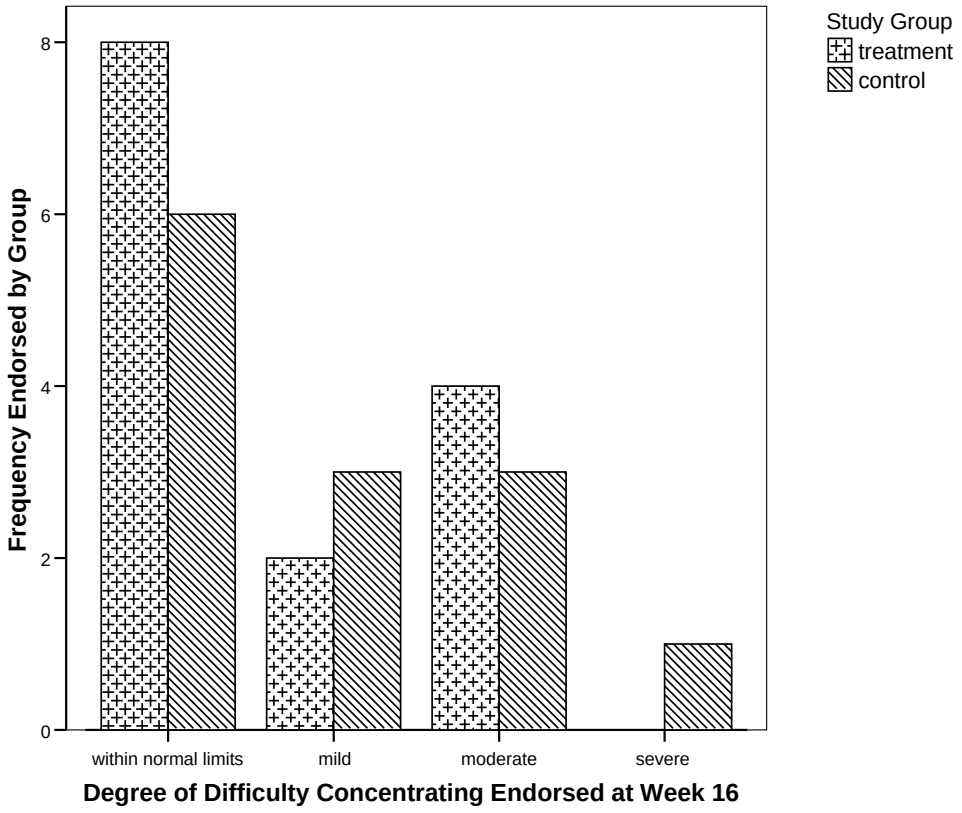
Note: Similar patterns of endorsement with respect to disturbance in concentration are seen in both groups at baseline.

Figure 5.6 (b)



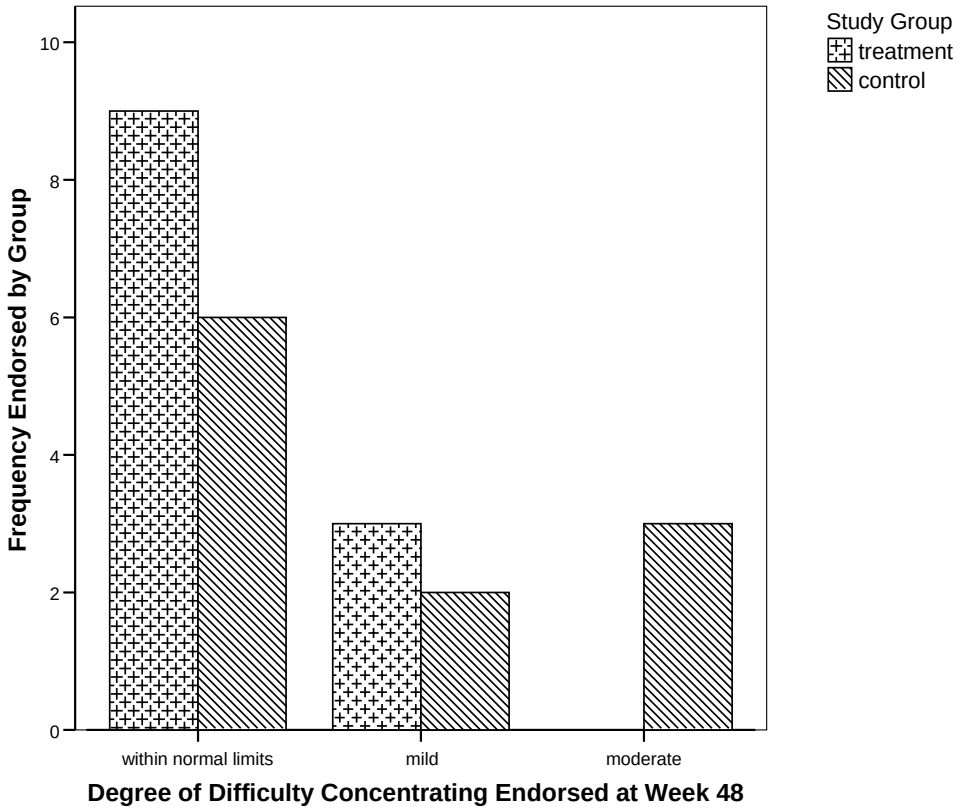
Note: At the end of the treatment period, the number of treatment group participants endorsing concentration within normal limits to mild disturbance exceeds that of the control group; however, moderate to severe disruption of concentration continued to be endorsed by treatment group participants.

Figure 5.6 (c)



Note: Treatment group participants show increased frequency with endorsing concentration within normal limits as compared to controls.

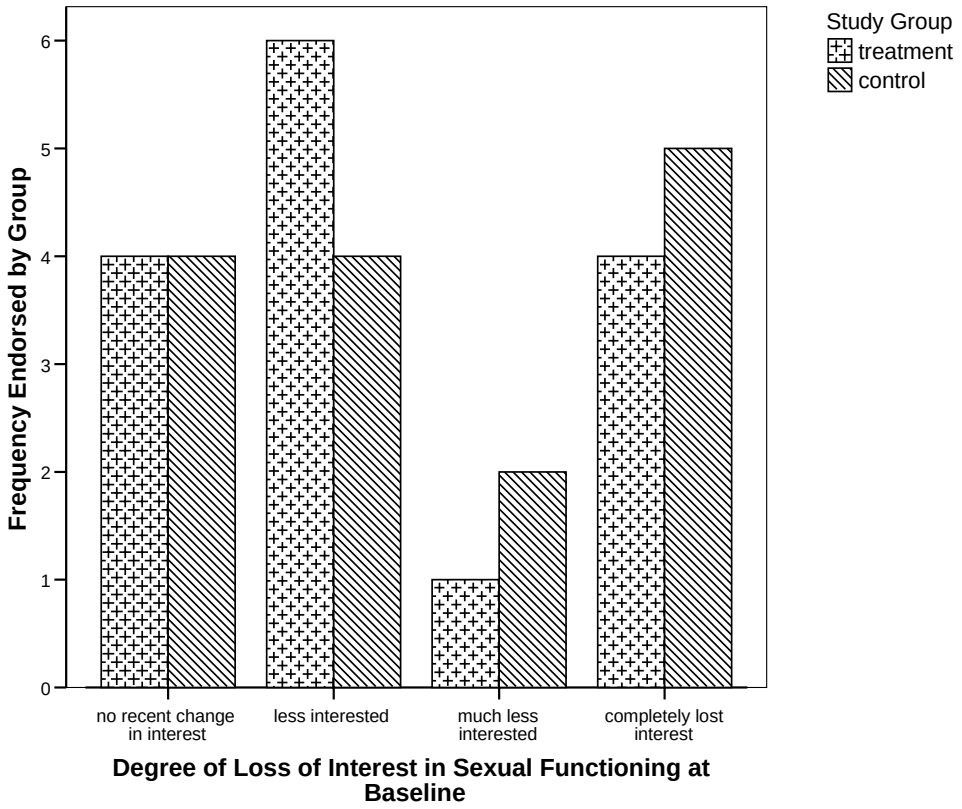
Figure 5.6 (d)



Note: Treatment group participants endorse concentration within normal limits to mildly disrupted at the end of the follow-up period whereas control participants continue to endorse moderate levels of concentration difficulty.

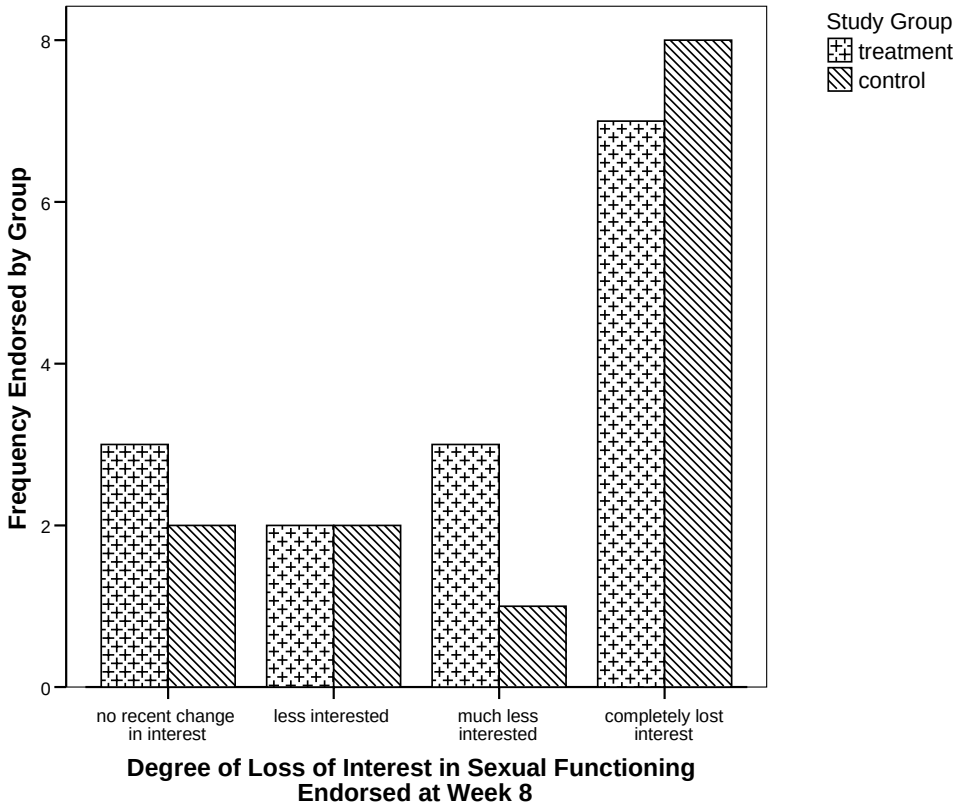
Figure 5.7 (a)

Frequency and Intensity of Endorsing Loss of Sexual Interest by Group



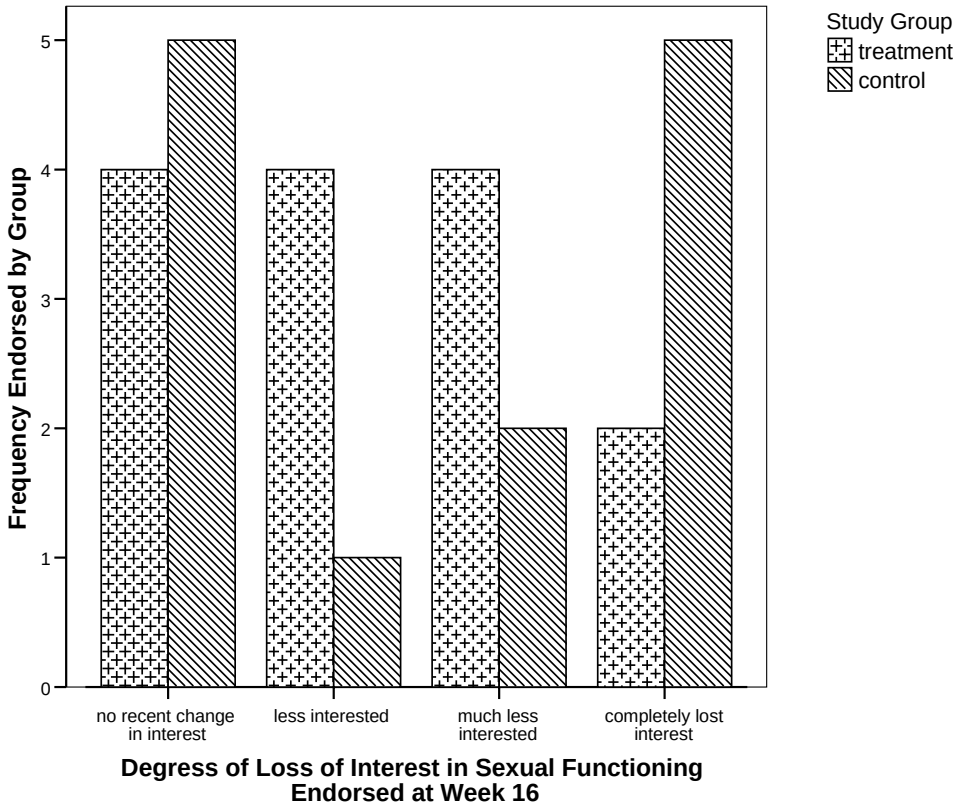
Note: Consistent with the literature, patients in both groups endorsed loss of interest in sexual functioning at similar frequency and intensity at baseline.

Figure 5.7 (b)



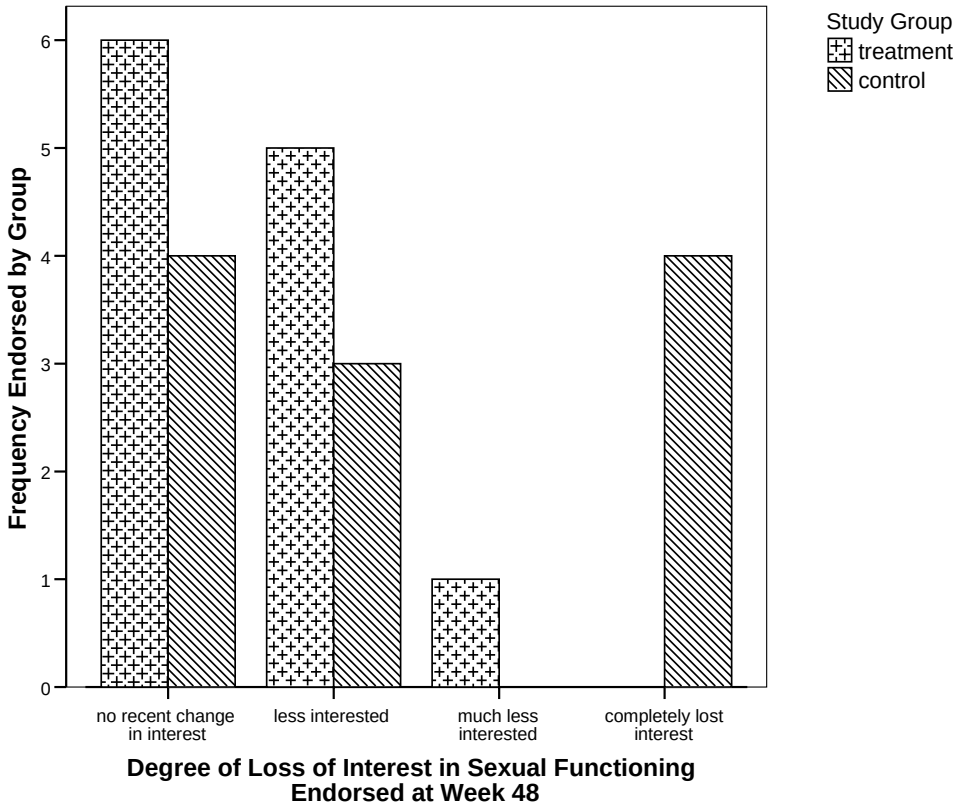
Note: As expected at this stage of treatment, participants in both groups are endorsing loss of interest in sexual functioning at similar frequency and intensity.

Figure 5.7 (c)



Note: At the beginning of the follow-up period, differences between groups in frequency and intensity of endorsing loss of sexual interest are beginning to emerge.

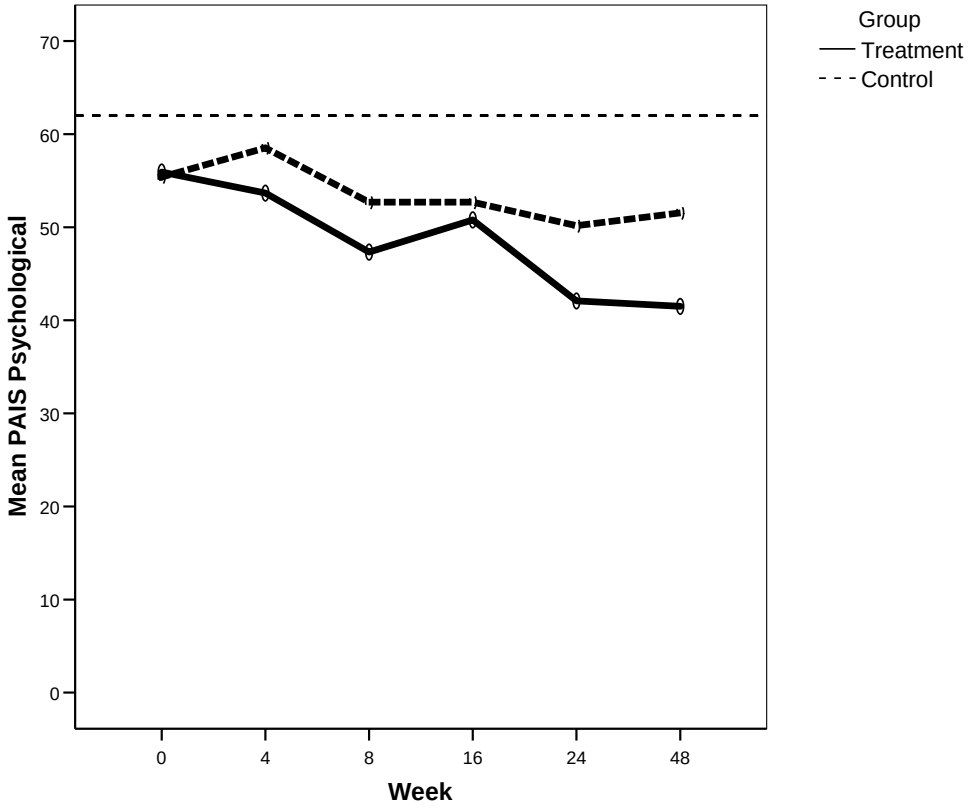
Figure 5.7 (d)



Note: By the end of the study, the intensity of loss of sexual interest endorsed by treatment group participants was reduced significantly compared to controls.

Figure 5.8

Mean T Scores for Depression Symptoms as Reported on the Psychological Distress Subdomain of the PAIS-SR



Note: A T Score of > 62 denotes psychological distress in the unhealthy range. This representation of psychological distress within and between groups in this study suggests that, on average, neither group reported significant psychological distress throughout the study. Comparatively, Figure 5.4 illustrates the levels of distress as measured by the BDI-II. Treatment group is represented by the solid black line.

State Anxiety

Descriptive Statistics of Observed Data

Reported anxiety symptoms varied both within and between groups at each wave of data collection. The distribution and central tendencies of observed scores for state anxiety symptoms by group across all six time points of the study are represented in Figure 5.9 (pg. 150). Descriptive statistics for state anxiety symptoms as measured by the Spielberger State Anxiety Inventory are presented by group in Table 5.7 (pg. 149). Descriptive statistics for trait anxiety, measured at baseline only, are also presented in Table 5.7. Figure 5.9 nicely illustrates the shape and variation of the distribution of state anxiety scores by group across all six time point of the study. At baseline, the shape of the distribution for the treatment group was negatively skewed, with the more treatment group participants endorsing state anxiety symptoms above the median of 34 than below. In contrast, the shape of the distribution of state anxiety scores for the participants in the control group was positively skewed with greater endorsement of state anxiety symptoms below the median of 49 than above. As illustrated in Figure 5.9 (b), the variability of state anxiety symptom scores around the mean was similar between treatment (SD= 18.17) and control (SD=17.93) groups. Interquartile ranges were also similar between treatment and control groups (36 and 34, respectively). The central tendencies of both groups were not statistically different; however, there may be clinical significance in the difference. The mean

state anxiety score endorsed by participants in the treatment group fell within the range of mild anxiety compared to the control group's mean endorsement of state anxiety within the moderate range. Considering the shape of both distributions (treatment group negatively skewed and control group positively skewed), it is more likely that the individual state anxiety scores are more clinically similar than different. At week 4, the shape of the distribution of state anxiety scores in the treatment group was relatively symmetrical suggesting a more normal distribution of scores around the central tendency of 38.00 (mild anxiety) and the variability within the scores decreased slightly from baseline (SD=16.33). The shape of the distribution of state anxiety scores in the control group remained positively skewed around the central tendency of 51.00 (moderate anxiety); however, there was a slight reduction in the variability of scores in the control group as was noted in the treatment group (SD=14.74). At the end of the treatment period of the study (week 8), the shape of the distribution of state anxiety scores for participants in the treatment group was positively skewed around the median of 34.00 (normal anxiety) and the variability within the scores has decreased significantly from week 4 (SD=9.73). The control group evidenced a relatively symmetrical shape, suggesting a more normal distribution of scores around the median of 42.00 (mild anxiety) and also evidenced a reduction in variability in scores as compared to week 4 (SD=10.01). At the beginning of the follow-up period (week 16), the shape of the distribution of state anxiety scores for

participants in the treatment group was negatively skewed around the median of 26.00 (normal) and the variability within treatment group state anxiety scores increased compared to week 8 (SD=12.47). The shape of the distribution of state anxiety scores endorsed by participants in the control group was positively skewed around the median of 38.74 (mild anxiety) and, concordant with the treatment group, evidenced an increase in the variability in scores compared to week 8 (SD=14.55). At week 24, the shape of the distribution of state anxiety scores endorsed by participants in the treatment group continued to be negatively skewed around the median of 23.00 (normal); however, the variability within scores decreased as compared to week 16. The shape of the distribution of scores endorsed by participants in the control group at week 24 returned to a more symmetrical presentation around the median of 33.00 (normal); however, unlike the treatment group, there was no reduction in the variability in scores at week 24 for the control group (SD=14.95). Finally, at week 48, the final point of data collection suggested that the shape of the distribution of scores endorsed by participants in the treatment group continued to be negatively skewed around the median of 24.00 (normal) with continued reduction in variability as compared to week 24 (SD=6.01). The shape of the distribution of state anxiety scores endorsed by participants in the control group at week 48 of the study appeared slightly negatively skewed around the median of 34.00 (normal) with no reduction in variability of scores from week 24 (SD=14.35). Figure 5.9 (c) illustrates the

within and between group variability in direction and rate of change in state anxiety symptoms endorsed by participants in the study across all six points of data collection.

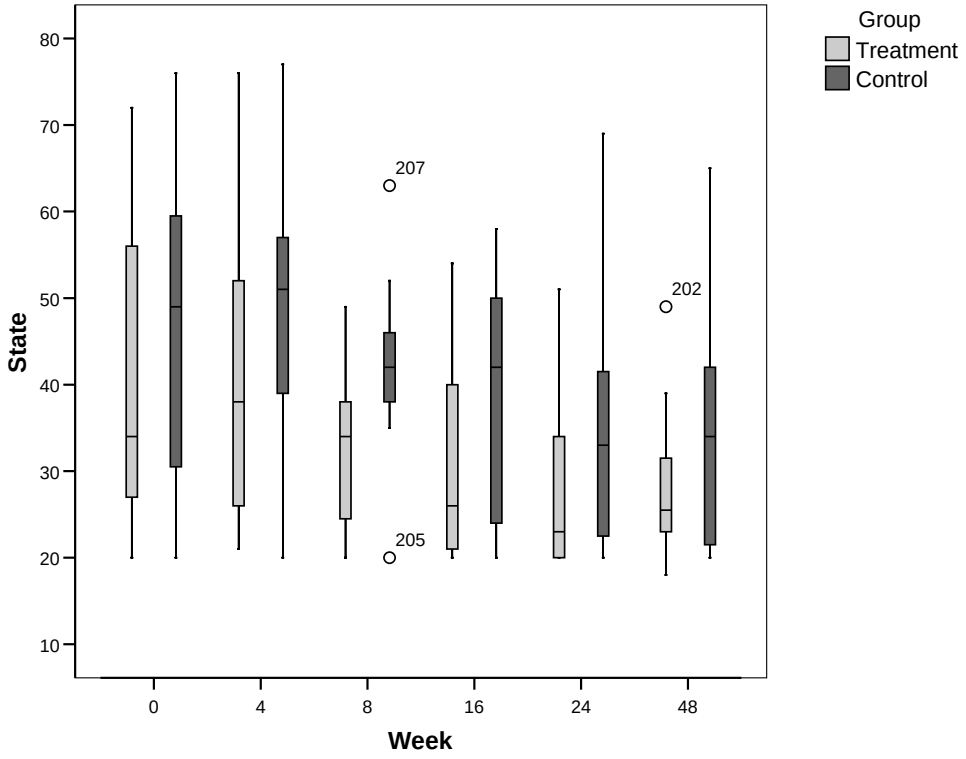
Table 5.7

Descriptive Statistics by Group for State Anxiety Across all Six Waves of Data Collection and Trait Anxiety Scores Completed at Baseline

Anxiety Scores	Group	Mean	Median	SD	Min	Max
Treatment Phase						
Trait	Treatment	32.87	33.00	9.41	20	57***
	Control	33.07	32.00	10.99	20	63***
Baseline State	Treatment	41.60*	34.00	18.17	20	72***
	Control	45.86**	49.00**	17.93	20	76***
Week 4	Treatment	41.13*	38.00*	16.33	21	76***
	Control	49.07**	51.00***	14.74	20	77***
Week 8	Treatment	32.66	34.00	9.73	20	49**
	Control	42.00**	42.05**	10.01	20	63***
Follow-Up Phase						
Week 16	Treatment	31.14	26.00	12.47	20	54***
	Control	38.76*	42.00*	14.55	20	58***
Week 24	Treatment	27.30	23.00	9.54	20	51***
	Control	35.25	33.00	14.95	20	69***
Week 48	Treatment	25.75	24.00	6.01	18	39*
	Control	34.00	34.00	14.35	20	65***

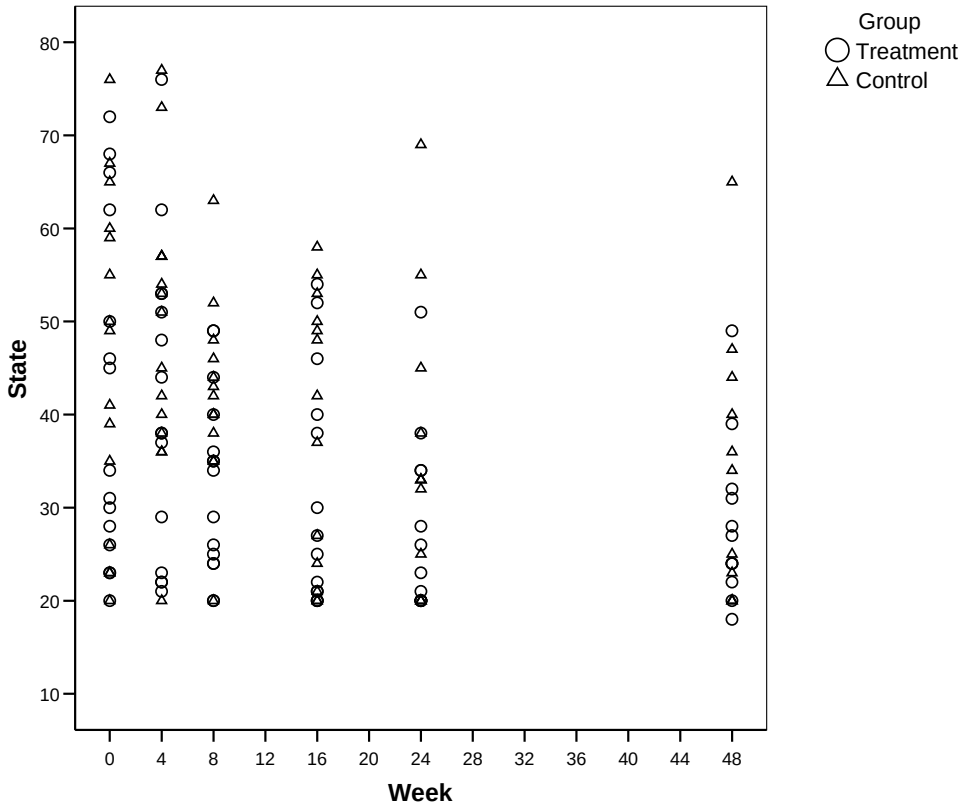
Note: *mild anxiety = 1 SD above the mean; **moderate anxiety = 2 SDs above the mean; *** severe anxiety = 3 SDs above the mean; normative sample mean = 29.60, SD = 6.91

Figure 5.9 (a)



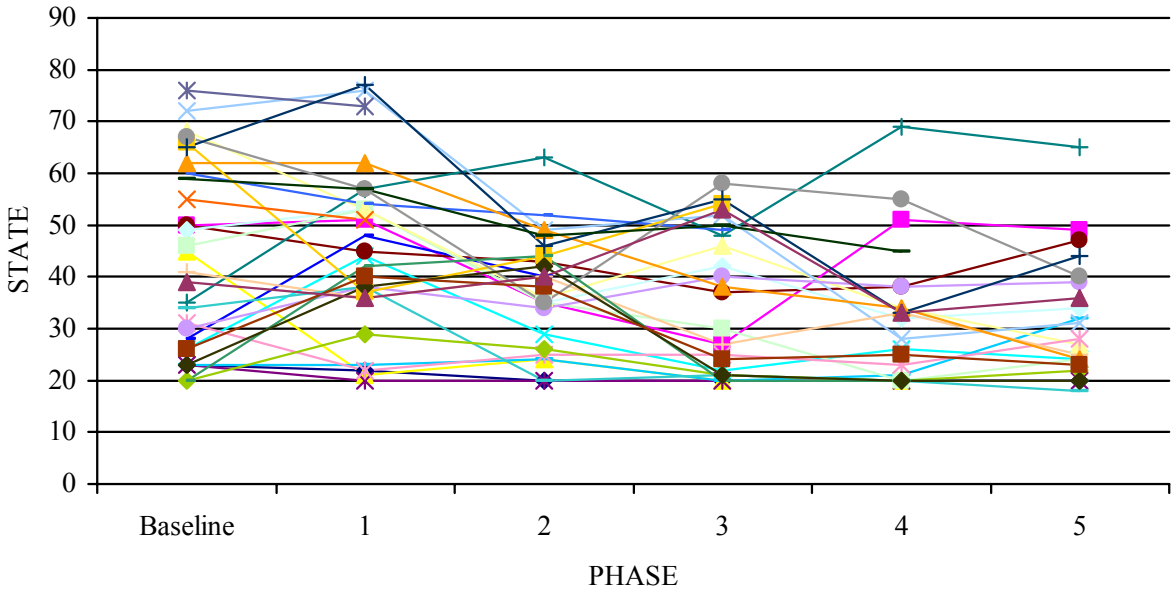
Note: Distribution and central tendency of state anxiety symptom scores as measured by the Spielberger State Anxiety Inventory by group across all six waves of data collection. Outliers, or extreme scores, that may require special consideration are denoted by patient identification number. Higher scores denote increased presence of anxiety symptoms.

Figure 5.9 (b)



Note: Distribution of individual state anxiety symptom scores on the Spielberger State Anxiety Inventory at each wave of data collection for treatment (circles) and control (triangles) group participants. This scatter plot highlights the variability in scores between individuals at each wave of data collection. Higher scores denote increased presence of anxiety symptoms.

Figure 5.9 (c)



Note: Combined group (treatment + control) individual empirical growth plots illustrate the within and between group variability in change over time with respect to endorsed state anxiety symptoms. Higher scores denote increased levels of state anxiety. State anxiety scores are presented as raw scores derived from the Spielberger State Anxiety Inventory. Phases correspond to the six points of data collection: Phase 1 = week 4; 2 = week 8; 3 = week 16; 4 = week 24; 5 = week 48.

Statistical Models of State Anxiety Symptoms

To answer the research question, is variation in within-individual weekly rate of change in state anxiety symptoms related to group membership, growth models were constructed using state anxiety scores for each participant during the treatment phase of the study. Beginning with an unconditional means model (Table 5.8), the fixed effects suggest that the average participant in the study endorsed state anxiety symptoms at the high end of the mild anxiety range (42.43). This model suggests an estimated 61% of the total variation in state anxiety symptoms during the treatment phase of the study is attributable to differences among women in our sample.

Next, the predictor time was introduced into Model B yielding a main effect ($p<.05$). The fixed effects suggest that the average participant in the study endorsed state anxiety symptoms in the moderate range (45.19) and evidenced a significant decrease in state anxiety symptoms at a rate of .74 points per week during the treatment period of the study.

Table 5.8

Growth Modeling for State Anxiety Symptoms: Treatment Phase (Weeks 1-8)

		Parameter	Model A	Model B	Model C	Model D	Model E
Fixed effects	Intercept	γ_{00}	42.43*** (2.45)	45.19*** (3.24)	38.58*** (10.13)	48.48** (15.84)	49.27* (19.24)
Initial status							
	Group	γ_{01}			4.38 (6.41)	4.08 (6.37)	6.14 (6.48)
	Age					-.167 (.206)	
	Education						-.992 (1.22)
Rate of change	Intercept	γ_{10}		-.74* (.35)	-1.93 (1.05)	-2.59 (1.87)	-2.95 (2.00)
	Group	γ_{11}			.82 (.67)	.791 (.687)	.644 (.681)
	Age					.011 (.025)	
	Education						.095 (.128)
Variance Components							
Level 1	Within person	σ^2_C	92.60*** (17.28)	61.22*** (15.75)	60.84*** (15.65)	59.80*** (15.38)	55.42*** (14.51)
Level 2	In initial status	σ^2_0	148.07 (47.35)	263.34*** (82.27)	257.53*** (80.69)	253.36*** (79.41)	254.98*** (80.04)
	In rate of change	σ^2_1		1.63 (1.03)	1.41 (.99)	1.53 (1.04)	1.52 (.968)
	Covariance	σ^2_{01}		-17.48* (8.00)	-17.87* (7.81)	-18.27* (7.98)	-17.67* (7.70)
R^2 Statistics & Goodness of Fit							
	R^2			.33	.006	.017	.089
	ρ		.61				
	Deviance		700.299	686.949**	678.806*	678.150	653.283***
	AIC		706.299	698.949	694.806	698.150	673.283
	BIC		713.731	713.35	714.625	722.924	697.709

***p<.001; **p<.01; *p<.05

Examining the variance components, a significant reduction (92.60 to 61.22) in scatter around the observed state anxiety scores was noted with the addition of time into Model B. Interestingly, there was a significant increase in the variability around the true initial status of state anxiety symptoms in Model B (148.07 to 263.34). The covariance of -17.48 ($p<.05$) suggests that participants who entered the study endorsing higher levels of anxiety were more likely to evidence a faster rate of reduction in anxiety symptoms over time. Time accounted for approximately 33% of the within-individual variation in rate of change in state anxiety symptoms during the treatment period of the study.

In Model C, the predictor Group was introduced but did not yield a main effect. Although the fixed effects of Model C suggest an improvement in anxiety symptoms compared to Model B, from moderate to mild for the average participant in the study (38.58), the rate of change predicted by group was not significantly different from zero suggesting that group was not a significant predictor of rate of change in anxiety symptoms during the treatment phase. Figure 5.10 (pg. 166) illustrates the rise and then decline in anxiety scores for both groups during the treatment phase of the study.

The variance components of Model C suggest a slight reduction in the scatter around the observed state anxiety scores and a slight reduction in the variability within the true initial status in state anxiety symptom scores. A small reduction was also noted in the variability in true rate of change of state anxiety

symptom scores with the introduction of group into the model. Although time was no longer a significant predictor of the within-individual variation in the rate of change in state anxiety symptom scores during the treatment period of the study, the covariance continued to be negative and strong ($p<.05$) suggesting that participants who began the study endorsing higher levels of state anxiety were more likely to evidence reduction in state anxiety at a fast rate as compared to those who entered the study endorsing lower levels of state anxiety.

To answer the research question: Is within-individual variation in rate of change in state anxiety scores during the treatment period of the study related to demographic variable of the participants, reported participant age and number of years of education were introduced into the model as substantive predictors. Age was introduced in Model D. Fixed effects suggest that the average participant endorsed mild anxiety (48.48) and there were no significant differences between groups in terms of variability of state anxiety scores. There were also no significant differences in the variability of age. No main effect of age was observed suggesting that participant age does not significantly impact the within-individual variation in rate of change in state anxiety symptoms during the treatment period of the study.

Variance components of Model D suggest a negligible reduction in scatter around the observed state anxiety scores as compared to Model C as well as a slight reduction in variation around the true initial status of state anxiety

symptoms endorsed by participants with the addition of age to the model. A slight increase in the variability in true rate of change was noted as compared to Model C. Covariance continued to be negative and strong ($p<.05$). Age accounted for approximately 1.7% of the within-individual variation in rate of change of state anxiety symptoms in the treatment period of the study.

Education was introduced as a substantive predictor in Model E. Fixed effects suggest that the average participant endorsed moderate anxiety (49.27) and no significant differences between groups were noted with respect to variability in state anxiety symptoms endorsed. No significant differences in variability in education were noted. No main effect of education was observed in Model E suggesting that the number of years of education reported by a participant did not significantly impact the within-individual variation in rate of change in state anxiety symptoms during the treatment phase of the study.

The variance components of Model E suggest a slight reduction in the scatter in observed state anxiety symptoms as compared to Model C as well as a slight reduction in the variability in the true initial status of state anxiety symptoms endorsed by participants. A slight increase was observed in the variation in the true rate of change of state anxiety symptoms with the introduction of education into the model. However, covariance continued to be negative and strong ($p<.05$) suggesting that participants who entered the study endorsing higher levels of state anxiety were more likely to evidence a faster rate

of decline in state anxiety symptoms compared to those who entered the study endorsing lower levels of state anxiety. Education accounted for approximately 8.9% of the remaining within-individual variation in rate of change in state anxiety symptoms.

We conclude that, although not stable when combined with other predictors, time appeared to be the most significant predictor of within-individual variation in rate of change in state anxiety symptoms. The predictors group, age, and education all made small contributions to the reduction of the variability in within-individual rate of change in state anxiety symptoms but were not significant contributors.

Deviance statistics were compared across all five of the treatment period growth models constructed. Significant improvements in goodness of fit were noted between Models A (no predictors) and B (time) ($p<.01$); Models B (time) and C (time + group) ($p<.05$), and Models C (time + group) and E (time + group + education) ($p<.001$). The deviance statistic for Model E was the smallest of all of the models suggesting it was the most parsimonious model in terms of goodness of fit.

To answer the research question, is variation in within-individual rate of change in state anxiety symptoms endorsed during the follow-up phase of the study related to group membership, a model was constructed using only data collected at weeks 16, 24, and 48 of the study (Table 5.9). The within-individual

variation in Model A is significant ($p<.001$) to suggest that differences in women in the sample account for changes in anxiety symptoms. Approximately 61% of the within-individual variability in rate of change in state anxiety symptoms endorsed in the follow-up period of the study was related to differences among women in our sample.

Time was introduced as a substantive predictor in Model B and did not demonstrate a main effect. The average participant endorsed normal anxiety (35.13) and evidenced negligible improvement in state anxiety symptoms at a rate of .07 points per week.

Examination of the variance components of Model B suggests that there was a slight reduction in the scatter in observed state anxiety scores with the addition of time to the model. Significant variability around the true initial status of state anxiety symptoms was noted in Model B ($p<.05$) and almost no variability was noted in the true rate of change in state anxiety symptoms endorsed (.002). Of interest is the fact that the negative and strong covariance relationship seen during the treatment period of the study no longer exists during the follow-up period of the study, meaning that there does not appear to be a relationship between the level at which state anxiety symptoms are endorsed at the beginning of the follow-up period and the rate at which state anxiety symptoms decrease during the follow-up period. Time accounted for

approximately 4.2% of the remaining within-individual variation in rate of change in state anxiety symptoms during the follow-up period of the study.

Table 5.9

Growth Modeling for State Anxiety Symptoms: Follow-Up Model (Weeks 16-48)

		Parameter	Model A	Model B	Model C	Model D	Model E	Model F
Fixed effects	Intercept	γ_{00}	33.12***	35.13***	23.04*	49.57**	16.36	-5.33
Initial status			(2.28)	(2.92)	(8.79)	(16.18)	(16.13)	(6.98)
	Group	γ_{01}			8.16	6.05	10.10	7.70*
					(5.62)	(5.42)	(5.50)	(3.53)
	Age					-.429		
						(.225)		
	Education						.197	
							(1.02)	
	Baseline State Anxiety							.683***
								(.104)
Rate of change	Intercept	γ_{10}		-.07	-0.02	-.473	-.043	.294
				(.06)	(.18)	(.380)	(.334)	(.832)
	Group	γ_{11}			-0.03	-.001	-.062	-.029
					(.12)	(.118)	(.119)	(.418)
	Age					.007		
						(.005)		
	Education						.004	
							(.021)	
	Baseline State Anxiety							-.007
								(.012)
Variance Components								
Level 1	Within person	σ^2_C	46.86***	44.88***	44.74***	44.01***	43.83***	38.43***
			(9.63)	(9.17)	(9.11)	(9.03)	(8.80)	(7.65)
Level 2	In initial status	σ^2_0	122.55	139.97*	123.51*	102.27*	107.75*	1.09
			(39.01)	(55.29)	(50.12)	(48.33)	(44.72)	(.000)
	In rate of change	σ^2_1		.002	0.02		.001	1.07
				(.00)	(.00)		(.000)	(.000)
	Covariance	σ^2_{01}		-.47	-.45	-.082	-.436	1.08
				(.67)	(.61)	(.640)	(.546)	(.000)
R^2 Statistics & Goodness of Fit								
	R^2			.042	.003	.016	.004	.141
	ρ							
	Deviance		557.74	556.24	553.63	550.04	542.83**	578.02***
	AIC		563.74	568.24	569.63	570.04	562.83	598.02
	BIC		570.70	582.15	588.17	593.22	585.87	621.19

***p < .001; **p < .01; *p < .05

Model C demonstrates the introduction of the predictor group into the model. The fixed effects suggest that the average participant endorsed normal anxiety (23.04) and no significant differences in the variability of state anxiety scores were noted between groups. There is not a main effect of Group in the follow-up phase. Group accounted for a negligible decrease in state anxiety symptoms of 0.03 points per week. In Model C, time accounted for a decrease in state anxiety symptoms at a rate of only 0.03 points per week.

The variance components of Model C suggest almost no reduction in scatter of observed state anxiety symptoms endorsed as compared to Model B. There was a small reduction in the variability in the true initial status of state anxiety symptoms with the introduction of group into the model and virtually no change in the variation in the true rate of change of state anxiety symptoms endorsed during the follow-up period of the study. Group accounted for approximately 0.3% of the remaining within-individual variation in rate of change in state anxiety symptoms endorsed during the follow-up period of the study.

To answer the research question: Is within-individual variation in rate of change in state anxiety symptoms during the follow-up period of the study related to demographic variables or baseline levels of state anxiety symptoms, the demographic variables age and education, as well as the level of state anxiety endorsed at baseline were introduced into the model as substantive predictors. Model D includes the predictor age. According to the fixed effects of the model,

the average participant endorsed state anxiety within the moderately anxious range (49.57). No significant differences were noted between groups with respect to variation in state anxiety symptom scores. No significant differences were noted with respect to variability in the distribution of reported participant age. Model D yielded no main effect of age, group, or time, suggesting that these three predictors did not significantly contribute to the within-individual variation in rate of change in state anxiety symptoms during the follow-up period of the study.

Analysis of the variance components suggests a negligible reduction in the scatter of observed state anxiety scores (Figure 5.9 (b)) and a small reduction in the variation within the true initial status of state anxiety symptoms with the introduction of age into the model. Approximately 1.6% of the within-individual variation in rate of change of state anxiety symptoms during the follow-up period of the study was accounted for by age.

Model E includes the introduction of the predictor education into the model. The fixed effects of Model E suggest that the average participant endorsed state anxiety levels within the normal range and no significant differences were noted in the variability of state anxiety scores with respect to group. No significant differences were noted in variability of reported number of years of education. Model E did not yield a main effect of education, group, or time, suggesting that these three factors did not significantly influence the within-

individual variation in rate of change in state anxiety symptoms during the follow-up period of the study.

The variance components of Model E suggest that there was a slight reduction in the scatter of observed state anxiety scores and an increase in the variability in true initial status of state anxiety scores with the introduction of education into the model. Education accounted for approximately 0.4% of the remaining within-individual variation in rate of change in state anxiety symptoms in the model.

The final predictor added to the model was the score for state anxiety symptoms endorsed at enrollment into the study (baseline). The fixed effects of Model F suggest that the average participant endorsed state anxiety symptoms within normal limits (-5.33) and that significant variation in the distribution of state anxiety scores was present between groups ($p<.05$). Significant variation in the distribution of baseline state anxiety scores was also present ($p<.001$). However, Model F did not yield a main effect of baseline state anxiety score, group, or time. As such, these factors did not significantly contribute to the within-individual variation in the rate of change in state anxiety symptoms during the follow-up period of the study.

The variance components suggest that the addition of baseline state anxiety symptom scores moderately decreased the scatter in observed state anxiety scores and significantly decreased the variability in true initial status of

state anxiety symptoms such that it was no longer significant in Model F. However, the addition of this predictor moderately increased the variability in the true rate of change in state anxiety symptoms from Model C to Model F. Baseline state anxiety symptom scores accounted for approximately 14% of the within-individual variation in the rate of change in state anxiety symptoms during the follow-up period of the study.

Analysis of deviance statistics across models suggests no significant improvements in goodness of fit from Models A through D. However, Model E (education + group + time) shows significantly better fit as compared to Model C (group + time) ($p<.01$). The difference in deviance statistics between Models C (group + time) and F (baseline anxiety + group + time) yielded a significant effect ($p<.001$); however, Model F's goodness of fit was significantly worse than that of Model C. As such, Model E (education + group + time) was the most parsimonious of the models.

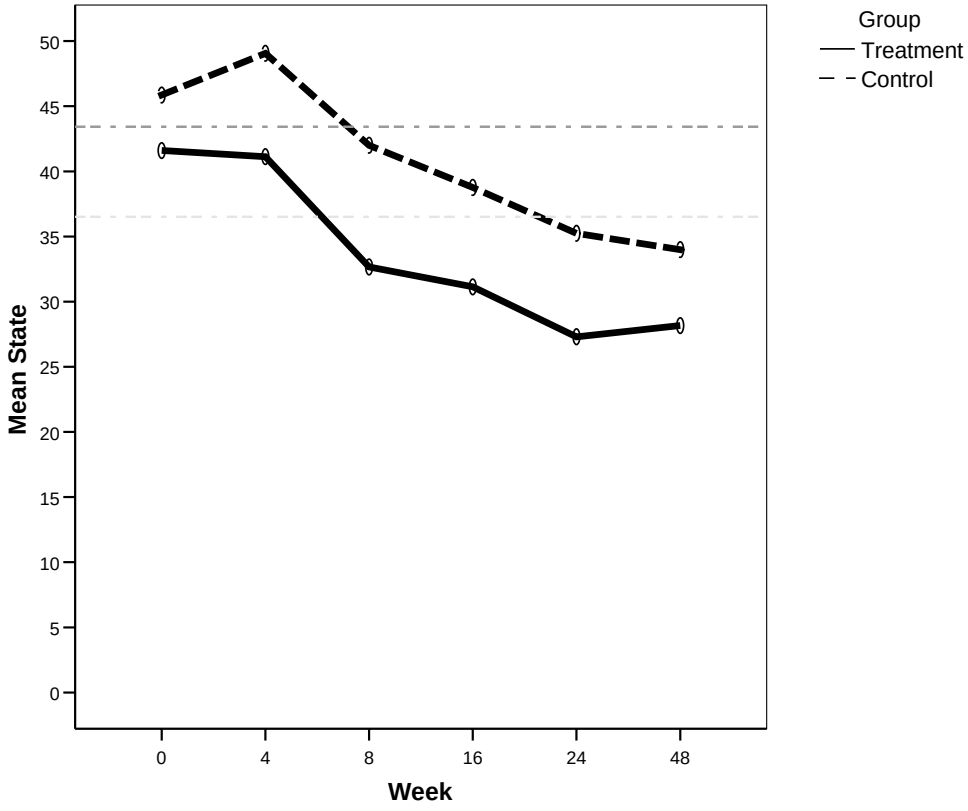
To assess the average state anxiety scores relative to group membership at each time point during the treatment phase of the study, repeated measures ANOVA was conducted using scores on the Spielberger State Anxiety Inventory (STAI) across the first three time points (baseline, week 4, week 8) of the study. The more conservative Greenhouse-Geisser test of within subjects effects was used to minimize Type I error for these analyses. Results suggest a main effect of time ($p<.05$) but no main effect of group over the 3 time points of the treatment

phase study. Post hoc analyses suggest that the main effect of time was most significant at week 8 ($p<.05$; effect size = .91). Although there was not a main effect of group, participants in the treatment group did evidence lower state anxiety scores compared to controls (Figure 5.10).

To assess average state anxiety symptoms relative to group membership at each time point during the follow-up phase of the study, repeated measures ANOVA analysis was conducted using the last three time points of the study (weeks 16, 24, and 48). A main effect of time ($p<.05$) and group ($p<.05$) was observed during the follow-up phase. With participants in the treatment group evidencing significantly lower state anxiety scores over time as compared to participants in the control group, most significantly at week 48 (Figure 5.10; effect size = .04).

Figure 5.10

Mean State Anxiety Symptoms by Group



Note: 1 standard deviation above the mean = mild anxiety; 2 standard deviations above the mean = moderate anxiety; normative mean = 29.60 (SD = 6.91) (Spielberger, 1983). The first grey dotted line represents the beginning of the mild anxiety range and the second, darker dotted line represents the beginning of the moderate anxiety range.

The intervention had an effect size of .43, which is considered large (Cohen, 1992), from baseline to week 48; however, when comparing the effect sizes during the treatment vs. follow-up periods, the data suggest that the intervention had the greatest effect on state anxiety symptoms during the treatment period.

There were no differences between groups in trait anxiety scores taken at baseline. The mean trait anxiety scores for both groups were measured within normal limits. Therefore, trait anxiety was not used as a predictor in our analyses.

Life Experiences Survey (LES)

The LES was collected at all 6 time points of the study; however, problems with the completion of the measure within participants emerged. The directions for completing the measure are somewhat unclear resulting in inconsistency within and between participants at each of the 6 time points. Although clarification was given in writing as well as verbally, participants continued to evidence difficulty with accurate completion of the measure. As a result, the data collected were not meaningful or reliable and could not be used as a substantive predictor for any of the analyses. However, the baseline measure was completed with the research coordinator and was the only time point providing meaningful information. When the mean number of significant events was compared, there were no differences between groups in baseline LES scores.

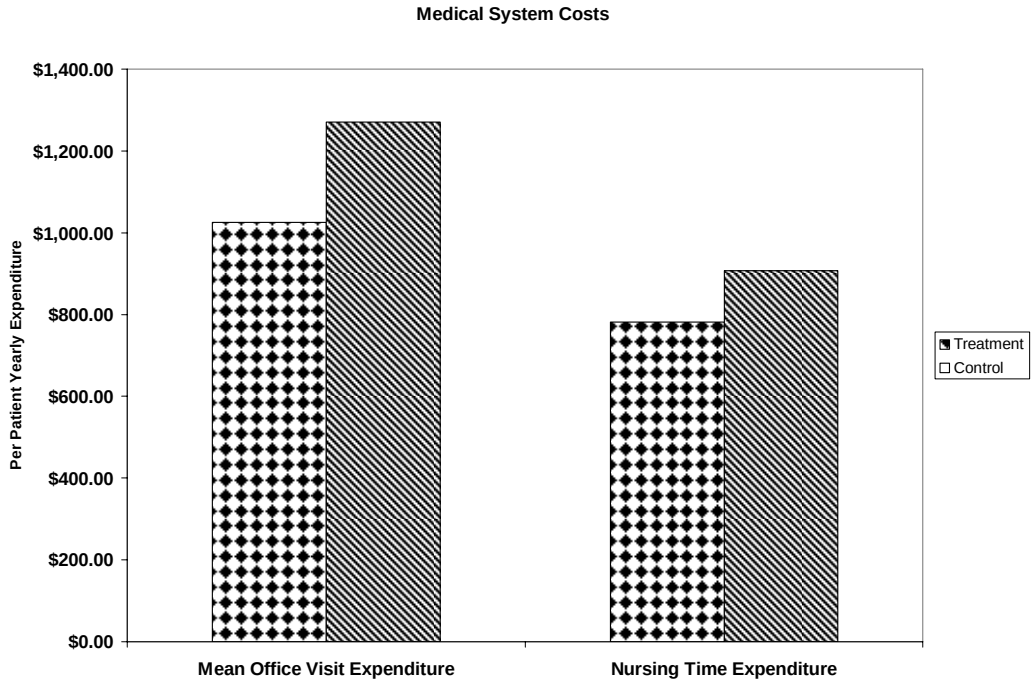
Cost Analyses

Self-report surveys were mailed to all study participants who completed the study at the end of the 12 month follow-up period. Response rate was 83% for the treatment group (10 of 12) and 100% for the control group (11 of 11). Table 5.10 provides the outcome of the self-report survey. Although not significantly different, participants in the treatment group reported a mean of 12.5 office visits during the 12 month period of the study whereas participants in the control group reported a mean of 15.5 office visits. Participants in the treatment group reported making slightly fewer phone calls to ask questions or make requests of the medical office staff (mean = 12.5) than did participants in the control group (mean = 13.2) over the 12 month period of the study. As all patients were recruited from the same treatment facility, the cost of an office visit was determined using the current billing prices for a routine office visit at Texas Oncology Physician Associates at Baylor Sammons Cancer Center ($82.00 per office visit). Figure 5.11 illustrates that, on average, patients in the treatment group spent $1025.00 per patient over a 12 month period on medical office visits, whereas patients in the control group spent $1271.00 per patient over the same amount of time. The total estimated cost differential between the groups is $246.00 per patient with the patients in the treatment group spending less than those in the control group on medical office visits during the 12 month study

period for an estimated total of $2,706.00 in additional costs spent by women in the control group.

Figure 5.11

Medical System Expenditures by Group



Note: Although not significantly different, the treatment group evidenced lower medical office visit costs and required less nursing time with returning phone calls as compared to controls.

Table 5.10

Self-Report Analyses of Medical Office Time and Medication Usage between Groups

		Treatment (n=10)	Control (n=11)
Pre-existing Mental Health Diagnoses (Prior to Ovarian Cancer Diagnosis)	Depression	2 of 10	3 of 11
	Anxiety	1 of 10	3 of 11
	Bipolar Disorder	0 of 10	0 of 11
	Insomnia	0 of 10	0 of 11
	Psychotic Disorder	0 of 10	0 of 11
Medical Visits & Phone Calls During 12 Months of the Study	Mean Office Visits	12.5	15.5
	Mean Phone Calls to Office	12.5	13.2
Post- Diagnosis Medications Prescribed	Depression	0 of 10	5 of 11
	Anxiety	1 of 10	4 of 11
	Bipolar Disorder	0 of 10	0 of 11
	Psychotic Disorder	0 of 10	0 of 11
	Insomnia	0 of 10	2 of 11
	Pain	4 of 10	8 of 11
Treatment	Mean # of Treatments	6.4	7.3
	Full Response to Treatment	9 of 10	11 of 11
	Recurrence in 12 Months	1 of 10	1 of 11

Note: 10 of 12 (83%) participants in the treatment group and 11 of 11 (100%) participants in the control group responded to the self-report survey of cost analyses data.

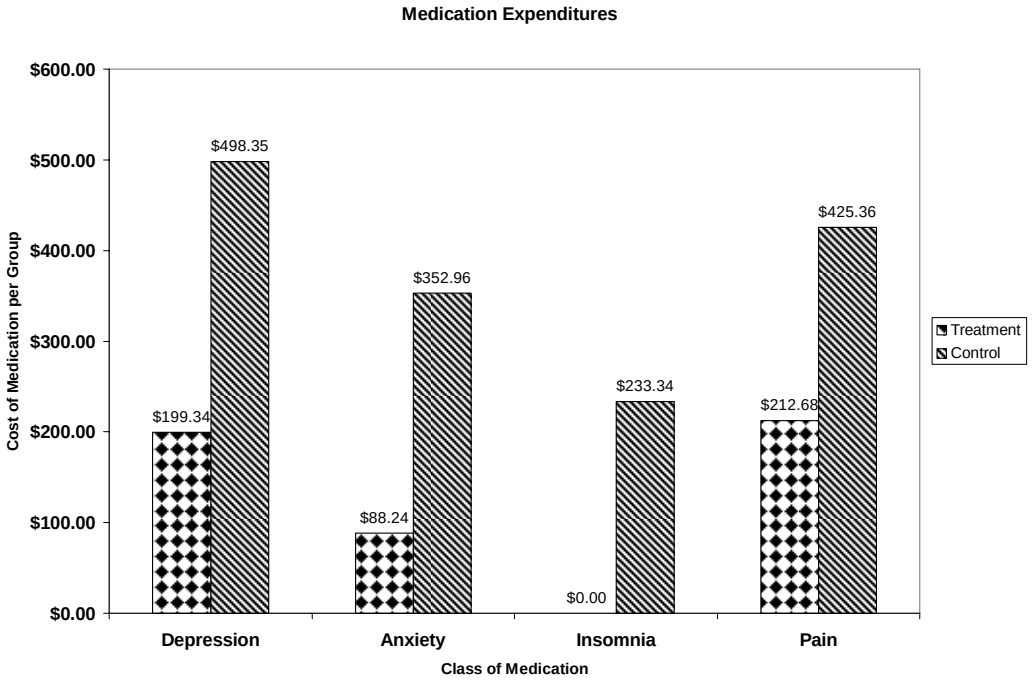
The cost of phone calls was determined in units of nursing time. The average phone call required an estimated 15 minutes of nursing time. We used an average salary of $25.00 per hour and divided it into 4 units of time equaling $6.25 per unit making the average cost of nursing time spent answering phone calls from patients in the treatment group $781.30 (equivalent to 31.25 hours of nursing time) compared to an estimated $907.50 (equivalent of 36.30 hours of nursing time) of nursing time spent answering phone calls from patients in the control group, a cost differential of $126.20 (a savings of approximately 5 hours of nursing time) over the course of 12 months.

In terms of requests for medication during the 12 month follow-up period of the study, Figure 5.12 illustrates that patients in the treatment group were less likely to request medication for depression symptoms, anxiety symptoms, insomnia, or pain than were participants in the control group. Using an internet search to compare prices of the most commonly prescribed drugs in each class, we obtained the prices of three different medications in each class and used the average cost of the three drugs as the cost in our analyses. Table 5.11 provides the medications and costs obtained from the internet comparison search. On average, patients in the treatment group spent $199.34 per month on antidepressant medication compared to an average of $498.35 spent on antidepressant medication by patients in the control group. It is noteworthy that the cost of antidepressant medication in the treatment group reflects only patients

who were taking antidepressant medication before being diagnosed with ovarian cancer (Figure 5.13). Five of 11 patients in the control group reported taking antidepressant medication after diagnosis of ovarian cancer, three of whom were taking antidepressant medication prior to their cancer diagnosis. The cost of anxiety medication was three times higher in the control group as compared to the treatment group ($352.96/ month and $88.24/ month respectively). Patients in the control group spent twice as much on pain medication than did patients in the treatment group ($425.36/ month vs. $212.68/ month). Finally, patients in the control group also evidenced a greater expenditure on insomnia medication ($233.34/ month) as compared to patients in the treatment group who reported no expenditure for insomnia medication over the 12 month period of the study.

Figure 5.12

Self-Report of Medication Expenditures by Group



Note: Control group participants incurred greater expenditures in all medication classes assessed. The control group's significantly increased use of psychiatric and pain medications underscores the significant differences between groups with regard to outcome measures. Even with the use of medication, the control group experienced increased levels of psychological distress as compared to the treatment group.

Table 5.11

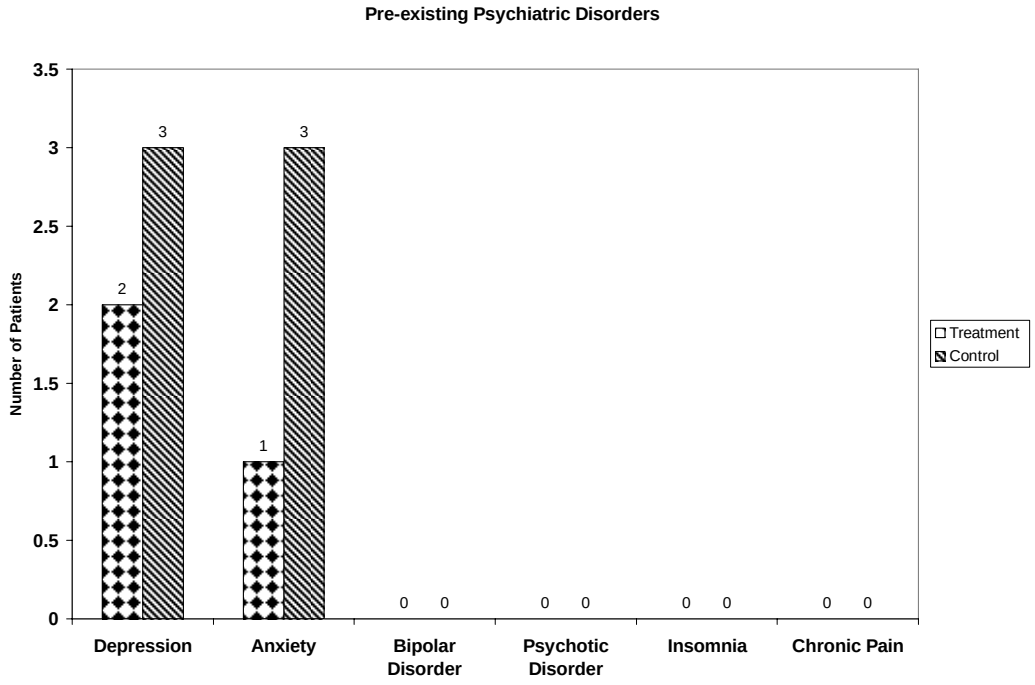
Comparison of Medication Prices by Classification

Class	Brand Name	Generic Name	Average Cost per Month	# of Pills
Antidepressants[a]	Celexa	Citalopram	$94.00	30
	Paxil	Paroxetine	$105.00	30
	Zoloft	Sertraline	$100.00	30
	Mean		$99.67	
Anxiety[b]	Xanax	Diazepam	$104.71	30
	Ativan	Lorazepam	$50.00	30
	Restoril	Temazepam	$110.00	30
	Mean		$88.24	
Insomnia[a]	Ambien	Zolpidem	$114.00	30
	Lunesta	Eszopiclone	$130.00	30
	Sonata	Zaleplon	$106.00	30
	Mean		$116.67	
Pain[b]	Darvocet	Propoxyphene	$45.65	30
	Lortab	Hydrocodone	$42.17	30
	Ultram	Tramadol	$71.69	30
	Mean		$53.17	

[a] Information obtained from the website of Consumer Reports Best Buy Drugs (www.CRBestBuyDrugs.org); [b] Information obtained from the website of Prescription Drug Planet (www.PrescriptionDrugPlanet.com), which is an online pharmaceutical sales company

Figure 5.13

Self-reported Treatment for Mental Health Diagnoses Prior to Cancer Diagnosis



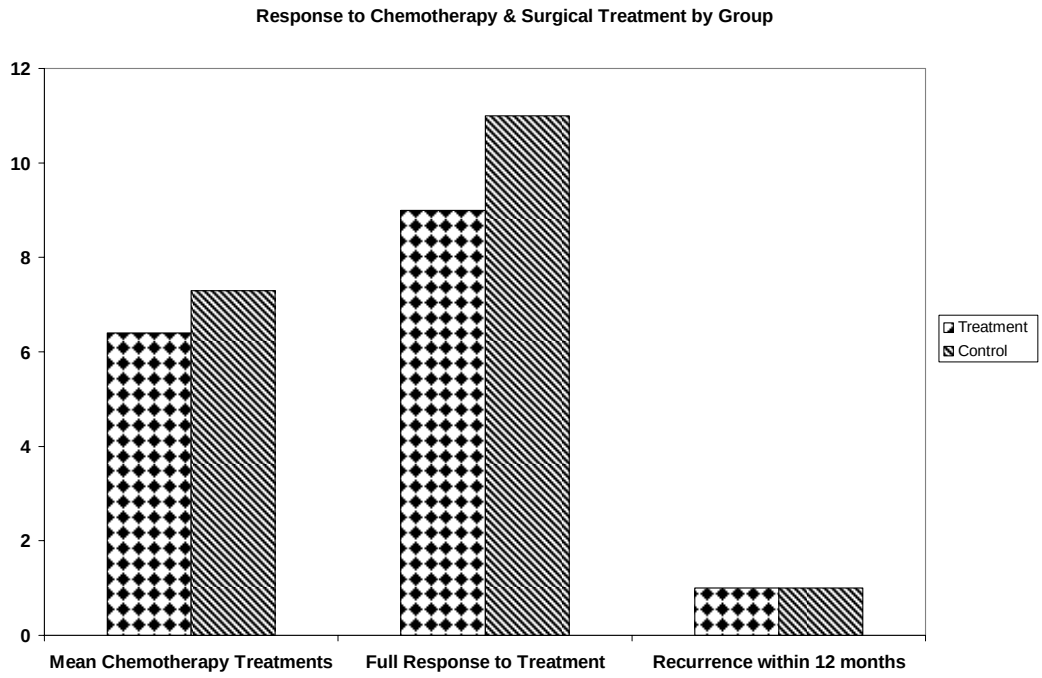
Note: This figure represents the number of patients who received medication and/ or psychotherapy as treatment for a psychiatric disorder prior to the diagnosis of ovarian cancer. No significant differences were observed between groups.

As illustrated in Figure 5.14, on average, participants in the treatment group received 6.4 chemotherapy treatments and participants in the control group received an average of 7.3 chemotherapy treatments (not significantly different). Of those patients who responded to the survey, 9 of 10 treatment patients and 11 of 11 control patients enjoyed a full response to treatment (no evidence of disease

at the end of chemotherapy treatments). Recurrence rates during the 12 month period of the study were similar in both groups (1 of 10 in the treatment group; 1 of 11 in the control group).

Figure 5.14

Response to Medical Treatment by Group



Note: No significant differences were noted between groups in the mean number of chemotherapy treatments received per patient, the number of patients who had a full response to treatment (i.e. no evidence of disease), or the number of recurrences following a full response to treatment. Although not represented in the figure, no significant differences were found between groups with respect to the type of chemotherapy received.

Treatment Group Satisfaction with the Intervention

Following the end of the 12 month study period, patients in the treatment group, who were still active in the study, were sent a survey to assess their satisfaction with the individual intervention. There were 12 of 15 treatment group patients active in the study at the time of the survey as 2 patients were deceased and one was lost to follow-up after week 16. Response rate was 83% (10 of 12 patients). Patients were asked to rate the usefulness/ helpfulness of each session (not helpful to very helpful). The survey also asked if participation in the individual intervention increased the likelihood that the patient would be willing to participate in a group support program and if she had actually participated in group since the end of the individual intervention. Surveys were not identified by study ID or name in an attempt to facilitate anonymity of responses. Ratings by session can be found in Table 5.12. In Figure 5.15, we see that overall, more than 50% of the respondents rated sessions 1 and 2, and 4 through 8 very helpful. Session 3, which involves a discussion of communication with the treatment team, was rated somewhat helpful by 50% of the respondents, very helpful by 40% of respondents, and neutral by 10% of respondents. No sessions were rated as being not helpful. Eighty percent of respondents (8 of 10) indicated that participation in the individual intervention increased their willingness to attend a group support program; however, only 40% of respondents indicated that they had participated in a group support program since completing the individual

intervention sessions. The remaining 20% of respondents indicated a preference for individual support programs as opposed to joining a group support program. Specifically, they expressed interest in volunteer training for the cancer survivor individual support program currently offered within the Cvetko Education Center.

Table 5.12

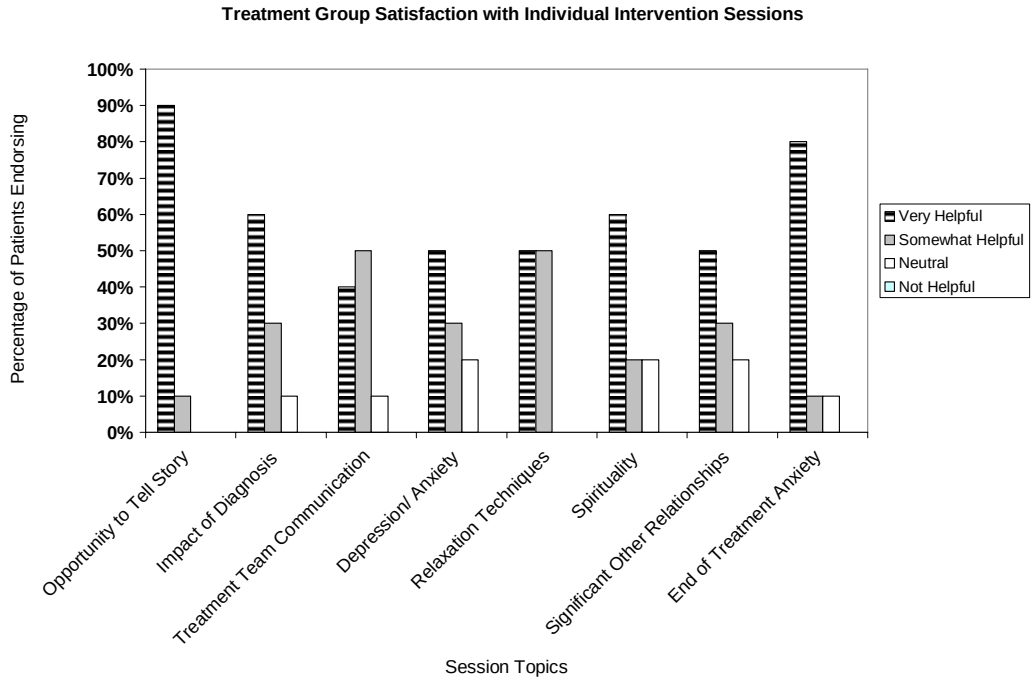
Treatment Group Satisfaction with Individual Intervention Sessions

Session Topic	Very Helpful	Somewhat Helpful	Neutral	Not Helpful
Opportunity to tell your story	90%	10%		
Impact of diagnosis on different areas of life	60%	30%	10%	
Communication with Treatment Team	40%	50%	10%	
Depression/ Anxiety	50%	30%	20%	
Relaxation Techniques	50%	50%		
Spirituality	60%	20%	20%	
Relationships with Significant Others	50%	30%	20%	
End of Treatment Anxiety	80%	10%	10%	

Note: This table represents the opinions of 10 of the 12 treatment group participants who completed the study. A total of 15 women completed the 8 week intervention; however, 2 of the original sample of 15 were deceased prior to the end of the 12 month follow-up and 1 was lost to follow-up after week 16.

Figure 5.15

Service Satisfaction Reported by Individual Intervention Participants



Note: Treatment group participants endorsed the greatest benefit from sessions 1 and 8 of the intervention. There were no sessions rated as "not helpful" by any of the participants. However, 6 of the 8 sessions received "neutral" ratings from at least one participant. Overall, satisfaction with the individual intervention was high and contributed to the perception of more personal and specific medical care received at BUMC.

CHAPTER SIX
Discussion

Psychosocial Adjustment to Illness

Analysis demonstrated a main effect of time for the total score of the psychosocial adjustment to illness. There was also an interaction between group and time for the total score, with the treatment group evidencing better psychosocial adjustment to illness as compared to controls. There were no significant predictors to explain the differences in the rate of change between groups during the treatment phase of the study. Although the treatment group evidenced a slightly more rapid rate of change in psychosocial adjustment to illness, the addition of time, group, age, and education did not significantly predict the variation in within-individual rate of change in psychosocial adjustment during the first eight weeks of the study. Time and group were significant predictors in rate of change in psychosocial adjustment during the follow-up period of the study. Education, age, and baseline psychosocial adjustment to illness contributed to the reduction in the variation in within-individual rate of change of psychosocial adjustment to illness when added to the models; however, no main effect of these predictors was observed. The most parsimonious of the models created for the follow-up period included the predictors time, group, and baseline psychosocial adjustment to illness scores. It

is important to note that, although significant differences exist in mean scores, both groups remained, on average, within the "healthy range" (T < 62) as compared to the normative group, with the exception of the control group at week 4 of the study. In general, the women in both groups endorsed positive supportive social environments (spouse, children, friends, church community, co-workers), all had good access to health care and a history of compliance with check-ups and yearly screens. Most of the study participants reported supportive work environments or did not have the financial need to continue working during treatment. As such, the patients represented in this study were less likely to experience, to a significant degree, the psychosocial stressors related to decreased socioeconomic status, poor access to health care, or poor social support found to be significant contributors to poor psychosocial adjustment to illness within the literature.

Depression Symptoms

A main effect of time was observed as well as an interaction between group and time in depression symptoms. Treatment group members evidenced lower depression scores as compared to controls and were scoring within normal limits by week 16, whereas women in the control group did not score within the range of normal limits until week 24 of the study. Although in the normal range, women in the control group continued to endorse more subjective cognitive

symptoms of depression through week 48 than did women in the treatment group. Supporting the hypothesis that depression scores would normalize across both groups near the end of the follow-up period as the majority of women completed treatment and were showing no evidence of disease, findings demonstrated that time was a significant predictor of the rate of change in depressive symptoms in the treatment as well as the follow-up model. The predictors group, age, education, and baseline depression symptom scores contributed to the reduction in within-individual variability in depression symptoms when added to the follow-up model; however, as no main effects of these predictors were observed, none were significant predictors of rate of change in depression symptoms.

Women in both groups entered the study with depression scores in the mildly depressed range, primarily due to endorsing subjective cognitive symptoms such as difficulty concentrating, difficulty with sleep and appetite, difficulty with memory, and difficulty making decisions. Given that participants were newly diagnosed upon enrollment into the study and faced with a number of treatment decisions pertaining to a life threatening illness, it is not surprising that the subjective cognitive symptoms just described were reported by both groups. Oncology patients often attribute the cognitive related symptoms to chemotherapy. Commonly known as "chemo brain," patients may experience significant disruptions in such cognitive processes as attention and concentration as well as short term memory.

Costanzo et al. (2006) found that the significantly treated patients with advanced stage gynecologic cancer, who were more likely to engage in coping strategies such as avoidance, reported greater distress in interpersonal functioning as well as an increase in anxiety symptoms. Specifically, an avoidance strategy Costanzo et al. (2006) calls "mental disengagement" evidenced particularly robust correlations with poorer emotional well-being and greater anxious and depressed mood.

During the individual sessions, treatment group members were given the opportunity to discuss their fears and concerns regarding the diagnosis, the treatment they were receiving, and the possible outcomes. Encouraging participants to discuss their concerns limited their use of avoidance techniques to some degree. Along with a discussion of their specific fears, the role such fears and concerns play in depression and anxiety was overtly addressed in different sessions along with techniques to cope with and/ or reduce anxiety.

Costanzo et al. (2006) suggested that cognitive processing of cancer-related stressors may be key to promoting improvements in mood. As the well established neuropsychological profile for patients with depression includes significant variability and disturbance in memory secondary to poor attention and concentration, one possible by-product of improvement in coping strategies is improvement in cognitive functioning secondary to improvement in subjective neurocognitive mood symptoms.

Concordant with the hypothesis that processing cancer-related stress translates to fewer reported disturbances in attention and memory, women in the treatment group of our study endorsed fewer subjective cognitive symptoms than those in the control group, suggesting that the intervention impacted their ability to cope with, or process, stress during the initial stages of treatment. In addition to a decreased frequency of reporting, women in the treatment group reported disturbances in subjective cognitive function at a lesser intensity than did those in the control group. Supporting the idea that subjective cognitive complaints are responsible for the difference in depression scores between groups is the lack of elevation in depression symptom ratings for either group when outcomes as measured by the BDI-II are compared to those measured by the psychological symptom subdomain of the PAIS-SR, a measure which does not assess subjective neurocognitive symptoms of depression. Further evidence of the similarities between subjective cognitive complaints and mood is that women in the control group reported that they benefited from such compensatory strategies, or cues, as writing notes to themselves and keeping a careful calendar of appointments, events, and medications. The benefits of cueing are often noted in neuropsychological testing profiles in individuals experiencing memory disruption of psychological etiology.

Circumscribed disruptions in cognitive processes, such as problems with attention and memory, within a depressive episode may partially explain the

phenomenon of "chemo brain"; however, there is also evidence mounting in the literature suggesting that the chemotherapy agents used to treat gynecologic cancers, specifically Cisplatin, have an impact on cognitive functioning (Troy et al., 2000). In a meta-analysis of neuropsychological effects of treatments for adults with cancer, Anderson-Hanley et al. (2003) found that mean cognitive test scores for cancer patients having received systemic treatment were on average lower than those obtained from normal samples, study controls, or pre-treatment baseline assessment of the same cancer patient. The magnitude of the effect of systemic treatment on executive functioning, verbal memory, and motor functioning ranged from negligible to large in size (Anderson-Hanley et al., 2003). Recently, Downie et al. (2006) found difficulties in language, specifically verbal repetition, fluency, reading, and writing to dictation, and attention and concentration in a group of 21 breast cancer patients receiving adjuvant chemotherapy. Downie et al. (2006) note that these changes are statistically but not necessarily clinically significant and propose that the experience of facing a life threatening illness may contribute to patients becoming more vigilant about changes in cognitive functioning and may influence their perception that their current cognitive changes are more severe than those experienced by individuals of the same age without cancer.

It is important to note that other medications given in conjunction with systemic chemotherapy may also contribute to disruption in cognitive function.

Bender (2001) found that hormonal treatments, such as Tamoxifen and Roloxifene, used in breast cancer patients have detrimental effects on cognitive functioning whereas research regarding hormonal treatments in other populations suggests a possible protective effect (Paganini-Hill & Clark, 2001; Yaffe et al., 2001). Synergistic effects of certain medications given to fight fatigue and nausea as well as the effects of radiation therapy are also implicated in possible mechanisms of impairing cognitive functioning in oncology patients (Anderson-Hanley et al., 2003). Radiation and hormonal treatment are not typical culprits in patients with ovarian cancer; however, other medications given to counter symptoms of nausea and fatigue may play a role.

Along with disruptions in neuropsychological domains, individuals experiencing depression may also experience disturbances in sexual functioning and decreased sexual interest. Consistent with the published literature (Holland, 1998), the majority of women in our study endorsed little to no interest in sexual relationships or body image issues during the first 8-16 weeks of the study. Upon query, participants consistently commented that their primary focus during the initial 6 months of treatment was on the outcome of survival. Lutgendorf et al. (2000) found that women with advanced-stage gynecologic cancers often receive extensive chemotherapy, sometimes leading to side effects such as pain, nausea, and fatigue, all of which contribute to a lack of interest in sexual functioning. However, the data from this study suggest a difference between groups in the

intensity with which participants reported disturbances in sexual interest and functioning in the absence of differences in the type and number of chemotherapy treatments received or differences in response to medical treatment. Although continuing to endorse a decreased interest in sexual activity, women in the treatment group were more likely to report this symptom as mild whereas women in the control group were more likely to endorse little to no interest in sexual activity. Although the study is limited by sample size and power (68%), the difference in the intensity of which disturbance in sexual functioning and/ or interest is reported between groups suggests the possibility that this symptom may be attributable, in part, to psychosocial factors akin to those implicated in patients experiencing a major depressive episode.

State Anxiety

A main effect of time but no interaction between group and time were noted on the measure of state anxiety. By week 24, both groups were scoring within normal limits as compared to the normative group. However, it is noteworthy that not only did women in the treatment group evidence lower state anxiety scores than those in the control group, but also treatment group members reached the within normal limits range at 16 weeks while the control group members continued to evidence mild anxiety until week 24.

While there are no significant differences in the mean scores of state anxiety between groups, time was a significant predictor of the within-individual variation in rate of change of state anxiety symptoms during the treatment phase, with treatment group participants evidencing a faster rate of decline in anxiety symptoms than controls. Although the addition of the predictor group to the model did not yield a main effect, it did significantly improve the goodness of fit of the model suggesting that group membership did significantly contribute to the reduction in anxiety symptoms experienced by treatment group participants as compared to controls during the first 8 weeks of the study. Neither time nor participation in the individual intervention significantly contributed to the rate of change in state anxiety symptoms when looking at only the follow-up period of the study. The predictors age and education did not yield main effects in the treatment or follow-up models. The predictor baseline state anxiety did not yield a main effect but was responsible for significantly *increasing* the variability within the model thereby significantly *reducing* the goodness of fit.

As depression and anxiety are highly correlated, similarities between the pattern of change with depression symptom scores emerged with anxiety symptom scores. Anxiety scores were highest during the initial stages of diagnosis and treatment. Once treatment decisions were made and treatment began, anxiety levels tended to decrease. This decrease in anxiety may be potentially explained by the fact that once patients have a plan in place and their

initial fears of losing their hair, taking chemotherapy, and recovering from surgery are put to rest with the passing of those events, their overall level of anxiety begins to decrease. As with depression symptoms, women in the treatment group were afforded the opportunity to discuss their fears and concerns openly during the sessions. This provided them with an outlet for their anxiety and an opportunity to have their fears "normalized."

The findings of this study are concordant with Pennebaker et al. (2004) and Gortner et al. (2006) showing significant decreases in stress following disclosure of thoughts of fear and negative experiences. In addition to Pennebaker et al. (2004), and Gortner et al. (2006), other research demonstrated the hypothesis that attempting to suppress a thought results in the paradoxical increase in the thought as well as an increase in the associated mood state (Wegner et al., 1987; Wenzlaff et al., 1991). Costanzo et al. (2006) propose that avoiding thoughts about cancer increases the frequency of distress associated with intrusive thoughts and may be particularly problematic in women who are facing more severe disease, for example, late stage ovarian cancer. Treatment group participants frequently reported that they were uncomfortable reporting fears to family and friends and were appreciative of being provided an environment in which such disclosure was not only welcomed but also encouraged as a key element in the individual intervention.

Efficacy of the Individual Intervention

Overall, the data suggest that, while some benefits are not statistically significant, women in the treatment group evidenced improved psychosocial adjustment to illness, fewer depression symptoms, specifically those related to subjective cognitive impairment, and a faster rate of improvement in anxiety and depression symptoms. Data collected at the end of the study suggested that participation in the individual intervention increased participants' willingness to attend a group support program, which was a significant aim of this project. Grande, Myers & Sutton (2005) compared 63 support group participants to 44 nonsupport group participants and found that support group participants were more likely to believe that significant others held favorable beliefs toward support group participation and perceived less difficulty in joining a group. Multivariate logistic analysis of their sample found that only psychosocial variables were independent predictors of group participation (Grande, Myers & Sutton, 2005). Maximizing the idea that psychological variables are amenable to change, Grande, Myers & Sutton (2005) suggest that support group participation can be increased by addressing patients' beliefs about support groups, as was the case with the individual intervention evaluated in this study.

Important to the quality of service provided by a treatment facility, intervention participants reported feeling as if they were receiving a higher standard of care and an increased level of attention to their personal needs while

being treated at BUMC as a result of the combination of their participation in this intervention and the sensitivity to psychosocial concerns exhibited by the medical and nursing staff of TOPA. Intervention participants consistently reported that, if given the choice between receiving treatment at BUMC or another major cancer center in our area, they would consistently chose BUMC again and would recommend treatment at BUMC to friends and family who may be diagnosed with cancer in the future.

Finally, women participating in the individual intervention also evidenced the benefit of slightly lower medical costs as compared to women in the control group. Specifically, women in the treatment group had fewer office visits and spent less money on psychiatric and pain medications as compared to those in the control group. Participation in the individual intervention benefited the facility in which it took place in that participation contributed to the conservation of staff resources by reducing the amount of time nursing staff spent returning phone calls to patients.

Bultz & Carleson (2006) suggested that neglecting the psychosocial distress of cancer patients exacerbates the illness and increases costs. Carleson & Bultz (2004) found that when the emotional needs of cancer patients are unresolved, they are more likely to use community health services and visit emergency facilities. Koocher et al. (2001) demonstrated benefit of psychosocial care with no increase in cost to the facility. The outcome of Simpson et al. (2001)

was a 25% decrease in billing to the medical system over a two year period as a result of a 6 week psychosocial intervention for breast cancer patients as compared to a control group. Chiles et al. (1999) conducted a meta-analysis of 90 studies and found that psychosocial care services significantly benefit the medical system by offsetting the cost of healthcare expenditures by an average of 20%. Finally, Bultz & Carleson (2006) suggested that reducing the emotional burden of cancer care will reduce the economic burden of care. Bultz & Carelson (2006) further state that full recognition of the psychological component of cancer care is vital to a well-managed and compassionate cancer center and makes ethical, emotional, and economic sense (Bultz & Carleson, 2006).

Albeit small given the size of this study sample and the scope of cost data collected, the data suggest that there may be financial benefits to the healthcare system, in billing as well as personnel resources, when patients participate in a short-term individual psychosocial intervention. There may also be an economic benefit to patients, specifically with regard to the cost of medication. Using the data from this study to create a conservative estimate of cost savings, it is conceivable that a psychologist providing approximately 25 individual therapy hours per week over the course of one year could potentially produce a savings in personnel resources equivalent to 750 hours of nursing time or $22,500 in nursing salary. The savings to the medical system, (i.e. insurance companies), could potentially be equivalent to $36,900.00 in medical office visits and $6100.00 in

drug reimbursement costs. Given that prescription drug coverage is often limited, especially in the case of patients covered solely by Medicare, the potential medication savings could be a benefit to patients as opposed to the medical system. Combined system savings could potentially approach $65,500.00 per year.

In addition to the cost savings potential generated by psychosocial interventions, the revenue producing possibilities must also be considered when evaluating the cost benefit of adding such services to a healthcare facility. Using the idea of "expanded inventory," reducing the number of additional medical office visits of one patient facilitates time to evaluate and treat another patient. The revenue generated from that additional patient includes chemotherapy treatment, laboratory and radiology expenses, as well as potential hospital stay expenses. Using a conservative reimbursement value of $50.00 per hour, a Ph.D. level psychologist could generate ~$65,000.00 of billable services per year if providing 25 hours per week of individual intervention alone. Adding neuropsychological evaluations as an optional service to monitor possible cognitive changes with treatment, a service reimbursed at a higher rate than psychotherapy alone, is yet another potential revenue generating mechanism. The revenue producing potential of adding psychosocial services to a cancer center far exceed the cost savings produced by such a service. Health care system savings combined with billable services provides a mechanism to justify such a service at

little to no cost to the healthcare facility. Cost feasibility together with the increase in patient treatment satisfaction and possible benefits in psychological and cognitive functioning, make the addition of individual psychosocial intervention services a valuable contribution to patient care.

The outcome of this study facilitated refining the individual intervention in such a way as to more fully address the psychosocial needs of women with ovarian cancer treated in at BUMC and highlighted the need for continued development and study of psychosocial services for this population. It may be of benefit to create an algorithm for adjusting the order in which individual modules are presented according to the specific needs and/ or symptom presentation of the patient being assessed. For example, the results of this study suggest that anxiety and cognitive problems are highly associated. Problems with attention, concentration, and memory have the potential to negatively impact psychosocial functioning as a whole and may need to be addressed immediately to prevent any such distress from being prolonged.

Finally, it will be necessary to continue seeking avenues to address the needs of patients who are NOT accessing psychosocial services but who may need them. Specifically, it is important to note that the results presented here apply only to women who responded to the invitation to participate in the study. Recall that approximately 1/3 of the women invited to participate, declined participation in the study. One explanation may be that ~1/3 of women do not

need, and therefore do not access, psychological services. Another reason may be that the timing from diagnosis or start of treatment at which the service was offered was not optimal. A closer look at the similarities between the women who declined participation may shed some light on developing a mechanism to increase their access to psychological support services if, and when, they are needed during their treatment process.

Phase I of this study lent some insight into reasons why women choose not to participate in group support. Of significant interest was the reported idea that participation in psychological services of any type would suggest a lack of faith in God to heal the individual. Chaplains at BUMC continually work with pastoral staff in the community to address this issue in hopes of removing this barrier. Volunteers, social workers, nursing staff, and physicians would benefit from additional training by the Chaplains in dealing with and addressing the potential spiritual barriers that may prevent a patient from accessing needed services.

Given the advances in psychosocial screening, Bultz & Carleson (2006) called for emotional distress to be considered the sixth vital sign and proposed that psychosocial oncology be a standard component of care of the cancer patient. In an effort to efficiently incorporate screening for psychosocial distress, some major cancer centers are integrating new technology such as computer check in services, which prompt the patient to report emotional and psychological concerns and then flags the chart to call the physician's attention to the concern. This

procedure theoretically alleviates the discomfort some patients may feel with initiating a conversation about emotional concerns with their physician and provides the medical staff with a tool for referring patients to appropriate services when necessary. Outcome studies of the utility of this service are now underway at multiple comprehensive cancer centers in the United States.

Limitations & Future Directions

The outcome of this pilot study is limited in a number of ways. The small sample size limits the power of the study; however, this limitation is difficult to address as ovarian cancer makes up only 4% of all cancers. One conceivable solution is to engage other oncology centers in collaborating to develop a multi-site protocol that would allow recruiting to take place from a larger pool of possible participants. To power a similar study at 80%, a total of 102 women (52 in each group) would need to be recruited. Second, this study is limited in the degree of demographic variability of the sample. Specifically, the majority of patients were Caucasian, well-educated, and middle to upper socioeconomic class. All had excellent access to health care services and were insured. The lack of demographic variability makes it difficult to generalize the results to other populations. In addition to increasing the sample size and power, a multi-site study may also help to increase the demographic variability in future studies.

There are a number of components of the therapy process that were not evaluated in this pilot study but may be significant contributors to the outcome. Future studies may consider including a method of analyzing the elements of the intervention that have the most impact. Such elements include, but are not limited to: evaluation of the therapist/ patient alliance, level of the information provided, and the impact of the component of self-disclosure. This may be achieved through video taping individual sessions and using trained raters to evaluate the process elements of the session. Alternatively, the value of written self-disclosure could be evaluated by asking participants to write about their experiences and measuring levels of distress before and after disclosure. Analyses of these elements were limited in this study secondary to confidentiality agreements made with patients prior to beginning individual sessions regarding who would have access to confidential information discussed during the sessions. Additionally, all intervention sessions were conducted by the same therapist. Future studies may consider including multiple therapists to compare outcomes.

A central theme underlying distress in cancer patients is the lack of personal control over the outcome of one's life. Osowiecki and Compas (1998) found that adult cancer patients who perceived more control over the progression and outcome of their disease process reported less anxiety and depression. Costanzo et al. (2006) proposed that gynecologic cancer patients who continue to undergo extensive treatment yet face a poor prognosis, lack a sense of control

over their disease, potentially rendering their active coping strategies ineffective. A measure of perception of control over disease progression in a future study would lend insight to this idea.

Central to the idea of control is the treatment approach of the medical staff involved in the patient's care. An evaluation of the degree to which the patient is encouraged to participate as a team member in treatment decisions vs. a more paternalistic treatment approach, where decisions are made for the patient, would be of interest.

Similar to a measure of perception of control, a measure of coping styles would be informative to delineate differences in psychosocial outcomes. Specifically, Costanzo, et al. (2006) found that gynecologic cancer patients who used primarily avoidant coping strategies were more likely to evidence poorer well being and more distressed mood. Furthermore, Costanzo et al. (2006) suggested that supportive interventions alone may not be effective at improving distress in gynecologic cancer patients. Instead, Costanzo et al. (2006) suggested that psychosocial interventions targeting this population might be more effective if the focus is on helping patients engage in cognitive processing of the cancer-related distress as well as decreasing the use of avoidant coping strategies. Given that the very nature of avoidant individuals is to avoid the stressor, it will be important to create a mechanism to identify those patients and increase their willingness to access psychosocial services.

Of particular interest to future investigations is the aspect of subjective cognitive dulling reported by the study participants and well documented as a significant complaint in other oncology populations. Future studies may want to include a neuropsychological assessment battery to delineate the specific deficits involved in the phenomenon described as cognitive dulling. Important components of the neuropsychological battery might include measure of verbal and non-verbal learning and memory, attention and executive functioning, processing speed, language fluency, and of significant importance, an objective personality assessment like the MMPI-2 or PAI. A functional magnetic resonance imaging component would lend significant insight into changes in brain function during treatment. A long-term follow-up study is potentially difficult given the relatively poor prognosis for long-term survival rates in ovarian cancer patients; however, a patient sample followed over 5-10 years would be ideal to address the long vs. short-term consequences of treatment.

Conclusion

The major finding of this study was that the short-term individual intervention for women with ovarian cancer was effective in decreasing anxiety and improving subjective neurocognitive related mood symptoms at a faster rate than women who did not receive the intervention. Such improvements likely contributed to the improvements in psychosocial adjustment to illness noted in the

follow-up period of the study. Additionally, women in the treatment group made fewer office visits and phone calls to their oncologist and required fewer psychiatric and pain medications as compared to controls. Participation in the individual intervention was well received by patients and improved willingness to attend the ovarian cancer support group already in place within the Cvetko Center of Sammons Cancer Center. The individual intervention served as an appropriate entry point into psychosocial services for patients who may not have been psychologically "ready" to process another person's disease experience in a group setting, while also addressing the barriers to group participation that prevent a patient from accessing the peer support empirically demonstrated to be of psychological benefit. Finally, implementing this intervention service was found to be feasible both in terms of staff resources and patient willingness to participate. Specifically, the intervention can be scheduled at the convenience of patients with the flexibility to arrange intervention visits around medical treatment visits. Implementing the intervention requires little in terms of materials and is manualized, yet flexible enough to meet the idiographic needs of this patient population, such that it may be conceivably implemented using the resources of a multidisciplinary team of psychologists, chaplains, social workers, and nurses to serve an optimal number of patients while not imposing significant fiscal burden on the healthcare facility.

APPENDIX A
Demographics

Current Age _____

Age at diagnosis _____

Stage of ovarian cancer at diagnosis _____

Date of diagnosis _____

Treatments undergone or planned

Surgery (date) _____

Radiation (date began) _____

Chemotherapy (date began) _____

Chemo. Medications

1.
2.
3.

Other _____

Marital Status (circle one)

Single Married Divorced Widowed Separated

Education (highest grade/ degree completed) _____

Ethnicity _____

Number of children _____

Ovarian/ breast cancer family history _____

Health Insurance YES NO

Household income (circle one)

< $25,000 $25,000 - $50,000 $50,000 - $100,000 > $100,000

Previous/ Current Psychiatric Diagnoses

Previous/ Current Psychiatric Medication

APPENDIX B
Phase I Interview

Interviewer: *I am going to ask you a series of questions regarding a service we are considering developing for women newly diagnosed with ovarian cancer. All of your answers will be kept confidential. Your name will not appear anywhere on this form. I will identify this document by a study number. Your responses will NOT affect your relationship with your doctor or Baylor Medical Center. Please answer freely as your feedback is important to the development of a service that will be helpful to women newly diagnosed with ovarian cancer. Do you have any questions for me before we begin?*

(1) Are you currently participating in any type of group support program?

YES_____ NO_____

(a) If YES, at what point in your diagnosis or treatment did you begin participation?

(b) What is the location/ name of organization that sponsors the group?

(c) How often does the group meet?

(d) What is the make-up of the group? (Check all that apply)

___ all types of cancer
___ only ovarian cancer
___ education combined with support
___ purely support

(e) What do you find appealing about participating in group?

(f) If your answer to question #1 was NO, what did you find UNAPPEALING about group participation?

(2) Are you aware that a group support program for women with ovarian cancer is available in the Cvetko Center?

(3) Are you currently seeing a therapist/ counselor/ psychologist/ psychiatrist/ or minister for supportive therapy or medication management of depression or anxiety?

(4) If it were available, would you be interested in participating in a short-term (8 weeks) individual program that incorporates education about ovarian cancer and supportive therapy?

(a) If YES, what is most appealing to you about an individual service?

(b) If NO, what are the reasons that would prevent your participation?

(5) Would it be helpful to have the ability to schedule individual sessions to coordinate with your regular clinic or treatment visits?

(6) The following topics have been suggested as important to women with ovarian cancer. Please rate the items from highest importance (1) to lowest importance (11)

_____ Spirituality

_____ Depression & Anxiety

_____ Body Image

_____ Sexuality

_____ Communication with your treatment team

_____ Genetics & heritability of ovarian cancer

_____ Impact of your diagnosis on your family

_____ Concerns about death

_____ Relaxation techniques

_____ Relationships with your spouse/ family/ friends

_____ Financial concerns

Are there any other topics that are of interest to you that are not represented in the list I just read?

(7) At this point, we are considering one hour sessions. Do you feel that is an appropriate amount of time? If NO, what amount of time do you suggest?

(8) Do you have a preference for the gender of the therapist?

_____ Female ____ Male ____ No Preference

(9) What would you consider a reasonable fee to charge for an individual service program?

___ $10/ session ___ $25/ session ___ $50/ session ___ $75/session

(10) I mentioned earlier that we are considering developing this program for women newly diagnosed with ovarian cancer. At what point, from the time of your diagnosis, would you think would be the most important time to offer such an intervention?

Interviewer: *That concludes the questions I have for you. Do you have anything you would like to add that you feel would be important to include in an individual program? Do you have any questions for me? Thank you for your time. I greatly appreciate the information you have provided.*

APPENDIX C
Education Material Reference List

American College of Obstetrician's and Gynecologists. (1999). Cancer of the ovary. ISSN 1074-8601.

Connor, K., Langford, L. (2003). Ovarian Cancer: Your guide to taking control. O'Reilly & Associates, Cambridge.

Genetics Institute. (1999). Chemotherapy and the cells: Patient information.

National Institutes of Health, National Cancer Institute. (2000). What you need to know about ovarian cancer. NIH Publication No. 00-1561. http://www.cancer.gov/publications

National Ovarian Cancer Coalition, Inc. It whispers…so listen. What every woman should know about ovarian cancer. http://www.ovarian.org

National Ovarian Cancer Coalition, Inc. Patient to patient: A patient resource for women with ovarian cancer. http://www.ovarian.org

APPENDIX D
Screening Log

NAME	PHYSICIAN	PHONE	ELIGIBLE?	REASON	ENROLLED?	DATE

APPENDIX E
Consent Forms

BAYLOR RESEARCH INSTITUTE
Cvetko Patient Education and Conference Center
Dallas, Texas

PARTICIPATION EXPLANATION AND CONSENT FORM

PROJECT TITLE: Developing & Evaluating the Efficacy of Delivering Psychoeducational Individual Interventions to Ovarian Cancer Patients: A Two Phase Study – Phase I

INVESTIGATORS: C. Allen Stringer, M.D.
Jann Aldredge-Clanton, Ph.D.
Kimberly C. Doyle, M.A., LPC
H.M. Evans, Ph.D.

TELEPHONE NUMBER: 214-820-7320

INTRODUCTION:

Before you say that you will be in this clinical trial (a kind of research study) you need to read this form. It is important for you to understand all the information in this form. This form will tell you what the clinical trial is about and how it will be done. It will tell you about some problems that might happen during the clinical trial. It will also tell you about the good things that might happen for you during the clinical trial. When you read a paper like this to learn about a clinical trial it is called "informed consent." The people who are doing this clinical trial are giving you very important information about the clinical trial. When you give your consent for something, it is the same as giving your permission. This consent form may contain words that you do not understand. Please talk with one of the doctors or their staff if you have questions. Do not sign this consent form unless all your questions have been answered and you feel comfortable with the information you have read. You will be given a copy of the form to keep.

You are being asked to take part in this study because you have been diagnosed as having ovarian cancer.

Why Is This Study Being Done?

This research study is designed to gather information about the topics beneficial to discuss when providing individual support and education about the many ways that ovarian cancer impacts the lives of women diagnosed with the disease.

It is important that you understand that the individual intervention we are proposing to offer is not experimental. Interventions similar to this one are well-established and part of standard care at major medical centers nation wide; however, such interventions are generally delivered in a group support environment. As there are no ovarian cancer specific individual support programs, this study seeks to determine the needs of ovarian cancer patients in order to provide the most efficacious program.

How Many People Will Take Part In The Study?

About ***15*** people will take part in this phase of the study.

What Is Involved In The Study?

A total of 15 women, who have been diagnosed with ovarian cancer, will be surveyed regarding the educational topics as well as the emotional, spiritual, and psychological topics they feel are key to helping promote the most positive outcome. The information gathering sessions will be conducted individually and will be facilitated by a licensed mental health professional who is a woman. The survey information will help us determine the educational information, to be provided in individual sessions, about the many ways that ovarian cancer impacts the lives of women during diagnosis, treatment, and recovery.

You will be asked to complete a series of questionnaires. The questionnaires will ask you about your mood, your energy level, how you are feeling about relationships with friends and family members, and how you are feeling about your ovarian cancer diagnosis. Some of the questions will be very personal, others will be more general. You will be provided with an opportunity to tell the clinical coordinator what material would be most helpful to you if you were to receive and individual psychoeducational intervention.

How Long Will I Be In The Study?

You will be in the study for only one day. This phase of the study requires only one interview. You will not be contacted to complete any additional questionnaires. You will not be asked to participate in Phase II of this study.

The researcher may decide to take you off the study if any of the following occur:

- He/She feels that it is in your medical best interest.
- Your condition worsens.
- New information becomes available.
- The study is stopped by the sponsor.

You can stop participating in this study at any time. However, if you decide to stop participating in the study, we encourage you to talk to the researcher and your regular doctor first.

What Are The Risks of The Study?

The risks of participating in this study are no greater than the risk of completing a routine psychological exam.

Your doctor may be an investigator in this research study. If so, s/he is interested both in your medical care and in the conduct of this research. Before you sign up for this study or at any time during the research, you may discuss your care with another doctor who is not associated with this research project. You are not under any obligation to participate in any research study offered by your doctor.

Are There Benefits to Taking Part in The Study?

If you agree to take part in this study, there may or may not be direct medical benefit to you. We hope that the information learned from this study will benefit other patients with this disease in the future.

The possible benefits of taking part in the study are the same as receiving individual psychosocial therapy **without** being in the study.

What Other Options Are There?

Instead of being in this study, you have the following options:

- You may choose to receive no therapy at this time and receive only care to help you feel more comfortable.
- You may choose not to participate in the study.
- You may choose to receive individual psychosocial therapy without participating in the study.
- You may choose to participate in group support therapy.

Please talk to your regular doctor about these and other options.

What are the Risks, Benefits, and Options?

There are no risks or benefits to you for participating in this study. Your alternative is not to participate in this study.

What about Confidentiality?

You have a right to privacy. This means that all the information about you from this study will only be shown to the people working on the study. The results of this study may be published in a scientific book or journal. If this is done, your name will not be used. All information about you from this research project will be kept in a locked office.

The privacy law requires that Baylor Research Institute get your permission before giving any of your health information to other people. There are people who need to review your information to make sure the study is done correctly. These people may look at or copy your information while they are doing this review. When you sign this form you give permission to Baylor Research Institute to give other people information about your health as needed for the research project. These groups include people who work for Baylor Research Institute, the US Food and Drug Administration, the Office for Human Research Protections and the Association for the Accreditation of Human Research Protection Programs. Even though we usually remove your name from the information, the people who get this information may be able to figure out who you are. The kinds of health information that might be given to these people include results from lab tests or other tests like x-rays. This information might also be notes written by your doctor from your medical record or notes written by your doctor asking for tests to be done on you. Information will be shared with your physician if, at any

time during the study, you state that you are thinking of harming yourself or another person.

You do not have to give this permission and it is all right to refuse to sign this form. Your doctor will still treat you and your insurance company will still pay your medical bills (according to their policy) even if you do not give your permission for us to release this information. However, since it is important for the people listed above to have access to your information, if you do not sign this form, you cannot be in the research study.

If you give permission to Baylor Research Institute to give other people information about your health and the other people are not part of the group that must obey this law, your health information will no longer be protected by the privacy law.

If you change your mind and later want to withdraw your permission, you may do so. You must notify Baylor Research Institute in writing at 3434 Live Oak, Suite 125, Dallas, TX 75204. If you decide to do this, it will not apply to information that was given before you withdrew your permission.

You may not be allowed to look at your health information during this study. However, at a later time, you will be able to look at this information. This later time will be sometime after the study is completed.

Unless permission is withdrawn, this permission will expire at the end of the research study.

What Are the Costs?

Taking part in the study may lead to added costs to you or your insurance company. Please ask about any expected added costs or insurance problems.

The study sponsor will pay for all costs related to your participation in this study.

The Investigator conducting this study is being paid for conducting this trial. This means that you or your insurance company will not be billed for a portion (or all) of his/her time and services.

Will I Be Paid For Participating in This Study?

You will not be paid for being in this study.

What are My Rights as a Participant?

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. If you agree to take part and then decide against it, you can withdraw for any reason. At certain times during the treatment, it may be unsafe for you to withdraw, so please be sure to discuss leaving the study with the principal investigator or your regular physician. Deciding not to be in the study, or leaving the study early, will not result in any penalty or loss of benefits that you would otherwise receive.

We will tell you about any new information that may affect your health, welfare, or willingness to stay in this study.

All of the people working on the project must be careful not to carelessly harm you. If you are hurt during this project, you have the right to seek legal counsel. Nothing in this consent form takes away that right if you are hurt during this research.

Whom Do I Call If I have Questions or Problems?

If you have questions about the study or have a research-related injury, contact C. Allen Stringer, M.D., at 214-820-7320.

For questions about your rights as a research subject, contact Lawrence R. Schiller, M.D., IRB Chair, at 214-820-2687.

Statement of Person Obtaining Consent:

I have explained to _____ the purpose of the research project, the procedures required and the possible risks and benefits to the best of my ability. They have been encouraged to ask questions related to participation.

_____ _____

Signature of Person Obtaining Consent Date and Time

Statement of Principal Investigator:

As Principal Investigator of this study, I confirm that to the best of my knowledge this subject has voluntarily agreed to participate in this study and has had an opportunity to ask questions and has received answers to these questions. If another individual was responsible for obtaining informed consent, then this individual has signed above.

_____ _____

Signature of Principal Investigator Date and Time

Confirmation of Consent by Research Subject:

You are making a decision about being in this research study. You will be asked to give your written consent if you want to be in the study. Giving consent is like giving permission. You should not give your permission to be in this study until you have read and understood all the pages in this form. If you cannot read, then someone can read the form to you. Make sure that all your questions about this research project have been answered before you sign this form. When you sign this form, you are giving your permission to be in the study. By signing this form, you have not given up any of your legal rights or released anyone from liability for negligence.

_____ has explained to me the purpose of the research project, the study procedures that I will have, and the possible risks and discomforts that may happen. I have read (or have been read) this consent form. I have been given a chance to ask questions about the research study and the procedures involved. I believe that I have enough information to make my decision. I have also been told my other options. To the best of my knowledge, I am not in any other medical research. Therefore, I agree to give my consent to participate as a subject in this research project.

_____ _____

Signature of Subject Date and Time

BAYLOR RESEARCH INSTITUTE
Cvetko Patient Education and Conference Center
Dallas, Texas

PARTICIPATION EXPLANATION AND CONSENT FORM

PROJECT TITLE: Developing & Evaluating the Efficacy of Delivering Psychoeducational Individual Interventions to Ovarian Cancer Patients: A Two Phase Study – Phase II

INVESTIGATORS: C. Allen Stringer, M.D.
Jann Aldredge-Clanton, Ph.D.
Kimberly C. Doyle, M.A., LPC
H.M. Evans, Ph.D.

TELEPHONE NUMBER: 214-370-1301

INTRODUCTION:

Before you say that you will be in this clinical trial (a kind of research study) you need to read this form. It is important for you to understand all the information in this form. This form will tell you what the clinical trial is about and how it will be done. It will tell you about some problems that might happen during the clinical trial. It will also tell you about the good things that might happen for you during the clinical trial. When you read a paper like this to learn about a clinical trial it is called "informed consent." The people who are doing this clinical trial are giving you very important information about the clinical trial. When you give your consent for something, it is the same as giving your permission. This consent form may contain words that you do not understand. Please talk with one of the doctors or their staff if you have questions. Do not sign this consent form unless all your questions have been answered and you feel comfortable with the information you have read. You will be given a copy of the form to keep.

You are being asked to take part in this study because you have been diagnosed as having advanced stage ovarian cancer.

Why Is This Study Being Done?

This research study is designed to determine the benefits and feasibility of providing individual support and education about the many ways that ovarian cancer impacts the lives of women diagnosed with the disease.

It is important that you understand that the individual intervention you will be offered is not experimental. Interventions similar to this one are well-established and part of standard care at major medical centers nation wide; however, such interventions are generally delivered in a group support environment. This study seeks to determine if an individual intervention will serve as a positive addition to standard care.

How Many People Will Take Part In The Study?

About ***30*** people will take part in this phase of the study.

What Is Involved In The Study?

This study is a randomized trial, which means that you will be randomly assigned to one of two groups. Randomization is similar to a flip of a coin. Each of the two groups is explained in detail in this consent form. You must be willing and able to participate in either of the groups in order to be eligible to participate in this research study.

There are the two groups in this study. Each group will be made up of 15 women who have been diagnosed with ovarian cancer. All of the intervention sessions will be facilitated by a licensed mental health professional who is a woman. Both study groups will provide educational information about the many ways that ovarian cancer impacts the lives of women during diagnosis, treatment, and recovery.

You will be asked to complete a series of questionnaires at different time points regardless of your group assignment. The questionnaires will ask you about your mood, your energy level, how you are feeling about relationships with friends and family members, and how you are feeling about your ovarian cancer diagnosis. Some of the questions will be very personal, others will be more general.

<u>Group I: Treatment Group</u>: If you are randomized to this group, you will be asked to attend an individual intervention session one time per week for a total of 8 sessions. Each session will last for approximately 60 minutes each. Each

meeting will begin with about 30 minutes of interactive discussion about a topic related to ovarian cancer and will end with about 30 minutes of open discussion pertaining to issues that are important to you at that time. Intervention sessions will be held in the Cvetko Center at Baylor Medical Center. Individual sessions will be scheduled on a week day, corresponding with your regular clinic or treatment visit, if at all possible. Light refreshments will be provided at each session. The clinical coordinator for this study will mail questionnaires to you after the completion of the 8 weeks of sessions. A self-addressed, stamped envelope will be included so that you may complete the questionnaires and return them to the clinical coordinator at no cost to yourself. This study will follow your progress for a period of one year. Group I participants will complete questionnaires at weeks 4, 8, 16, 24, and 48.

Group II: Control Group: If you are randomized into the control group, you will be given educational materials pertaining to diagnosis and treatment as is standard of care. You will not be asked to participate in the individual intervention of this study. The clinical coordinator for this study will mail questionnaires to you at weeks 4, 8, 16, 24, and 48. You will complete the measures in person at enrollment. A self-addressed, stamped envelope will be included so that you may complete the questionnaires and return them to the clinical coordinator at no cost to yourself. This study will follow your progress for a period of one year.

How Long Will I Be In The Study?

You will be in the study for approximately 12 months. If you are in the treatment group, the intervention phase of this study will require that you attend 8 one hour intervention sessions.

The researcher may decide to take you off the study if any of the following occur:

- He/She feels that it is in your medical best interest.
- Your condition worsens.
- New information becomes available.
- The study is stopped by the sponsor.

You can stop participating in this study at any time. However, if you decide to stop participating in the study, we encourage you to talk to the researcher and your regular doctor first.

What Are The Risks of The Study?

The risks of participating in this study are no greater than the risk of completing a routine psychological exam.

Your doctor may be an investigator in this research study. If so, s/he is interested both in your medical care and in the conduct of this research. Before you sign up for this study or at any time during the research, you may discuss your care with another doctor who is not associated with this research project. You are not under any obligation to participate in any research study offered by your doctor.

Are There Benefits to Taking Part in The Study?

If you agree to take part in this study, there may or may not be direct medical benefit to you. We hope that the information learned from this study will benefit other patients with this disease in the future.

The possible benefits of taking part in the study are the same as receiving individual psychosocial therapy **without** being in the study.

What Other Options Are There?

Instead of being in this study, you have the following options:

- You may choose to receive no therapy at this time and receive only care to help you feel more comfortable.
- You may choose not to participate in the study.
- You may choose to receive individual psychosocial therapy without participating in the study.
- You may choose to participate in group support therapy.

Please talk to your regular doctor about these and other options.

What are the Risks, Benefits, and Options?

There are no risks or benefits to you for participating in this study. Your alternative is not to participate in this study.

What about Confidentiality?

You have a right to privacy. This means that all the information about you from this study will only be shown to the people working on the study. The results of this study may be published in a scientific book or journal. If this is done, your name will not be used. All information about you from this research project will be kept in a locked office.

The privacy law requires that Baylor Research Institute get your permission before giving any of your health information to other people. There are people who need to review your information to make sure the study is done correctly. These people may look at or copy your information while they are doing this review. When you sign this form you give permission to Baylor Research Institute to give other people information about your health as needed for the research project. These groups include people who work for Baylor Research Institute, the US Food and Drug Administration, the Office for Human Research Protections and the Association for the Accreditation of Human Research Protection Programs. Even though we usually remove your name from the information, the people who get this information may be able to figure out who you are. The kinds of health information that might be given to these people include results from lab tests or other tests like x-rays. This information might also be notes written by your doctor from your medical record or notes written by your doctor asking for tests to be done on you. Information will be shared with your physician if, at any time during the study, you state that you are thinking of harming yourself or another person.

You do not have to give this permission and it is all right to refuse to sign this form. Your doctor will still treat you and your insurance company will still pay your medical bills (according to their policy) even if you do not give your permission for us to release this information. However, since it is important for the people listed above to have access to your information, if you do not sign this form, you cannot be in the research study.

If you give permission to Baylor Research Institute to give other people information about your health and the other people are not part of the group that must obey this law, your health information will no longer be protected by the privacy law.

If you change your mind and later want to withdraw your permission, you may do so. You must notify Baylor Research Institute in writing at 3434 Live Oak, Suite

125, Dallas, TX 75204. If you decide to do this, it will not apply to information that was given before you withdrew your permission.

You may not be allowed to look at your health information during this study. However, at a later time, you will be able to look at this information. This later time will be sometime after the study is completed.

Unless permission is withdrawn, this permission will expire at the end of the research study.

What Are the Costs?

Taking part in the study may lead to added costs to you or your insurance company. Please ask about any expected added costs or insurance problems.

The study sponsor will pay for all costs related to your participation in this study.

The Investigator conducting this study is being paid for conducting this trial. This means that you or your insurance company will not be billed for a portion (or all) of his/her time and services.

Will I Be Paid For Participating in This Study?

You will not be paid for being in this study.

What are My Rights as a Participant?

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. If you agree to take part and then decide against it, you can withdraw for any reason. At certain times during the treatment, it may be unsafe for you to withdraw, so please be sure to discuss leaving the study with the principal investigator or your regular physician. Deciding not to be in the study, or leaving the study early, will not result in any penalty or loss of benefits that you would otherwise receive.

We will tell you about any new information that may affect your health, welfare, or willingness to stay in this study.

All of the people working on the project must be careful not to carelessly harm you. If you are hurt during this project, you have the right to seek legal counsel.

Nothing in this consent form takes away that right if you are hurt during this research.

Whom Do I Call If I have Questions or Problems?

If you have questions about the study or have a research-related injury, contact C. Allen Stringer, M.D., at 214-370-1301.

For questions about your rights as a research subject, contact Lawrence R. Schiller, M.D., IRB Chair, at 214-820-2687.

Statement of Person Obtaining Consent:

I have explained to _____ the purpose of the research project, the procedures required and the possible risks and benefits to the best of my ability. They have been encouraged to ask questions related to participation.

_____ _____
Signature of Person Obtaining Consent Date and Time

Statement of Principal Investigator:

As Principal Investigator of this study, I confirm that to the best of my knowledge this subject has voluntarily agreed to participate in this study and has had an opportunity to ask questions and has received answers to these questions. If another individual was responsible for obtaining informed consent, then this individual has signed above.

_____ _____
Signature of Principal Investigator Date and Time

Confirmation of Consent by Research Subject:

You are making a decision about being in this research study. You will be asked to give your written consent if you want to be in the study. Giving consent is like giving permission. You should not give your permission to be in this study until you have read and understood all the pages in this form. If you cannot read, then someone can read the form to you. Make sure that all your questions about this research project have been answered before you sign this form. When you sign this form, you are giving your permission to be in the study. By signing this form, you have not given up any of your legal rights or released anyone from liability for negligence.

_____ has explained to me the purpose of the research project, the study procedures that I will have, and the possible risks and discomforts that may happen. I have read (or have been read) this consent form. I have been given a chance to ask questions about the research study and the procedures involved. I believe that I have enough information to make my decision. I have also been told my other options. To the best of my knowledge, I am not in any other medical research. Therefore, I agree to give my consent to participate as a subject in this research project.

_____ _____

Signature of Subject Date and Time

APPENDIX F
Taxonomy of the Multilevel Growth Models

	Level-1/ Level-2 Specification		
Model	level-1 model	level-2 model	Composite Model
A[1]	$Y_{ij} = \pi_{0i} + \epsilon_{ij}$	$\pi_{0i} = \gamma_{00} + \zeta_{oi}$	$Y_{ij} = \gamma_{00} + (\epsilon_{ij} + \zeta_{oi})$
B[2]	$Y_{ij} = \pi_{0i} + \pi_{1i}TIME_{ij} + \epsilon_{ij}$	$\pi_{0i} = \gamma_{00} + \zeta_{0i}$ $\pi_{1i} = \gamma_{10} + \zeta_{1i}$	$Y_{ij} = \gamma_{00} + \gamma_{10}TIME_{ij} +$ $(\epsilon_{ij} + \zeta_{0i} + \zeta_{1i}TIME_{ij})$
C[3]	$Y_{ij} = \pi_{0i} + \pi_{1i}TIME_{ij} + \epsilon_{ij}$	$\pi_{0i} = \gamma_{00} + \gamma_{01}GROUP + \zeta_{0i}$ $\pi_{1i} = \gamma_{10} + \gamma_{11}GROUP + \zeta_{1i}$	$Y_{ij} = \gamma_{00} + \gamma_{01}GROUP_i + \gamma_{10}TIME_{ij} +$ $\gamma_{11}GROUP_i \text{ X } TIME_{ij} + (\epsilon_{ij} + \zeta_{0i} + \zeta_{1i}TIME_{ij})$
D[4]	$Y_{ij} = \pi_{0i} + \{\pi_{1i}TIME - 16\} + \epsilon_{ij}$	$\pi_{0i} = \gamma_{00} + \gamma_{01}GROUP + \zeta_{0i}$ $\pi_{1i} = \gamma_{10} + \gamma_{11}GROUP + \zeta_{1i}$	$Y_{ij} = \gamma_{00} + \gamma_{01}GROUP_i + \{\gamma_{10}TIME - 16\} +$ $\gamma_{11}GROUP_i \text{ X } TIME_{ij} + (\epsilon_{ij} + \zeta_{0i} + \zeta_{1i}TIME_{ij})$
E	$Y_{ij} = \pi_{0i} + \{\pi_{1i}TIME - 24\} + \epsilon_{ij}$	$\pi_{0i} = \gamma_{00} + \gamma_{01}GROUP + \zeta_{0i}$ $\pi_{1i} = \gamma_{10} + \gamma_{11}GROUP + \zeta_{1i}$	$Y_{ij} = \gamma_{00} + \gamma_{01}GROUP_i + \{\gamma_{10}TIME - 24\} +$ $\gamma_{11}GROUP_i \text{ X } TIME_{ij} + (\epsilon_{ij} + \zeta_{0i} + \zeta_{1i}TIME_{ij})$
F	$Y_{ij} = \pi_{0i} + \pi_{1i}TIME - 48\} + \epsilon_{ij}$	$\pi_{0i} = \gamma_{00} + \gamma_{01}GROUP + \zeta_{0i}$ $\pi_{1i} = \gamma_{10} + \gamma_{11}GROUP + \zeta_{1i}$	$Y_{ij} = \gamma_{00} + \gamma_{01}GROUP_i + \{\gamma_{10}TIME - 48\} +$ $\gamma_{11}GROUP_i \text{ X } TIME_{ij} + (\epsilon_{ij} + \zeta_{0i} + \zeta_{1i}TIME_{ij})$
Taxonomy of Intraclass Correlation and Psuedo R^2 Calculations			
ρ	Intraclass Correlation	$\rho = \frac{\sigma^2_0}{\sigma^2_0 + \sigma^2_\epsilon}$	
R^2	Psuedo R^2	$R^2_\epsilon = \frac{\sigma^2_\epsilon \text{ (Unconditional Model A)} - \sigma^2_\epsilon \text{ (Unconditional Model B)}}{\sigma^2_\epsilon \text{ (Unconditional Model A)}}$	
		$R^2 = \frac{\sigma^2_\zeta \text{ (Unconditional Growth Model)} - \sigma^2_\zeta \text{ (Later Model)}}{\sigma^2_\zeta \text{ (Unconditional Growth Model)}}$	

Note: 1: Unconditional means model with no predictors at either level; 2: unconditional growth model with TIME as the only predictor; 3: uncontrolled effects of group model with GROUP as a substantive level 2 predictor. 4: Models D, E, and F represent re-centering at weeks 16, 24, and 48 respectively with GROUP as the only substantive level 2 predictor. This table is adapted from Singer and Willet (2003).

APPENDIX G
Interpretation of Growth Model Parameters

	Symbol		Illustrative Definition
Level-1 Model			
	π_{0i}	Intercept	An individual patient's true value of psychosocial adjustment at her true initial status
	π_{1i}	Slope	An individual patient's weekly rate of change in psychosocial adjustment
Variance Component	σ^2_C	Level-1 residual variance	Summarizes the net scatter of the observed data around an individual patient's hypothesized change trajectory
Level-2 Model			
Fixed Effects	γ_{00}		Population average of the level-1 intercepts for psychosocial adjustment
	γ_{01}		Population average for the difference in level-1 intercepts between treatment and control groups
	γ_{10}		Average of level-1 slopes for patients in the control group
	γ_{11}		Average difference in slopes between groups
Variance Components	σ^2_0 (ζ_{0i})		Population residual variance controlling for group
	σ^2_1 (ζ_{1i})	Level-2 residual variance in true slope	Population residual variance for true rate of change controlling for group
	σ_{01}	Covariance	Population residual covariance between true initial status and true weekly rate of change controlling for group

Note: This table was adapted from Singer and Willet (2003).

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CURRICULUM VITAE

KIMBERLY C. DOYLE, M.A.

Licensed Professional Counselor

Ph.D. Candidate in Clinical Psychology

Date of Birth: June 20, 1971

Home Address: 1605 Adams Drive
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Education:

Clinical Psychology Doctoral Student
University of Texas Southwestern Medical Center Dallas, TX
Dissertation Defense Date: April 4, 2007
Anticipated Graduation Date: August 2007
Dissertation Chair:
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Master of Art – Clinical & Counseling Psychology
Southern Methodist University
Dallas, TX

Bachelor of Art – Psychology
University of Texas at Dallas
Dallas, TX

Professional Licensure:

State of Texas
Licensed Professional Counselor
License # 17021

Professional Organizations

American Psychological Association
American Psychosocial Oncology Society
Chi Sigma Iota Honor Society for Counselors

Honors and Awards:

Region 10 Shero Award – 2005

Chancellor's List for Academic Excellence: 2005-2006

2nd place poster presentation at The American Psychosocial Oncology Society's meeting February 2006

Doctoral Clinical Training Experience:

August 2006 – present
Department of Neuropsychology
Presbyterian Hospital
Outpatient Neuropsychological Assessment
Neuropsychology Intern

August 2005 – August 2006
Baylor Institute for Rehabilitation
Department of Neuropsychology
Traumatic Brain Injury Inpatient Treatment Team &
Day Neuro Outpatient Program
Neuropsychology Intern

May 2004 – August 2005
Baylor University Medical Center
Women's Health Psychology Consultation Service
Department of Obstestrics & Gynecology
Department of Gyn Oncology
Psychology Intern

May 2004 – April 2006
Parkland Memorial Hospital
Psychiatric Emergency Room (2 shifts/ month)
Psychology Intern

May 2004 – present
UT Southwestern Medical Center
Southwestern Psychotherapy Referral Service
Psychology Intern
Supervisor: Tim Proctor, Ph.D., Forensic Psychologist (May 2004 – August 2005)
Supervisor: Stephen Chock, Ph.D., Neuropsychologist (September 2005 – August 2006)
Supervisor: Antoinette McGarrahan, Ph.D., Forensic Psychologist (August 2006 – present)

Doctoral Research Training Experience:

May 2006 – present
Green Oaks Center for Neuropsychiatric Study
Lisa Fitzgibbons, Ph.D., Licensed Psychologist - supervisor
Research Coordinator

August 2005 – May 2006
UT Southwestern Medical Center
Psychosocial Research and Depression Clinic
Robin Jarret, Ph.D., Licensed Psychologist - supervisor
Research preceptorship

May 2004 – April 2007
Baylor University Medical Center
Sammons Cancer Center
Cvetko Psychosocial Education Center
C. Allen Stringer, M.D. - supervisor
Dissertation research

Professional Experience:

October 2002 – April 2003

UT SOUTHWESTERN MEDICAL CENTER
DEPARTMENT OF PSYCHIATRY
CLINICAL DATA SPECIALIST – Part Time

JOB DUTIES:

- Assist with the development of a standardized manual for Compliance Therapy with adult patients with schizophrenia
- Coordinate seroquel double-blind study for sexual functioning

May 2000 – June 2002

WAKE FOREST UNIVERSITY BAPTIST MEDICAL CENTER
DEPT. OF PUBLIC HEALTH SCIENCES & GENERAL SURGERY
RESEARCH ASSOCIATE – Joint Appointment

JOB DUTIES: Psychosocial Services Coordinator –
WFUBMC Comprehensive Cancer Center
Breast Care Center

- Establish research protocols to study quality of life issues in breast cancer patients: Studies in progress include: (1) The Effect of Surgical Choices on the Quality of Life of Breast Cancer Patients & (2) Pain Management in Stereotactic Breast Biopsy
- Designed & implemented short term (8 week) group therapy/ support sessions for newly diagnosed patients with breast cancer
- Produced a patient education video illustrating surgical choices for breast cancer
- Provide individual & family psychosocial support for breast cancer patients on an as needed basis

- ❖ Established Mindfulness Based Stress Reduction Program for the treatment of Mastalgia
- ❖ Serve on various university committees for breast cancer research & publication review
- ❖ Establish research protocols to study quality of life issues related to metabolite correction for endocrine abnormalities
- ❖ Facilitate hiring and integrating new members of psychosocial support team in the breast center
- ❖ Oversee medical student research projects

JOB DUTIES: Research Associate – Dept. of Public Health Sciences

- ❖ Site monitor for the Women's Health Initiative Memory Study (WHIMS)
  - quality assurance reviews for cognitive batteries including the CERAD battery; site visits to 8 of the 29 sites involved in the study
  - training site coordinators on use of CERAD battery and other study measures
- ❖ Supervise summer student intern

August 2001 – June 2002

Consultant for Pfizer Pharmaceutical Company's Women's Health Group

- ❖ Team member for cognitive training sessions for the CO-HRTFEM trial
- ❖ Train coordinators to do Trails A & B, Digit Symbol, Digit Span, MMSE, BDI-II, CVLT-II, POMS, misc. self-administered questionnaires
- ❖ Quality Assurance reviews of cognitive battery administrations

August 1998 – May 2000

THE UNIVERSITY OF TEXAS SOUTHWESTERN
MEDICAL CENTER
DEPARTMENT OF PSYCHIATRY
BIPOLAR DISORDERS RESEARCH CLINIC
PSYCHOLOGICAL ASSOCIATE III

JOB DUTIES:

- Individual & Group Therapy with adult patients with Bipolar Disorder
- Family Education Workshops
- Patient Intakes & Clinical Assessments
- Various pharmaceutical studies including atypical antipsychotics, antidepressants, and mood stabilizers
- Wellness Program Coordinator (adjunctive treatments including yoga & acupuncture)
- Psychological Assessement using WAIS III, MMPI-2, MCMI, and projective testing; proficient with Structured Clinical Interview (SCID)
- Working Knowledge of DSM-IV diagnostic criteria
- Grant & Research Proposal Writing; publication writing
- Recruitment & Advertising for clinic services & research studies
- Liason with industrial & other professional groups with respect to ongoing research in the clinic

Other Relevant Research Experience:

- October 2002 – April 2003: volunteer time with Dr. Ann Maddrey assisting with development of breast cancer modules.
- July 2002 – Present: volunteer research assistant to Dr. Cindy Claassen, UTSW Dept. of Psychiatry
- 2001 National Grant Review Committee Member for the Susan G. Komen Breast Cancer Foundation Section on Psychosocial Studies and Treatment Adherence & Compliance
- 1997 – 1999: Southern Methodist University: Designed and conducted a major research project with chronic

pain patients which was eventually published as a master's thesis

- 1996 – 1997: University of Texas at Dallas: Assisted with research in the Dept. of Neuroscience and Behavioral Psychology which resulted in a publication in the journal Perception
- October 1990 – December 1991: University of Texas Medical Branch in Galveston, TX: Research Assistant in the Dept. of Physiology & Biophysics
- 1989 – 1990: University of Washington, Seattle, WA: Managed a laboratory in the Dept. of Behavioral Psychology involving animal research & eating disorders

Grants Awarded:

Baylor Research Foundation Grant: July 2004; renewed July 2005; renewed July 2006
PI: C. Allen Stringer, M.D.; Co-Investigator: Kimberly C. Doyle, M.A.
Developing & Evaluating the Efficacy of Individual Psychoeducational Interventions for Women Newly Diagnosed with Advanced Ovarian Cancer: A Two Phase Study.

NC TRIAD Susan G. Komen Affiliate Grant**:** 01/01/02 – 12/31/02
PI: Nancy D. Perrier, M.D.; Co-Investigator: Kimberly C. Doyle, M.A.
Establishing Support Groups for African American Women Recently Diagnosed with Breast Cancer

NC TRIAD Affiliate of the Susan G. Komen Breast Cancer Foundation: 2002
Promoting Educational Videos for Breast Cancer Patients- Renewal Award
PI: Nancy D. Perrier, M.D.; Co-Investigator: Kimberly C. Doyle, M.A.

American Cancer Society Institutional Research Pilot Grant: 2002
PI: Nancy D. Perrier, M.D.; Co-Investigator: Kimberly C. Doyle, M.A.
Evaluating the Optimal Modality of Delivering Cognitive Behavioral Therapy Group Interventions (CBT) to Cancer Patients: A Randomized Comparison of Three CBT Group Interventions with Breast Cancer Patients.

National Ladies Auxiliary to the Veterans of Foreign Wars: 2001-2002
PI: Nancy D. Perrier, M.D.; Co-Investigator: Kimberly C. Doyle, M.A.
Mindfulness Based Stress Reduction for Breast Pain Management

NC TRIAD Susan G. Komen Affiliate Grant: 01/01/01 – 12/31/01
PI: Nancy D. Perrier, M.D.; Co-Investigator: Kimberly C. Doyle, M.A.
Patient Education Video for Surgical Treatment Choices

Timberlawn Psychiatric Research Foundation, Inc. 1999
PI: Dr. Diane S. Myers & Dr. Trisha Suppes; Co-Investigator: Kimberly C. Doyle, M.A.
Efficacy of Psychoeducational Group Treatment for Newly Diagnosed Bipolar Patients

Presentations:

Doyle, K.C., Fitzgibbons, L., Rollins, P., and Stringer, C.A. Changes in depression, anxiety, and psychosocial adjustment to illness following an individual intervention for women with advanced stage ovarian cancer. Accepted as a podium presentation at the American Psychosocial Oncology Society's annual meeting. March 2007.

Doyle, K.C. Behavioral and Cognitive strategies for managing anxiety after weight loss surgery. Presented at the Texas Weight Loss Surgery Summit in Dallas, Texas. January 2007.

Doyle, K.C. Impact of anxiety and depression on cognitive function. Presented at the Obesity Health and Weight Loss Surgery Conference in Hawaii. November 2006.

Depression in Oncology Patients
Invited Speaker: Virginia R. Cvetko Psychosocial Oncology Center
Baylor Sammons Cancer Center
February 2005, March 2006, June 2006, August 2006

Keynote Address
Region 10, First Annual Shero Recognition Ceremony
March 2005

Kimberly C. Doyle, M.A. & Nancy D. Perrier, M.D. Short-term Psychoeducational Support Group for Newly Diagnosed African American Women with Breast Cancer. Hawaii International Conference on Social Sciences. June 2002

Maggie Dailey, Ph.D., **Kimberly C. Doyle, M.A**., Janeen Manuel, Ph.D., Kristin Kidd, M.A., Nancy D. Perrier, M.D. Mindfulness Based Stress Reduction in Treatment of Mastalgia. Hawaii International Conference on Social Sciences. June 2002.

Nancy D. Perrier, M.D. & **Kimberly C. Doyle, M.A**. Does Surgical Cure of Hyperparathyroidism Significantly Decrease Use of Outpatient Care and Oral Medications? Accepted for presentation at the Mayo Course, The Mayo Clinic, Rochester, MN. March 2002.

Starting Support Groups for Breast Cancer Patients
NC Electrical Cooperative Volunteer Organization
Greensboro, NC
October 2001

Breast Cancer Research Meeting
Wake Forest University Baptist Medical Center
Overview of December Breast Cancer Conference in San Antonio
January 2001

Diane S. Myers, **Kimberly C. Dambach**. Family Education Workshop for Bipolar Disorder: Pharmacology & Crisis Management. July 1999, October 1999, January 2000, June 2000

Kimberly C. Dambach. Psyche Link "The Missing Elements of Treatment for the Bipolar Patient"; PBS Special Presentation for continuing medical education November 1999

Poster Presentations:

Fields, J., **Doyle, K**., Hester, A., Cullum, C.M., Lacritz, L. Differences in recognition performance on the CVLT and CVLT-II in Alzheimer's vs. Parkinson's subjects. Accepted for presentation at the International Neuropsychological Society's 35th Annual meeting. February 2007

Kimberly C. Doyle, M.A., C. Allen Stringer, M.D., Jann Aldredge-Clanton, Ph.D. Developing & Evaluating the Efficacy and Feasibility of a Psychoeducational Individual Intervention for Ovarian Cancer Patients: A Two Phase Study: Phase I Outcome. Accepted for presentation at the American Psychosocial Oncology Society's annual meeting , Amelia Island, Florida. February 2006. – Awarded 2nd Prize

Diane S. Myers, Patricia Suppes, **Kimberly Doyle**. Psychoeducational Support Group for Newly Diagnosed Bipolar Patients. Presented July 2003 at The American Psychological Association's annual meeting in Hawaii.

Kimberly C. Doyle, M.A., & Nancy D. Perrier, M.D. A novel curriculum for newly diagnosed breast cancer patients. Presented December 2002 at the San Antonio International Breast Cancer Symposium.

Kimberly C. Doyle, M.A. The Effects of Self-Disclosure with and without supportive feedback on the management of chronic pain. Accepted for presentation at the Society of Behavioral Medicine's 23rd Annual Meeting. April 2002.

Suchi Shaw, **Kimberly C. Doyle, M.A.,** Shana Carter, Edward Levine, M.D., Nancy D. Perrier, M.D. Tamoxifen Therapy Decreases Recurrences of Breast Cancer in Elderly Patients. Accepted for presentation at the Southeastern Surgical Congress, February 2002.

Nancy D. Perrier, M.D. & **Kimberly C. Doyle, M.A**. The One-Stop Shop- A Multidisciplinary Treatment Approach to Breast Cancer. Presented at the National Association of Women's Health Executive Summit. October 2001.

Publications:

Jarrett, R.B., Vittengle, J.R., **Doyle, K.C**., and Clarke, L. (2006). Changes in cognitive content during and following cognitive therapy for recurrent depression: Substantial but not predictive of change in depressive symptoms. Journal of Clinical and Consulting Psychology. In Press.

Suchi Shaw, **Kimberly C. Doyle, M.A.,** Shana Carter, Edward Levine, M.D., Nancy D. Perrier, M.D. Tamoxifen Therapy Decreases Recurrences of Breast Cancer in Elderly Patients. Surgery 2002

Kimberly C. Doyle, M.A. The Effects of Self-Disclosure with and without supportive feedback on the management of chronic pain. Annals of Behavioral Medicine 24:S024 2002.

Kimberly C. Doyle, M.A., Ellen Dennehy, Ph.D., Trisha Suppes, M.D., Ph.D. Case Report for Olanzapine as Monotherapy Treatment for Bipolar Patients in Acute Mania. 2000

O'Toole, A., **Dambach, K.C**. A Moving Shadow Diminishes the Pulfrich Phenomenon. Perception 27 (5):591; 1998