EVALUATION OF A RANDOMIZED CLINICAL TRIAL OF A PSYCHOEDUCATIONAL INTERVENTION ON LONG-TERM QUALITY OF LIFE, NEGATIVE AFFECT, PROGRESSION AND SURVIVAL IN HEAD AND NECK CANCER PATIENTS

by

LARA A. TREVINO

Presented to the Faculty of the Graduate School of
The University of Texas at Arlington in Partial Fulfillment
of the Requirements
for the Degree of

DOCTOR OF PHILOSOPHY

THE UNIVERSITY OF TEXAS AT ARLINGTON
August 2011

ACKNOWLEDGEMENTS

There are a number of people I would like to thank for their support, encouragement and guidance. I would first like to thank my mentor, Dr. Angela Liegey Dougall for her support, encouragement and guidance throughout my development as a researcher. She has taught me the importance of conducting thoughtful research, the importance of perseverance in the face of adversity, and the ability to handle it with grace. Thanks to the members of my dissertation committee, Drs. Verne Cox, Laurie Jensen-Campbell, Daniel Levine, and Pablo Mora for their insightful ideas and commitment to this project. I would like to thank the cancer patients and their families for their time and participation during this difficult time in their lives. Thanks to my syntax and multilevel modeling guru, Jeff Swanson, who assisted in data analysis, and I would like to thank Micah Eimerbrink, Gabriela Blaskovicova, and Chase Bost for their assistance in data entry and cleaning.

I would like to thank Dr. Megan Uhelski for her support and encouragement throughout my graduate school career. She helped me in so many ways that I could not possibly list them all here. I would like to thank Samara Bobzean for her encouragement and support, as well as her willingness to listen to me talk about my project for the millionth time. Thanks to Deborah McArthur and John Biggan, whose friendships through the years in the trenches made it that much more bearable. I would like to thank my parents for their encouragement, support and understanding throughout the years. I would like to thank my sister, Colleen, for her encouragement and support throughout my years in graduate school. Thanks to my in-laws for their support, and encouragement, and the occasional meal to get me through the busy times. I would like to especially thank Dr. Andy Baum for his ability to see my potential as a researcher,

and for encouraging me to reach it. For that I am truly grateful. Though you are not here, I know you are cheering me on in spirit! Lastly, I would like to thank my husband, Ken, whose undying support, patience, advice, encouragement, love and belief in me as a researcher have helped me get to where I am today. Thanks to all who have encouraged, enlightened, and supported me throughout my academic career. I greatly appreciate you all.

July 21, 2011

ABSTRACT

EVALUATION OF A RANDOMIZED CLINICAL TRIAL OF A PSYCHOEDUCATIONAL INTERVENTION ON LONG-TERM QUALITY OF LIFE, NEGATIVE AFFECT, PROGRESSION AND SURVIVAL IN HEAD AND NECK CANCER PATIENTS

Lara A. Trevino, PhD

The University of Texas at Arlington, 2011

Supervising Professor: Angela Liegey Dougall, PhD

The relationship between psychological and physiological factors that impact health is an important consideration for daily life, illness prevention, treatment, and recovery in cancer patients. Psychological functioning may impact overall immune functioning, which may affect efficacy of cancer treatment and disease outcomes. Unfortunately, how psychological variables and quality of life during treatment may impact progression or survival has not been systematically studied. There is a growing body of research suggesting that psychological factors are important predictors of quality of life among cancer survivors. The purpose of the present study was to evaluate the effects of a randomized clinical trial of a psychoeducational intervention and to understand the effects of psychological variables and quality of life on progression and survival in patients with head and neck cancer. Patients (N=91) receiving treatment for head and neck cancer at the University of Pittsburgh Medical Center were

randomized to the intervention group (*n*=51) or the information control group (*n*=40). Data collection included psychological and health behavior variables at the time of the intervention, and at one month, six months and 12 months following completion of the intervention. Medical chart information was collected including recurrence and survival information up to five years following initial treatment. Patients with head and neck cancers who had higher levels of baseline depression, anxiety, and distress and received the intervention did not differ on their levels of depression, anxiety, and subjective distress compared to an information control group. Quality of life did not significantly change after the intervention, and there were no differences between the intervention group and the control group. Patients with head and neck cancer who received the intervention and were smokers at baseline, did not show a reduction in smoking behaviors compared to smokers in the usual care control group. The survival rate was higher than expected in the present study, and the proposed models could not be analyzed. However, exploratory Kaplan Meier and Cox regression analyses were conducted. Exploratory Cox regression analysis showed that baseline levels of depression, anxiety, distress and quality of life did not predict recurrence and survival times within the first five years following initial diagnosis and treatment. However, cancer stage was predictive of survival and weekly tobacco and alcohol use was predictive of progression. Understanding the long-term effects of psychological variables and quality of life among cancer patients undergoing treatment can improve our understanding of how a patient's overall psychological health may impact progression and survival.

TABLE OF CONTENTS

LIST OF ILLUSTRATIONS

Figure Page

LIST OF TABLES

CHAPTER 1

INTRODUCTION

Head and neck cancer is a debilitating disease that comprises 2% of all cancers currently diagnosed in the United States (American Cancer Society, 2010). This type of cancer can be especially disfiguring due to the surgical interventions that are used to treat the cancer. Following surgery, patients may lose functionality of speech, and experience disruptions in eating and drinking behaviors. These adverse effects of treatment may decrease patients' quality of life, and many may become self-conscious regarding these behaviors, resulting in an increase in psychological distress (Vickery, Latchford, Hewison, Bellew, & Feber, 2003). Psychological stress may, in turn, impact cancer progression and survival through its relationships with health behaviors, quality of life (QOL), and underlying physiological changes. Activation of stress pathways can cause the release of neuroendocrine factors that impact immunity. Due to the relationship between cancer and the immune system, it has been proposed that psychological distress and psychiatric diagnosis may impact development and progression of cancer, and ultimately impact survival. Additionally, intermediate outcomes, such as health behaviors and quality of life have been examined as predictors of cancer progression in relation to psychological variables. Therefore, it is important to examine factors that may improve progression and survival in these patients in order to develop targeted interventions that could improve progression and survival outcomes.

Though improvements to cancer treatments have been made in the last few decades, the survival rate of this cancer demographic has remained stable over the last 30 years (Sturgis & Cinciripini, 2007). Previous interventions for patients with head and neck cancers have targeted improving quality of life and psychological functioning or have focused on smoking cessation as possible ways of improving progression and survival. Unfortunately, the effects of

these psychological or educational interventions have been examined independently. The current study combined these two approaches so that both psychological and educational information was provided to patients in order to provide maximum benefit. The present study had two primary aims. First, to examine a combined psychoeducational intervention as part of a randomized clinical trial in order to determine its effectiveness at decreasing depression, anxiety, and distress, promoting smoking cessation, and improving quality of life over one year following the intervention. The second aim was to examine these post-intervention outcomes as predictors of five-year disease progression and survival outcomes. These effects were examined after taking into account important demographic, disease, and treatment variables that are known predictors of progression and survival.

To begin, I will review the scope of head and neck cancer and discuss a conceptual model of the relationship between head and neck cancer and psychological variables, such as stress, specifically looking at how stress may affect progression and identifying mechanisms associated with stress and progression. I will then review some of the factors that have been identified as significant predictors of progression and survival, including psychological variables, such as depression, anxiety, and distress, QOL, and health behaviors, especially smoking cessation (De Graeff et al., 2001; Duffy et al., 2002; Fang, Liu, Tang, Wang, & Ko, 2004). Other predictors of survival, such as demographic variables, disease, and treatment-related predictors, will be discussed. Additionally, interventions that have been developed to target these predictors and improve treatment outcomes in this specific population will be reviewed.

1.1 Head and Neck Cancer

Head and neck cancer is a debilitating form of cancer that can cause disfigurement and loss of functionality as a result of treatment. Almost half of head and neck cancer patients (45.7%) undergo surgery as the initial form of treatment (Funk et al., 2002). The disfiguring effects of surgery on a patient can cause distress, affecting treatment outcomes as a result (Pandey et al., 2007). The distress experienced by the patient has been shown to be positively

related to anxiety and depression following treatment (Pandey, et al., 2007), and depression has been indicated as a predictor of progression and survival in cancer patients (Satin, Linden, & Phillips, 2009). The relationship between stress and cancer and moderators of that relationship will be discussed next.

When genetic mutations occur that govern cell proliferation, the immune system, in a healthy individual, detects these changes and acts to eliminate the potentially rapid cell proliferation. Cancer develops as a result of the failure of the immune system to detect cancerous neoplasms that developed as a result of genetic mutations governing cell proliferation (Reiche, Nunes, & Morimoto, 2004). When the tumor is discovered and a diagnosis of cancer is made, the patient undergoes various treatments, such as surgery, radiation, chemotherapy, or immunotherapy that puts additional physical stress on the body (Baum, Trevino, & Dougall, 2011). Additionally, the diagnosis and treatment process may be especially distressing to the patient and may cause additional physiological stress to occur, possibly affecting the response to further mutations. The relationship between cancer, stress and disease outcomes has been examined, as well as factors, such as health behaviors, that may alter disease outcomes. Andersen et al. (1994) proposed a model that showed the relationship between cancer, stress, and disease course (Figure 1.1). This model proposed that cancer diagnosis and treatment caused the patient to experience stress. This stress directly affected immunity through central nervous system innervations and the release of neuroendocrine factors (i.e. the sympathetic nervous system and the hypothalamus-pituitary-adrenal axis), which, in turn, affected immunity and disease course. Additionally, the stress associated with cancer diagnosis and treatment reduced quality of life. Patients with head and neck cancer have to adapt to changes in physical appearance and functionality as a result of treatment. These adjustments can lead to increased depression and anxiety and reduced quality of life, ultimately impacting disease course (Fang, et al., 2004; Gritz et al., 1999). For example, Fang et al. (2011) found that head and neck cancer patients who reported higher

depressive and anxiety symptoms showed higher levels of vascular endothelial growth factor, which promotes angiogenesis and vasculogenesis. This indicated that the impact of psychological variables on physiological factors may ultimately impact progression of head and neck cancers.

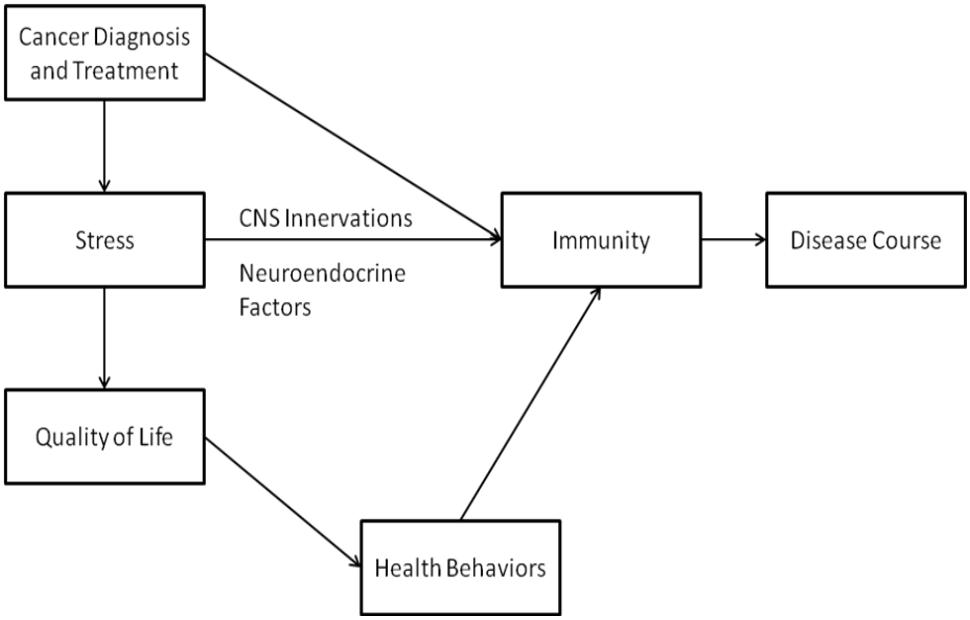

Figure 1.1. Modified proposed model of cancer, stress, and disease course by Andersen et al. (1994).

Decreases in quality of life can have a direct impact on health behaviors, such as diet, exercise, and smoking. Patients with head and neck cancer have to adjust to eliminating smoking and alcohol use, which has proven difficult in this population (Gritz et al., 1993). These health behaviors affect immunity, which again, ultimately impacts disease course (Andersen, Kiecolt-Glaser, & Glaser, 1994). Therefore, this model has been useful in conceptualizing the ways that stress can impact immunity and disease course in head and neck cancer patients.

Factors that affect stress levels in cancer patients that can ultimately impact progression and survival include psychological variables, such as depression, anxiety, or distress, behavioral variables, such as smoking and alcohol cessation, and quality of life in

various domains of the patient's life, such as social or physical functioning. Improving psychological functioning, quality of life, and educating patients on the importance of eliminating or adopting certain health behaviors have been the target of many psychological and educational interventions that have been developed by researchers in the hopes of improving disease outcomes in cancer patients. Using this model of disease course in cancer patients, the present study examined the relationship between psychological variables, health behaviors and their impact on QOL and progression and survival in head and neck cancer.

1.2 Predictors of Progression and Survival

Though there have been reductions in smoking incidence rates and improvements in treatment, five year survival rates in head and neck cancers have remained stable over the past 30 years at 57% (Piccirillo, Costas, & Reichman, 2007). It is important to identify variables that may determine a patient's potential for progression of the disease and whether or not they will survive in order to improve the survival rates of this cancer demographic. Based on Andersen's theoretical model of the relationship between stress and cancer, researchers have sought variables that predict progression and survival and can be targeted by psychological or educational interventions to improve disease outcomes. Psychological variables, such as depression, anxiety and distress, and quality of life and functioning following treatment have been examined as possible predictors of progression and survival (Mehanna, De Boer, & Morton, 2008). Several demographic variables, such as age, gender, and marital status have been identified as significant predictors of survival three years following curative treatment (Karvonen-Gutierrez et al., 2008; Mehanna, et al., 2008). Variables related to diagnosis, such as cancer stage, site of cancer, and nodal involvement have also been identified as predictors of progression and survival (Karvonen-Gutierrez, et al., 2008). The following section will review the findings related to psychological variables, health behaviors, quality of life, demographic factors, and treatment factors as predictors of progression and survival in head and neck cancer patients.

1.2.1 Depression, Anxiety and Distress

Depression has been studied to determine its relationship to survival in head and neck cancer patients. A recent meta-analysis found that depression was a weak predictor of survival among patients with various cancers (Satin, et al., 2009). Depression did not seem to be a significant predictor of progression; however, the authors' note that the relationship between depression and cancer progression is still unclear due to a limited number of studies. (Satin, et al., 2009). This meta-analysis looked at all cancers and included only one study of head and neck cancers. This one study did not look at depression as a predictor of survival in head and neck cancer patients, but rather looked at how QOL predicted survival (De Graeff, et al., 2001). However, Brown et al. (2003) found that higher depression levels were associated with shortened survival time in head and neck cancer patients (Brown, Levy, Zeev, & Edgar, 2003). These studies indicated that there may be a subtle relationship between depression and survival in head and neck cancer patients.

Depression may be indirectly related to progression and survival in head and neck cancer through its relationship with QOL. Kohada et al. (2005) found that depression was significantly related to QOL and that treatment of depressive symptoms greatly improved QOL in head and neck cancer patients. Brown et al. (2003) found that depression was related to poorer QOL, which has been shown to be a predictor of shorter survival. Depressive symptoms and poorer QOL following diagnosis were significant predictors of poor QOL at one year. In another study, depression and moderate to severe comorbidities were significant predictors of poor QOL at diagnosis (Ronis, Duffy, Fowler, Khan, & Terrell, 2008).

The impact of anxiety and distress have not been studied in relation to progression or survival in head and neck cancer, but have been related to established predictors of survival, such as QOL (Kohda et al., 2005), and fear of recurrence (Hodges & Humphris, 2009). Anxiety and distress have been more commonly reported at time of diagnosis (Hammerlid et al., 1999),

compared to during or following treatment, which may limit the time frame for assessing these variables.

Psychological state may impact survival; however, not enough studies have looked at its effect on progression to make definitive conclusions. Depression seems to be a weak predictor of survival in cancer patients, whereas anxiety and distress have not been adequately examined. Anxiety may be related to QOL, which has been shown to be a predictor of survival. The current study planned to address this by looking directly at the relationship of depression, anxiety, and distress through the mediator, QOL.

1.2.2 Health Behaviors

Health behaviors, such as smoking and drinking, have been associated with progression and survival in head and neck cancer patients. Smoking increased incidence of head and neck cancers, specifically of the oral cavity, oro-pharynx, and larynx cancers, compared to non-smokers (Freedman, Abnet, Leitzmann, Hollenbeck, & Schatzkin, 2007). Smoking and alcohol cessation has been recommended to patients with head and neck cancer because those who quit smoking have a better response to treatment, decreased complications, and are less likely to have recurrence (Browman et al., 1993). Continuing to smoke and drink following diagnosis has been shown to be related to more recurrence and shorter survival (Khuri et al., 2001; León et al., 2008). Survivors of head and neck cancer have been shown to have lower smoking rates compared to the national smoking average (Campbell, Marbella, & Layde, 2000). However, patients that believed their cancer was not a result of their smoking behavior were three times less likely to quit (Christensen et al., 1999). Therefore, smoking cessation and a patient's beliefs regarding their smoking behavior may be important variables to consider in order to improve progression and survival rates in head and neck cancer.

Though alcohol has been identified as a risk factor for head and neck cancers, alcohol cessation has been examined on a limited basis. Deleyiannias, Thomas, Vaughan, and Davis (1996) found that abstinence from alcohol consumption was related to reduced risk of death

from head and neck cancer. However, it seems that the risk for developing head and neck cancer among drinkers is highest in those that also smoke (Feldman, Hazan, Nagarajan, & Kissin, 1975). Light drinkers who are non-smokers are only at a slightly higher risk of developing head and neck cancer compared to non-drinkers. However, heavier drinkers and drinkers that smoke are at an increased risk for developing head and neck cancers compared to light drinkers that do not smoke and the general population (Feldman, et al., 1975). It seems that though alcohol has been identified as a possible risk factor for developing head and neck cancer, to my knowledge, no studies have looked at alcohol cessation as a predictor of progression or survival.

Smoking and alcohol use are identified risk factors for developing head and neck cancer. The literature indicates that smoking cessation improves treatment outcomes, as well as progression and survival. Alcohol has been looked at on a limited basis, and currently, no studies have looked at this health behavior as a predictor of progression and survival in head and neck cancer patients. The current study looked at the relationship between continued smoking and drinking behaviors and how they may predict survival and progression.

1.2.3 Quality of Life

Quality of life is a general term that is assessed on several domains, including emotional well-being, physical well-being, and social well-being (Cella et al., 1993). Emotional well-being encompasses how a patient is feeling regarding their diagnosis, treatment, and side effects associated with their treatment. Physical well-being is quantified in terms of levels of fatigue, nausea, and ability to physically function as a result of treatment. Due to the disfiguring nature of head and neck cancer treatment, physical functioning may be assessed in terms of ability to speak, swallow or eat. Social well-being addresses an individual's social functioning in terms of satisfaction of social relationships, such as spouse or family relationships, and also in terms of social support received from these relationships. The following section will look at the

relationship between these variables and progression and survival in head and neck cancer patients.

Health-related quality of life (QOL) has been shown to be related to cancer survival in cancer patients (Chida, Hamer, Wardle, & Steptoe, 2008). Quality of life at the beginning of treatment and changes in QOL across treatment have been evaluated to determine the impact on cancer progression (Fang, et al., 2004; Karvonen-Gutierrez, et al., 2008; Ronis, et al., 2008). Changes in QOL across treatment did not predict survival; however, better QOL at baseline predicted longer survival (Fang, et al., 2004). Specific components of QOL that predicted survival were physical functioning, such as fatigue, nausea, pain and insomnia, and social functioning, such as social contact and sexuality (Fang, et al., 2004).

Improvements in global QOL two to three years after diagnosis were found to predict survival, indicating that changes in QOL during treatment may not be as strong an indicator for survival in head and neck cancer patients compared to post-treatment QOL (Hammerlid, Silander, Homestam, & Sullivan, 2001; Morton, 2003). Mehanna and Morton (2006) found that low QOL following treatment was highly associated with death, even after controlling for demographic and treatment-related variables (H. M. Mehanna & R. P. Morton, 2006). Patients who were disabled and were not working had reduced QOL compared to those that were not disabled (Terrell, Nanavati, Esclamado, Bradford, & Wolf, 1999). Additionally, the placement of a feeding tube and comorbid conditions were strong predictors of global QOL (Terrell et al., 2004). Emotional well-being has not shown a strong relationship to survival in head and neck cancer patients (Coyne et al., 2007); however, methodological concerns, such as, small sample size and the use of questions from the QOL measure, Functional Assessment of Cancer Therapy-General (FACT-G), have been raised (Spiegel & Kraemer, 2008). These studies have shown that QOL predicts survival; however, whether patients were in remission or had recurrence was not clearly stated or controlled for in these studies. Therefore, it is difficult to determine how tumor status or recurrence may impact QOL, and ultimately, survival. Quality of

life seems to be a good predictor of survival in head and neck cancer patients. Quality of life at the beginning of treatment seems to be the best predictor of subsequent QOL and survival in head and neck cancer patients. Physical and social functioning seems to be the best predictors of survival in head and neck cancer patients. However, to my knowledge, no studies have looked at QOL as a predictor of progression in the same cancer population. The present study attempted to address how QOL in head and neck cancer patients may affect progression.

1.2.4 Demographic Predictors

The demographic variables that have been identified as possible significant predictors for survival and prognosis are age, gender, and marital status, and to a lesser degree education status. Based on the literature, those who are older, male, single, and have less education are predicted to have faster progression and reduced survival compared to those who are younger, female, married or cohabitating, and have more education (Karvonen-Gutierrez, et al., 2008; Kugaya et al., 2000). These factors may be related to additional variables that predict survival, such as quality of life. Therefore, the following section will discuss these variables in terms of their direct relationship to survival and their indirect relationship of survival through other predictors, such as quality of life.

Age has been found to be a significant predictor of survival in head and neck cancer patients (Karvonen-Gutierrez, et al., 2008). For example, Allison et al. (2004) found that patients who were younger had a lower chance of survival one year following curative treatment. However, Faye-Lund et al. (1996) found young patients with head neck cancer had better survival rates three years post-curative treatment than did older patients. The reason for the discrepancies in these findings could be due to the difference in follow-up time period. Allison et al. (2004) looked at patients one year following treatment, whereas, Faye-Lund et al. (1996) looked at patients at three years following treatment. Based on these studies, age as a predictor of survival may depend on the number of years following post-curative treatment,

where older patients are more likely to survive one year following post-curative treatment, and younger patients are more likely to survive three years following post-curative treatment.

Age has also been related to additional predictors of survival. For example, QOL is a predictor of survival, and age is related to variables associated with quality of life. Younger patients have been shown to have more functional problems than their older counterparts (Hassanein, Musgrove, & Bradbury, 2001), and age impacted general health and was negatively associated with satisfaction with appearance (Duffy, et al., 2002; Liu, 2008). However, age was not related to levels of depression, distress, or fear of recurrence in patients with head and neck cancer, and did not predict later QOL (D'Antonio et al., 1998; Jenewein et al., 2008; Llewellyn, Weinman, McGurk, & Humphris, 2008; H. M. Mehanna & R. P. Morton, 2006).

Gender has been implicated as a predictor of survival; however, the findings have not been consistent. For example, it could be due to the distribution of men (71.5%) to women (28.5%) who are diagnosed with the disorder (Carvalho, Nishimoto, Califano, & Kowalski, 2005; Tadbi, Mehrabani, & Heydari, 2009). Though gender has been shown to be a predictor of survival (Faye-Lund & Abdelnoor, 1996), gender appears to be related to additional predictors related to survival. For example, women report more functional problems, specifically with physical and emotional functioning (de Graeff et al., 2000). However, de Graeff et al. (2000) also found that women reported lower scores on fatigue and pain measures. Gender was not related with distress or depression levels (Bjordal & Kaasa, 1995; D'Antonio, et al., 1998; Hutton & Williams, 2001; Verdonck-de Leeuw et al., 2007). However, female head and neck cancer patients reported more anxiety, whereas, major depression was mostly reported in males (Hammerlid, Persson, Sullivan, & Westin, 1999; Katz, Kopek, Waldron, Devins, & Tomlinson, 2004). Additionally, there were no gender differences between disfigurement (Katz, Irish, Devins, Rodin, & Gullane, 2003), although, females reported having less satisfaction with their appearance than did men (Liu, 2008). Females reported higher levels of health-related quality

of life, whereas men reported worse health-related quality of life compared to population norms (Hammerlid & Taft, 2001).

Marital status or whether the patient lived alone has also been shown to be a significant predictor of survival in patients (Karvonen-Gutierrez, et al., 2008; Mehanna, et al., 2008). Those that were married, reported having a significant other, or cohabitated with a significant other showed better survival rates one or three years following curative treatment (Mehanna, et al., 2008). Additionally, marital status predicted progression and survival, in that married patients demonstrated slower progression and increased survival compared to their unmarried counterparts (De Graeff, et al., 2001). Marital status or living with a significant other predicted lower levels of distress in head and neck cancer patients (Kugaya, Akechi, Okamura, Mikami, & Uchitomi, 1999; Kugaya, et al., 2000); however, marital quality did not appear to be related to psychological distress (Jenewein, et al., 2008). Depression scores were also not related to marital status in head and neck cancer patients (D'Antonio, et al., 1998). Though marital status was predictive of survival, the mechanism through which married head and neck cancer patients survive was unclear.

1.2.5 Treatment-related Predictors

Predictors related to diagnosis, such as stage of cancer, site of cancer, nodal involvement of cancer, and presence of a feeding tube have been shown to predict progression and survival. Stage of cancer at time of diagnosis significantly predicted survival, with those in the earlier stages of cancer faring better than those in the later stages (Brown, et al., 2003; De Graeff, et al., 2001; Faye-Lund & Abdelnoor, 1996; Karvonen-Gutierrez, et al., 2008). Advanced stages were also predictors of recurrence (De Graeff, et al., 2001). Site of cancer has been implicated as a predictor of survival (Brown, et al., 2003; Faye-Lund & Abdelnoor, 1996). Those that had cancer of the pharynx had less chance for survival compared to those with cancer of the larynx (Brown, et al., 2003). The chances of survival for those with cancer of the oral cavity fell between those with cancer of the larynx and cancer of the pharynx (Brown, et

al., 2003). Degree of nodal involvement has been shown to be a strong predictor as well, with those with lesser nodal involvement faring better in one and three year survival (Brown, et al., 2003). Other factors that were related to poorer survival were longer time since diagnosis, more comorbidities, and if a patient had received surgery or radiation therapy as part of their treatment (Karvonen-Gutierrez, et al., 2008).

Predictors of survival and progression in head and neck cancer patients have included psychological predictors, such as depression and quality of life, health behaviors, such as smoking, demographic variables, such as gender or marital status, and treatment-related factors, such as stage of cancer. Identifying these predictors is important in order to develop targeted psychosocial or educational interventions that would ultimately improve progression and survival rates in head and neck cancer. The next section will discuss the interventions that have been developed to target these identified predictors of progression and survival.

1.3 Interventions for Head and Neck Cancer

Interventions have been used in cancer populations to target a variety of health outcomes, such as, improvement in functioning in various quality of life domains, depressive or anxiety symptoms related to treatment and diagnosis, as well as improving health behaviors, such as smoking cessation, that may increase survival. The number of interventions that have been developed to target the specific needs and concerns of head and neck cancer patients has been limited. Interventions that have been developed for head and neck cancer patients have focused on education regarding smoking cessation or some type of psychosocial skills training, such as coping skills training or relaxation techniques. The following section will discuss the findings regarding both psychosocial and educational interventions for head and neck cancer patients.

1.3.1 Psychosocial Interventions

Psychosocial interventions have been used successfully to improve quality of life and health outcomes among cancer patients. These interventions have targeted coping skills in

order to deal with aspects of diagnosis or treatment. Relaxation techniques have also been used as a way to reduce stress and improve health outcomes among cancer patients. Most of the interventions that have been developed for head and neck cancer patients have looked at smoking cessation or quality of life as the main outcomes (Allison, Edgar, et al., 2004; Allison, Nicolau, et al., 2004; Schnoll et al., 2005). Some interventions that have targeted head and neck cancer have taught patients to cope with their disease and addressed the areas of personal control and self-blame associated with their cancer diagnosis (Allison, Edgar, et al., 2004). The intervention developed by Allison et al. (2004) was administered in three formats: one-on-one with the researcher, in a group setting with additional participants, or at home through a self-study modality. This intervention showed improvements in depressive symptoms and health-related quality of life. Additionally, findings suggested that the best way to administer the intervention was through one-on-one sessions with the patient (Allison, Nicolau, et al., 2004).

Interventions using group therapy have also been developed for head and neck cancer patients. Hammerlid et al. (1999) used a group therapy intervention, where patients discussed their feelings regarding their disease and treatment. Compared to the control group, those who participated in group therapy showed improvements in emotional and social functioning, global quality of life, and improvements in anxiety and depressive symptoms, one year following the intervention (Hammerlid, Persson, et al., 1999). This study indicated that a patient's discussion of their feelings related to their disease and treatment may improve quality of life, and may be best delivered in a group format. Though there are a limited number of psychosocial interventions that have been developed for head and neck cancers, the results indicated that improvements are needed in the delivery of interventions, and that the interventions should focus on the discussion of the patient's feelings regarding their disease.

1.3.2 Educational Interventions

Though smoking cessation has been shown to improve survival and reoccurrence rates in oral cancer patients (Chandu, Smith, and Rogers, 2006), the risk of relapse is especially prevalent among this patient population (Gritz, 2000; Gritz, et al., 1999; Gritz, et al., 1993). The educational interventions that have been developed for patients with head and neck cancer have focused on smoking cessation and have measured degree of cessation and quality of life as the main outcomes for these interventions. Gritz et al. (1991) found that patients who received educational material regarding how to quit smoking and how to avoid relapse had increased self-efficacy and higher perceived social support, both of which increased their chances of smoking cessation one year following diagnosis. Duffy, Ronis, and Valenstein (2006) examined an intervention that targeted smoking and drinking cessation, and was modeled after cognitive behavioral therapy (CBT) that consisted of 9 to 11 sessions. This intervention was effective in decreasing smoking behavior; however, it did not significantly improve drinking behavior or improve depressive symptoms among participants (Duffy, et al., 2006). Additionally, smoking cessation interventions that were administered post-operatively showed improved short-term abstinence rates (Stanislaw & Wewers, 1994).

Individual counseling sessions have also been used in educational interventions in head and neck cancer patients to improve smoking cessation. Schnoll et al. (2005) looked at the effects of four CBT sessions in an intervention group versus general education regarding smoking cessation in a control group. The CBT sessions were developed to target psychological correlates and barriers to smoking cessation. The individualized CBT sessions did not significantly enhance smoking cessation among these patients. It is important to note that the sample was a combination of head and neck cancer patients and lung cancer patients, who each have very different concerns associated with treatment. However, this intervention that targeted psychological correlates and barriers to smoking cessation did not work, and indicates that factors other than barriers to smoking cessation may be important to consider.

A comprehensive educational approach has been used to improve smoking cessation outcomes, as well as improve emotional and social functioning in head and neck cancer patients. Hammerlid et al. (1999) used a more comprehensive approach, where patients received the intervention as in-patients that consisted of a one-week intensive training program. Participants received "an individual meeting with an oncologist, an educational program administered by a physician, individual and group educational sessions administered by a physiotherapist, separate group sessions for patients and their spouses by a trained nurse, and leisure activities, such as walking or painting" (Hammerlid, Persson, et al., 1999). The results for this study showed that patients showed improvements in emotional and social functioning, but there were no improvements in anxiety and depression scores. This intervention targeted education regarding the disease, and did not address patients' feelings and fears regarding treatment and prognosis, which may be why this intervention did not show improvements in anxiety and depressive symptoms. Smoking cessation should be an essential component of an intervention with psychosocial targets as well. Though educational interventions improved smoking rates among head and neck cancer patients, unfortunately, they did not directly improve quality of life or anxiety and depressive symptoms.

1.4 Purpose and Hypotheses

The interventions that have been developed for head and neck cancer patients have used education on smoking cessation or psychosocial training to improve quality of life. However, to my knowledge, no intervention has taken a combination approach, where education about smoking cessation and psychosocial skills training, such as coping skills or relaxation techniques, has been used to improve smoking cessation, quality of life, depression, anxiety or distress levels in head and neck cancer patients. The current study aimed to determine the effects of a combination of education and psychosocial skills training intervention on quality of life, depression, anxiety and distress levels in head and neck cancer patients currently undergoing treatment.

There have been a limited number of studies that have looked at psychological variables and the impact they may have on progression and survival in head and neck cancer patients. The results have been inconsistent regarding psychological predictors of survival and have been on a limited time frame post-diagnosis (i.e. one or three years) in head and neck cancer patients. The risk for developing a second tumor increases as the years following cancer diagnosis increase (Cooper et al., 1989). Therefore, the studies that have looked at survival within this time frame, may not demonstrate accurate relationships between psychological variables and recurrence and survival rates.

The purpose of the present study was to evaluate the effects of a completed randomized clinical trial evaluating a psychoeducational intervention in head and neck cancer patients, and to understand the effects of psychological variables, health behaviors, and quality of life on progression and survival in patients with head and neck cancer.

Hypothesis 1: Patients with head and neck cancer who experienced depression, anxiety, and distress at baseline and completed the psychoeducational intervention would report lower levels of depression, anxiety and distress after the intervention compared to the control group, and to their pre-intervention levels.

Hypothesis 2: Patients with head and neck cancer who completed the psychoeducational intervention would report significantly higher levels of quality of life compared to the control groups, or to their pre-intervention levels.

Hypothesis 3: Patients with head and neck cancer who were smokers at baseline and completed the intervention would report higher smoking cessation rates compared to smokers in the control group across time.

Hypothesis 4: The relationship between baseline depression, anxiety and distress would predict progression through the mediators, QOL and smoking and alcohol use (Figure 1.2).

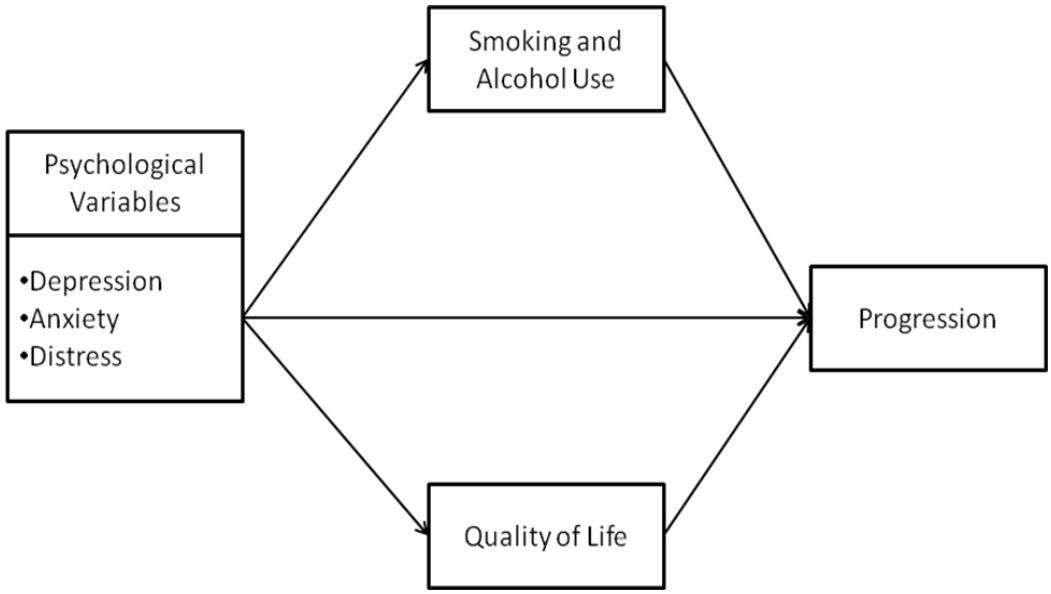

Figure 1.2. Mediation model of hypothesis four.

Hypothesis 5: The relationship between baseline depression, anxiety, and distress and survival would be mediated by QOL and health behaviors (i.e. smoking and alcohol use) (Figure 1.3).

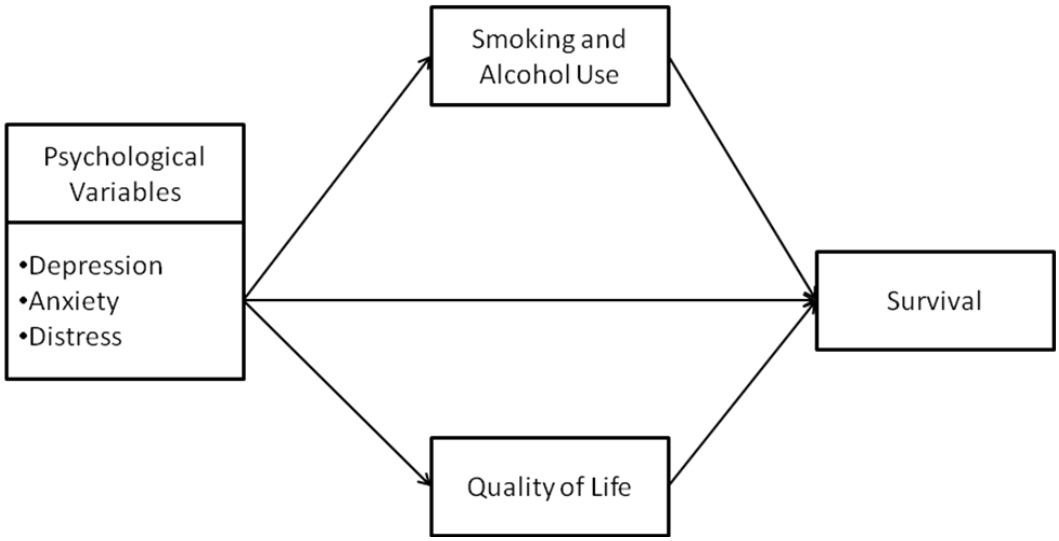

Figure 1.3. Mediation model for hypothesis five

CHAPTER 2

METHODS

2.1 Participants

Participants (*N*=91) for this study were patients with an initial diagnosis of head and neck cancer who participated in a psychoeducational intervention study that was completed at the University of Pittsburgh Medical Center. Individuals were excluded if they had a history of psychiatric illness, prior cancer diagnosis (excluding basal cell carcinoma of the skin due to the nonmetastatic nature and relative ease of treatment associated with this cancer), were unable to read or write English, or were pregnant. Participants were identified by their treating surgeon, oncologist, or a member of the health care treatment team familiar with the potential subject's cancer care. Once identified, research nurses interviewed the patients to determine eligibility, and if they were determined to be eligible, informed consent was obtained. Potential participants were notified that there was no penalty for refusal to participate in the study. Informed consent for this study was obtained under an approved protocol at the University of Pittsburgh Medical Center. Patients who agreed to participate were randomized into the information control group (*n*= 40) or the intervention group (*n*= 51). Demographics, such as gender, ethnicity, marital status, employment status, cancer stage, and site of cancers of the participants are presented in Table 2.1. The mean age of participants was 57.2 years old (*SD*: 11.64; range: 22-89). The majority of our sample were white and males who were married, graduated high school, current tobacco users and were unemployed at the time of recruitment. The number of patients that were randomized to the control group who were smokers (*n*=24) and non-smokers (*n*=15) and those that were randomized to the intervention group who were smokers (*n*=12) and non-smokers (*n*=12) were evenly distributed, χ^2 (1)=1.99, *p*=0.16.

2.2 Measures

To assess depression, anxiety, stress, and quality of life, the questionnaires, the Beck Depression Inventory (BDI), the State/Trait Anxiety Inventory (STAI), the Impact of Event Scale (IES), and the Functional Assessment of Cancer Therapy-Head and Neck (FACT-HN) were completed by the participants following diagnosis of cancer (baseline), and one month, six months, and 12 months following the completion of the intervention. The Beck Depression Inventory (BDI) consisted of 21 questions scored from 0 to 3 to assess depression (Beck, Ward, & Mendelson, 1961). Items on this measure assessed different aspects of depression criteria, such as disturbances in mood, sleep or appetite. See Appendix A for the full questionnaire. The BDI was scored by summing the responses to get a total score. Internal consistency was excellent for this measure (Cronbach's alphas= 0.87-0.91).

To assess cancer-related stress, the Impact of Event Scale (IES), a 15-item, self-report measure that assesses avoidant or intrusive thoughts, was used (Horowitz, Wilner, & Alvarez, 1979). The questions were based on a five-point Likert scale, and a total score was obtained by summing the responses to all 15 items. An example of items that were on the intrusion subscale included questions like, "Any reminder brought back feelings" (Appendix A). The intrusion subscale was scored by summing responses to the eight items on the scale. An example of items that were on the avoidance subscale were "I tried not to think about it" (Appendix A). The avoidance subscale was scored by summing responses to the seven items on the scale. Internal consistency was excellent for this measure (Cronbach's alphas= 0.83-0.96).

Quality of life was measured using the Functional Assessment of Cancer Therapy-General (FACT-G) and the Functional Assessment of Cancer Therapy-Head and Neck (FACT-HN; (Cella, et al., 1993), which measured quality of life on five separate subscales: physical well-being, social/family well-being, emotional well-being, functional well-being, and additional concerns. The FACT-G consisted of the subscales on well-being, whereas the FACT-HN

consisted of the subscale related to additional concerns. Patients were asked to report how true each statement had been for them during the past seven days on a five-point Likert scale with the responses, not at all, a little bit, somewhat, quite a bit, and very much. The physical well-being subscale consisted of seven items, and an example item on this subscale was "I have a lack of energy". The social/family well-being subscale consisted of seven items, and statements like "I feel close to my friends" were rated by patients. The emotional well-being subscale consisted of six items and statements like "I feel sad" were rated. The functional well-being subscale contained seven items and contained statements like "I am able to enjoy life". The additional concerns subscale contained 11 items that were specific concerns to individuals with head and neck cancer. Items like, "I am able to communicate with others" were rated by the patients. Subscale scores for the FACT-G were obtained by summing up the item responses on that scale, and a total score for the FACT-G was calculated by summing up the subscale scores. The additional concerns subscale was scored by summing up the item responses, and a total score was calculated by adding the subscale score to the FACT-G total score. If there were missing responses on the subscales, a pro-rated score was calculated if more than 50% of the items were answered on that subscale. In order to be a good indicator of quality of life, patients had to respond to at least 80% of all items on this questionnaire. The prorated subscale score was calculated by multiplying the number of subscale items by the sum score of the subscale, and then dividing by the actual number of questions answered. The total score was then calculated by adding the unweighted subscale scores (Cella, et al., 1993). Internal consistency was good for this measure (Cronbach's alphas= 0.79-0.95).

The State/Trait Anxiety Scale (STAI) was a 40-item self-report questionnaire that measured current anxiety state, as well as how anxious patients generally were, or their trait anxiety (Spielberger, 1983). The 20-item state anxiety subscale of this measure was used in this study. For the state anxiety subscale, the patient rated how they felt on a four-point Likert scale, from the responses: not at all, somewhat, moderately so, and very much so. The state

anxiety subscale asked the individual to rate how they were feeling at this moment. Items were given scores that were weighted one to four. Anxiety-present items were weighted based on the response on the questionnaire.

Table 2.1 Demographic Statistics for Participants

Variable	Sample Size	Percentage
Gender		
Males	58	63.7
Females	33	36.3
Ethnicity		
Native American	2	2.2
Black, not of Hispanic origin	2	2.2
White, not of Hispanic origin	88	95.7
Education Level		
Some high school	16	17.4
High school graduate	34	37.4
Some college	17	18.7
College degree	10	11.0
Some graduate work/Graduate degree	9	9.9
Marital Status		
Married	64	70.3
Not married	23	25.3
Smoking Status		
Never a smoker/ quit years ago	27	29.7
Current smoker/ quit within 1 month of diagnosis	61	67.0
Employment status		
Yes, full time	39	42.4
Yes, part time	8	8.7
No	41	44.6
Stage of Cancer		
I	16	17.6
II	15	16.5
III	20	22.0
IV	38	41.8
Site of Cancer		
Lip and oral cavity	48	52.7
Pharynx	22	24.2
Larynx	17	18.7
Morphology of Cancer		
Squamous cell	74	81.3
Non-squamous cell	16	17.6

However, anxiety-absent items were reverse scored. The weighted scores for the 20 items were then added up after taking into account the reversed scored items. An example of an anxiety-present item was “I feel tense”, whereas an example of an anxiety-absent item was “I

feel calm". See Appendix A for the full questionnaire. If participants did not respond to one or two items on the scale, a pro-rated full score was used. A pro-rated full score was obtained by multiplying the mean weighted score for the scale items by 20, and then rounding the product to the next highest whole number (Spielberger, 1983). Internal consistency was excellent for this measure (Cronbach's alpha= 0.92-0.95).

A modified version of the daily Record Form (DRF) was used to assess weekly tobacco and alcohol consumption, as well as smoking cessation tools and attempts (Baum, Breslin, O'Keefe, Raliff-Crain, & Burrell, 1994). The DRF assessed additional variables, such as weekly stress and current medications; however, only the items assessing tobacco and alcohol use were used for the present study (Appendix A). The DRF was filled out weekly by participants throughout the one year study period. The units of tobacco were calculated from the weekly DRF responses, where the total amount of tobacco was summed from each weekly questionnaire, and then averaged over the course of the follow-up period. For example, the one month follow-up tobacco units were an average of their responses on the DRF for weeks one through four. The six month follow-up tobacco units were an average of weeks five to week 26, and the 12 month follow-up was an average of their tobacco units from week 27 to week 52. Baseline tobacco use was calculated based on their reported daily tobacco use, by multiplying their daily tobacco use by seven, in order to obtain their weekly tobacco use at baseline. Prior to the Cox regression survival analysis, weekly alcohol was calculated by averaging their reported baseline use of alcohol and their responses on items about their alcohol use from the weekly DRF questionnaire. Weekly tobacco use was calculated the same way as weekly alcohol use.

Additional demographic information was collected regarding stage of cancer, gender, type of cancer treatment(s), education level, ethnicity, smoking history, and marital status from the patient or the Tumor Registry at the University of Pittsburgh Medical Center. Data were also collected as part of a long-term follow-up, where information from medical charts regarding

recurrence, additional treatment(s) associated with recurrence, and status (i.e. active, deceased or no information) was collected for up to10 years following initial diagnosis and treatment of cancer. For the purpose of this study, the first five years of this follow up period were used. Additional measures, such as self-report measures related to nutrition or recent life changes, and measurements of immune cell activity were taken; however, these measures were not included in the present study.

2.3 Intervention

The intervention consisted of seven 45 minute sessions with a doctoral level therapist that began on the third day following surgery. Session one was an introduction to the program and was spent gathering historical information, such as their history of coping, current tobacco use, and attempts to quit, and informing patients of what would be covered in future sessions. Session two consisted of assessing current stress levels, an overview of the changes that occur in the body during stress in relation to their specific stressors, benefits of relaxation, and an introduction of three relaxation techniques. These techniques were diaphragmatic breathing, progressive relaxation and imagery. A tape of this session was given to each subject to facilitate practice of these techniques between sessions.

Session three introduced the importance of smoking cessation, and covered topics such as, reasons to quit, cold-turkey quitting, how to cope with urges, and self-rewards. Patients compiled a list of usual triggers to smoke and ways to avoid or cope with these triggers. They were also instructed on how to remove smoking equipment from their homes, vehicles, and other places they frequent. Session four focused on cognitive coping strategies and reviewed how appraisal and interpretations of events can affect stress and urges to smoke. Methods to cope with quitting were reviewed, and cognitive distortions were introduced. The participant and the therapist worked together to address the patient's specific concerns and their patterns of coping. Participants were then introduced to the RESOLVE method of coping

that emphasizes evaluation of many responses to the problem and each possible solution and outcome (Goldfried & Davison, 1994).

Session five emphasized smoking relapse prevention, and participants were taught a specific problem solving technique. A review of this technique and how it applies to smoking cessation was discussed. Session six addressed consequences of treatment of oral cancer, such as communication problems, body image concerns, and pain. Session seven concluded the intervention with a review of ways to learn to cope with future events and possible recurrence. Patients who were randomized to the information control group met with the doctoral level therapist who administered the intervention for brief information sessions regarding information about cancer only.

2.4 Procedure

Participants were admitted to the University of Pittsburgh Medical Center for surgical treatment associated with their diagnosis, and completed their baseline paper and pencil questionnaires prior to surgery. On day three following surgery, session one of the intervention began, or the control patients met with the therapist. The sessions were administered once a day, unless the patient was expected to be discharged prior to completion of the intervention, in which case the sessions were administered twice a day.

Follow-up measures were conducted at one month, six months and 12 months following completion of the intervention and were scheduled during the patient's regular follow-up visits with their surgeons. The five-year follow up data were collected from the patient's medical records from the University of Pittsburgh Medical Center, after the patient completed an authorization form to allow access to this information.

2.5 Statistical Analysis

Prior to analyses, all variables were screened for univariate outliers and the distributions of the data were examined. The data were analyzed using the PASW 18 Statistics package (SPSS Inc., Chicago, IL, USA). Repeated measures analysis of variances (ANOVA)

and Chi-square tests were performed for the covariates, gender, cancer morphology, smoking status, cancer stage, education, marital status, therapist who administered the intervention, surgeon who performed their surgery, and site of cancer, to reduce the number of the *a priori* covariates in order to increase the statistical power of the analyses. The continuous variables, depression (BDI), anxiety (STAI), distress (IES), quality of life (FACT-HN), and tobacco use (DRF) were grand mean centered. A coding variable for time was created where the square root of the one month, six month, and 12 month follow-up period was used. Additionally, 14 dummy variables were created for each possible pattern of missing data for each of the four time points. A dummy variable for the pattern where data was missing for all four time points was not calculated. Dummy variables were also created for completers versus non-completers, those who completed the 12 month follow-up and those who did not, those who completed the six month follow-up and those who did not, and those who completed the one month follow-up and those who did not. Frequency analysis was conducted to determine which patterns of missing were applicable to the sample.

For hypotheses one, two, and three, pattern mixture modeling was used to determine the effect of the intervention across time on depression, anxiety, distress, quality of life, and tobacco use. Analyses were conducted in a stepwise approach following recommendations by Peugh and Enders (2005) and Hedeker and Gibbons(1997). First, a full maximum likelihood model was conducted with the covariates, gender, cancer morphology, smoking status at baseline, cancer stage, and education added as fixed factors. Next, the calculated time variable was added to the model as a repeated factor and individual t-tests with a Bonferroni correction were calculated. This model was compared to the covariates only model to determine if there was an improvement in model fit. Then, group was added to the model as a fixed factor, and this model was compared to the previous model to determine improvement of model fit. Baseline measurement of the respective measure was added as a moderator to this model. Finally, each dummy variable for the pattern of missing data was added to the individual

models. These models were compared to the group, time, and covariates model to determine improvement of fit. Post hoc interpretations were calculated using the marginal means and standard errors produced by the centered mean of the outcome variables from the models. For hypotheses four and five, exploratory Kaplan-Meier and Cox Regression survival analyses were used for survival (time to death from baseline), progression (time to progression was defined as time from baseline to date of first metastasis or first recurrence, whichever occurred first), time to new primary tumors (time from baseline to date of development of first new primary tumors), and time to event (time from baseline to time to death, progression, or new primary tumors, whichever came first). Patients who were still alive at the time of analysis were censored for survival. The survival analyses were performed in 12 month increments starting at one year following baseline to five years following baseline, in order to maximize the number of cases for the survival analysis. For the Kaplan Meier analysis, survival was assessed for all participants, and then by those who received the intervention, smoking status, gender, education, cancer morphology, and cancer stage. The log rank test was performed to test the equality of survival distributions for the different levels of treatment, smoking status, gender, education, cancer morphology and stage of cancer. For the Cox regression survival analysis, group, smoking status, gender, education, morphology, and cancer stage were entered into the equation in a sequential manner. Baseline BDI, IES, STAI, FACT-HN scores, and weekly alcohol and tobacco use were entered in the second step. The structural equation models were not performed due to the small number of cases for survival, progression, time to development of new primary tumors, and time to event at five years following baseline.

CHAPTER 3

RESULTS

A square root transformation was performed to reduce positive skewness in baseline Beck Depression Inventory (BDI), State/Trait Anxiety Inventory (STAI), and Impact of Event Scale (IES) scores. A square root (reflected) transformation reduced negative skewness on Functional Assessment of Cancer Therapy-Head and Neck (FACT-HN) total scores. A series of chi-square analyses were conducted to determine associations between groups and the covariates, gender, cancer morphology, smoking status, cancer stage, education, marital status, therapist who administered the intervention, surgeon who performed their surgery, and site of cancer. There were no associations between group and gender, χ^2= (*n*=92, *df*=1) =1.53, *p*=0.27; cancer morphology, χ^2= (*n*=92, *df*=2) =1.26, *p*=0.57; smoking status, χ^2= (*n*=92, *df*=2) =1.93, *p*=0.17; cancer stage, χ^2= (*n*=92, *df*=4) =2.31, *p*=0.43; education, χ^2= (*n*=92, *df*=5) =5.42, *p*=0.34; marital status, χ^2= (*n*=92, *df*=1) =0.62, *p*=0.32; therapist who administered the intervention, χ^2= (*n*=92, *df*=6) =9.20, *p*=0.14; surgeon who performed their surgery, χ^2= (*n*=92, *df*=3) =4.12, *p*=0.26. However, there was a significant association with site of cancer, χ^2= (*n*=87, *df*=2) =11.51, *p*=0.003. There were more patients with cancer of the pharynx in the intervention group (*n*=19) than the control group (*n*=3). There were also more patients with cancer of the larynx in the control group (*n*=11) compared to the intervention group (*n*=6). Cancer of the lip or oral cavity was similar for the control group (*n*=23) and the intervention group (*n*=25).

Repeated measures ANOVAs were conducted to determine effects of the covariates, smoking status, gender, cancer morphology, marital status, education, cancer site, cancer

stage, clinician who administered the intervention, and the surgeon who treated the patients, on the outcome measures of depression, anxiety, distress, quality of life, and tobacco use at each time point. Smoking status predicted BDI scores, F (3, 109) = 4.64, p=0.004. Non-smokers (M=2.16, SE=0.34) reported less symptoms of depression than did smokers (M=3.01, SE=0.20). Tobacco use was significantly predicted by smoking status (F(3,108)=4.00, p=000), gender (F(3, 171) =3.06, p=0.03), cancer morphology (F(6,168)=3.25, p=0.005), marital status (F(3, 171)=3.75, p=0.012), education level (F(12,159)=6.20, p=0.00), and cancer stage (F(9, 162)=2.134, p=0.029), Non-smokers (M=0.03, SE=7.68) reported significantly less tobacco use than did smokers (M=27.89, SE=4.80). Women (M=24.14, SE=7.31), reported significantly more tobacco use than did men (M=16.98, SE=5.23). Patients with squamous cell carcinoma (M=21.03, SE=4.60) reported more tobacco use than did patients that had other types of morphology (M=5.96, SE=10.73), Patients that were not married (M=27.20, SE=8.40) reported significantly more tobacco use than did those that were married (M=16.75, SE=4.90). Patients that had some high school education (M=52.18, SE=8.16) reported significantly more tobacco use than did high school graduates (M=20.20, SE=6.32), those with some college education (M=4.47, SE=7.84), college graduates (M=5.46, SE=10.69), or those with some graduate work or degree (M=3.11, SE=11.55). Post-hoc tests (Bonferroni adjusted) showed there were no significant differences in tobacco use between patients with cancer in stage I (M=9.57, SE=9.79), stage II (M=35.15, SE=9.37), stage III (M=15.92, SE=8.68), or stage IV (M=18.83, SE=7.09). Based on these analyses, gender, smoking status, education level, cancer morphology, and cancer stage were included in subsequent analyses.[1]

---

[1] The covariates, marital status, age, and alcohol use were also looked at in pattern mixture models, Kaplan Meier and Cox regression survival analysis as well. However, these covariates did not change the results. The covariates, clinician who administered the intervention, the surgeon who treated the patient, and site of cancer were excluded as covariates.

3.1 The Effects of the Intervention

3.1.1. Covariates only model

Mixed linear models were conducted using the covariates gender, cancer morphology, smoking status, cancer stage, education level, and baseline measurement of the respective outcome measure. This was done for all five outcome variables (BDI score, STAI score, IES score, FACT-HN total score and tobacco use; see Tables 3.1 and 3.2). Depression levels (BDI scores) were predicted by cancer morphology (F (1, 159) =4.22, p=0.04), smoking status (F=1, 159) =6.69, p=0.01), education level (F (4, 159) = 3.45, p=0.01) and the baseline depression score (F (26, 159) =4.05, p=0.00). Those who had squamous cell carcinoma (M=0.08, SE=0.16) reported significantly lower levels of depression than their non-squamous cell counterparts (M=0.72, SE=0.32), p=0.04. Smokers (M=0.70, SE=0.19) reported significantly higher levels of depression than non-smokers (M=0.10, SE=0.26), p=0.01. High school graduates (M=0.04, SE=0.21) reported less depression than those with some college education (M=0.91, SE=0.31, p=0.04), p=0.04. There were no differences between those with some high school education (M=0.86, SE=0.34), college graduates (M=0.09, SE=0.31), or those with some graduate work or degree (M=0.09, SE=0.35). Anxiety (STAI scores) was predicted by cancer morphology (F (1, 166) = 6.38, p=0.01) and baseline STAI scores (F=40, 166) =7.90, p=0.00). Those who had squamous cell carcinoma (M=-0.16, SE=0.08) reported lower levels of anxiety compared to those that did not have squamous cell carcinoma (M=0.49, SE=0.26), p=0.01.

Table 3.1 Coefficients for Covariates Only Models for the BDI, STAI, and the IES

	Model					
	BDI Score		STAI Score		IES Score	
Effect	*b* (SE)	*t*(159)	*b* (SE)	*t*(166)	*b* (SE)	*t*(152)
Gender	-0.36 (0.25)	-1.47	-0.25 (0.18)	-1.42	-1.04 (0.33)	-3.09****
Cancer Morphology	-0.65 (0.32)	-2.05**	-0.65 (0.26)	-2.53**	-0.80 (0.51)	-1.57

Table 3.1 -Continued

	Model					
	BDI Score		STAI Score		IES Score	
Effect	*b* (SE)	*t*(159)	*b* (SE)	*t*(166)	*b* (SE)	*t*(152)
Smoking Status	-0.60 (0.23)	-2.59***	-0.02 (0.18)	-0.11	-1.06 (0.32)	-3.36****
Cancer Stage (I v. IV)	-0.15 (0.33)	-0.47	-0.46 (0.26)	-1.76	-0.08 (0.36)	-0.24
Cancer Stage (II v. IV)	-0.76 (0.33)	-2.26**	-0.28 (0.22)	-1.28	-0.90 (0.42)	-2.16**
Cancer Stage (III v. IV)	-0.12 (0.30)	-0.41	-0.27 (0.28)	-0.98	1.28 (0.37)	3.51****
Education Level (SHSvSGW)	0.77 (0.40)	1.92	0.13 (0.0.35)	0.38	1.70 (0.55)	3.09***
Education Level (HSGvSGW)	-0.05 (0.35)	-0.14	-0.27 (0.34)	-0.80	0.58 (0.47)	1.23
Education Level (SCEvSGW)	0.82 (0.39)	2.13**	0.01 (0.36)	0.02	1.31 (0.60)	2.17**
Education Level (CGvSGW)	0.01 (0.41)	0.01	-0.46 (0.44)	-1.03	1.37 (0.72)	1.92#

Note: The values represent the unstandardized coefficients and their standard errors. Gender was coded as 1=men and 2=women. Cancer morphology was coded as 1=squamous cell and 2=not squamous cell. Smoking status was coded as 0= never smoked/quit years ago and

1=current smoker/quit within one month of diagnosis. Cancer stage was coded according to AJCC staging. SHS=Some high school education; HSG= High school graduate; SCE=Some college education; CG=College graduate; SGW=Some graduate work or degree. *p<.05; **p<.04; ***p<.01; ****p<.001; #p=0.052.

Gender (F (1,152) =9.55, p=0.002), smoking status (F=1, 152) =11.30, p=0.001), cancer stage (F (3, 152) = 9.94, p=0.00), education level (F (4, 152) =3.06, p=0.02), and baseline IES scores (F=39, 152) = 11.94, p=0.00) were predictive of subsequent distress (IES scores). Females (M=0.83, SE=0.38) reported more distress than their male counterparts (M=-0.21, SE=0.21), p=0.002, and smokers (M=0.84, SE=0.29) reported more distress than did non-smokers (M=-0.22, SE=0.32), p=0.001. Those with stage III cancer (M=1.52, SE=0.29) reported significantly more distress than did patients with stage I (M=0.15, SE=0.42, p=0.006), stage II (M=-0.67, SE=0.35, p=0.00), or stage IV (M=0.24, SE=0.37, p=0.004). Those who had completed some graduate work (M=-0.68, SE=0.49) reported significantly lower distress than those with some high school education (M=1.01, SE=0.38), p=0.02. There were no differences for high school graduates (M=-0.10, SE=0.22), those who completed some college (M=0.63, SE=0.43), or those who completed a college degree (M=0.69, SE=0.54).

Table 3.2 Coefficients for Covariates Only Models for the FACT-HN scores and Tobacco Use

	Model			
	FACT-HN Total Score		Tobacco Use	
Effect	*b* (SE)	*t*(154)	*b*(SE)	*t*(187)
Gender	2.75 (0.55)	5.04****	4.07 (3.43)	1.19
Cancer Morphology	-0.46 (0.71)	-0.65	-3.97(4.66)	-0.85
Smoking Status	-1.09 (0.57)	-1.89	-2.25 (3.41)	-0.66
Cancer Stage (I v. IV)	4.64 (0.83)	5.59****	0.06(4.46)	0.01
Cancer Stage (II v. IV)	-3.07 (0.56)	-5.49****	-6.66 (4.07)	-1.63
Cancer Stage (III v. IV)	-0.77 (0.78)	-0.98	-1.90 (4.27)	-0.45

Table 3.2 -Continued

	Model			
	FACT-HN Total Score		Tobacco Use	
Effect	*b* (SE)	*t*(154)	*b*(SE)	*t*(187)
Education Level (SHSvSGW)	0.29 (0.99)	0.30	12.55(6.65)	1.89
Education Level (HSHvSGW)	-1.05 (0.78)	-1.34	-4.42 (5.79)	-0.76
Education Level (SCEvSGW)	-2.11 (0.80)	-2.65****	-4.16 (5.38)	-0.77
Education Level (CGvSGW)	-0.87 (0.86)	-1.01	-0.50 (6.36)	-0.08

Note: The values represent the unstandardized coefficients and their standard errors. Gender was coded as 1=men and 2=women. Cancer morphology was coded as 1=squamous cell and 2=not squamous cell. Smoking status was coded as 0= never smoked/quit years ago and 1=current smoker/quit within one month of diagnosis. Cancer stage was coded according to AJCC staging. SHS=Some high school education; HSG= High school graduate; SCE=Some college education; CG=College graduate; SGW=Some graduate work or degree. *p<.05; **p<.04; ***p<.01; ****p<.001; #p=0.052.

Quality of life (FACT-HN scores) was predicted by gender (F (1, 154) =25.35, p=0.00), cancer stage (F (3, 154) =38.76, p=0.00), education level (F (4, 154) =5.37, p=0.00), and baseline QOL (F (46, 154) =8.46, p=0.00). Women (M=-1.40, SE=-0.47) reported lower QOL compared to their male counterparts (M=1.35, SE=0.37), p=0.00. Those with stage I cancer (M=4.41, SE=0.69) reported greater QOL compared to stage II (M=-3.30, SE=0.59, p=0.00), stage III (M=-0.99, SE=0.62, p=0.00), or stage IV (M=-0.23, SE=0.41, p=0.00). Stage II patients reported significantly lower levels of QOL than stage III (p=0.00) and stage IV (p=0.04). There were no differences in QOL between stage III and stage IV cancer patients. Those who had some high school education (M=1.01, SE=0.56) reported significantly higher levels of QOL

compared to those with some college education (*M*=-1.39, *SE*=0.51; *p*=0.002). There were no differences for high school graduates (*M*= -0.33, *SE*=0.40) college graduates (*M*=-0.15, *SE*=0.57) and those who had completed some graduate work (*M*=0.72, *SE*=0.78). Tobacco use was predicted by education level (*F* (4, 187) =3.68, *p*=0.007) and baseline tobacco use (*F* (17, 187) =4.46, *p*=0.00). Those with some high school education (*M*=-2.68, *SE*=4.31) reported significantly higher levels of tobacco use than high school graduates (*M*=-19.65, *SE*=3.55, *p*=0.003) and those who had completed some college (*M*=-19.39, *SE*=4.64; *p*=0.02). There were no differences for those who had completed a college degree (*M*=-15.73, *SE*=5.27) and those who had completed some graduate work (*M*=-15.23, *SE*=6.06).

3.1.2 The Effect of the Intervention and Time

The effects of time and the intervention were added to the covariates model. The subsequent model was not a significantly better fit for depression (-2 Log likelihood=442.28 for covariates only vs. 431.71 for group and time, *df*=19, *p*>.05). The subsequent model was a significantly better fit for anxiety (-2 Log likelihood=296.25 for the covariates only model vs. 397.49 when including group and time, *df*=33, *p*<.05), distress (-2 Log likelihood=368.15 for the covariates only model vs. 469.81 when including group and time, *df*=19, *p*<.05), quality of life (-2 Log likelihood=426.58 for the covariates only model vs. 545.34 when including group and time, *df*=19, *p*<.05), and tobacco use (-2 Log likelihood= 1577.39 for covariates only vs. 1552.48 when including group and time, *df*=19, *p*<.05).

There was not a significant change across time in depression levels, F (2, 94.73) =0.64, *p*=0.53; anxiety levels, *F* (2,111.60) =0.33, *p*=0.72; distress, *F* (2, 100.36) =1.42, *p*=0.25; QOL, *F* (2, 99.46) =0.32, *p*0.73; or tobacco use, *F* (2, 110.90) =0.44, *p*=0.65(Figures 3.1 and 3.2). There were no differences between the control group and the intervention group for depression, *F* (1, 64.76) =0.00, *p*=1.00; anxiety, *F* (1, 72.66) =0.03, *p*0.87; distress, *F* (1, 62.76) =0.09, *p*=0.77; QOL, *F* (1, 66.65) =1.03, *p*=0.31; or tobacco use, *F* (1, 59.32) =0.24, *p*=0.63 (Figures 3.3 and 3.4). There were no significant group by time interaction effects for depression, *F* (2,

94.56) =2.82, *p*=0.07; anxiety, *F* (2,111.76) =0.29, *p*=0.75; distress, *F* (2, 100.34) =0.66, *p*=0.52; QOL, *F* (2, 99.82) =1.34, *p*=0.26 or tobacco use, *F* (2, 110.97) =0.53, *p*=0.59 (Figures 3.5 and 3.6). The unstandardized coefficients and standard errors for the outcome measures and covariates are presented in Tables 3.3 and 3.4.

Table 3.3 Coefficients for Effects of the Intervention and Time Model for the BDI, STAI and IES

	Model					
	BDI		STAI		IES	
Effect	*b*	*SE*	*b*	*SE*	*b*	*SE*
Gender	0.39	0.29	0.27	0.20	1.27	0.28
Cancer Morphology	0.43	0.37	0.30	0.25	0.97	0.36
Smoking Status	0.73	0.29***	0.02	0.20	0.55	0.28
Cancer Stage	0.05	0.12	-0.02	0.08	0.24	0.12
Education	-0.11	0.11	-0.11	0.07	-0.03	0.10
Baseline	0.23	0.26	0.56	0.19***	0.88	0.15****
Group	-0.93	0.89	0.13	0.26	-0.02	0.86
Time (1vs12)	-0.64	0.79	-0.08	1.50	1.31	0.79
Time (6vs12)	-1.22	0.63	-0.77	1.33	0.44	0.62
Group x Time (1vs12)	1.06	0.91	1.23	2.05	-0.79	1.10
Group x Time (6vs12)	1.72	0.74***	1.33	1.79	0.28	0.92
Group x Baseline	0.36	0.30	0.13	0.26	-0.02	0.22
Time x Baseline (1vs12)	0.29	0.27	0.02	0.22	-0.34	0.20
Time x Baseline (6vs12)	-0.39	0.31**	0.13	0.20	-0.00	0.16
Group x Time x Baseline (1vs12)	-0.39	0.31	-0.19	0.31	0.20	0.28
Group x Time x Baseline (6vs12)	-0.56	0.25**	-0.21	0.27	-0.23	0.23

Note: Values represent unstandardized coefficients and standard errors for the estimate.*p<.05. **p.<01. ***p<.005.

Table 3.4 Coefficients for Effects of the Intervention and Time model for the FACT-HN and Tobacco Use

	Model			
	FACT-HN		Tobacco Use	
Effect	*b*	*SE*	*b*	*SE*
Gender	0.44	0.49	-4.43	4.05
Cancer Morphology	0.49	0.56	-0.99	5.17
Smoking Status	0.34	0.45	-2.43	4.08
Cancer Stage	0.04	0.20	0.84	1.63
Education	-0.34	0.17	-0.31	1.61
Baseline	0.53	0.17	0.22	0.04***
Group	1.58	1.80	3.17	5.58
Time(1vs12)	0.96	0.94	-1.98	4.83
Time (6vs12)	-0.66	0.70	2.40	4.02
Group x Time(1vs12)	-1.33	1.82	0.42	6.40
Group x Time (6vs12)	0.86	1.47	-3.81	5.32
Group x Baseline	-0.23	0.30	-0.15	0.05**
Time x Baseline(1vs12)	-0.05	0.17	0.02	0.05
Time x Baseline (6vs12)	0.18	0.12	-0.13	0.04****
Group x Time	0.21	0.30	-0.06	0.06
x Baseline(1vs12)				
Group x Time x	-0.09	0.24	0.11	0.05**
Baseline (6vs12)				

Note: Values represent unstandardized coefficients and standard errors for the estimate. *p<.05. **p<.01. ***p<.005.

3.1.3 The Effect of the Intervention and Time for Completion Status

A dichotomous variable of whether participants had completed all time points or not was created and added to the group, time and covariates (GTC) model. [2] The resulting group, time, covariates, and non-completers vs. completers model (GTCN) was not a significantly better fit for depression (-2 Log likelihood= 431.71 for the GTC model vs. 422.15 for the GTCN model, *df*=6, *p*>.05), anxiety (-2 Log likelihood= 397.49 for the GTC model vs. 385.90 for the GTCN model, *df*=6, *p*>.05), distress (-2 Log likelihood= 469.81 for the GTC model vs. 466.32 for the GTCN model, *df*=6, *p*>.05), or tobacco use (-2 Log likelihood= 1552.478 for the GTC model vs. 1545.97 for the GTCN model, *df*=6, *p*>.05). However, the GTCN model was a significantly better fit for quality of life (-2 Log likelihood= 545.34 for the GTC model vs. 530.11 for the GTCN model, *df* =6, *p*<.05).

There were no differences between the control group and the intervention group for depression, *F* (1, 71.83) =0.13, *p*-0.72; anxiety, *F* (1, 73.77) =0.003, *p*=0.96; distress, *F* (1, 68.02) =0.15, *p*=0.70; QOL, *F* (1, 68.71) =0.26, *p*=0.61; or tobacco use, *F* (1, 62.78) =0.88, *p*=0.35 (Figures 3.9 and 3.10). There were no differences between completers and non-completers for depression, *F* (1, 98.93) =0.05, *p*=0.83; anxiety, *F* (1, 91.44) =2.77, *p*=0.10; distress, *F* (1, 113.65) =1.66, *p*=0.20; or tobacco use, *F* (1, 61.01) =3.63, *p*=0.06 (Figures 3.11 and 3.12). However, those who completed the study (*M*=-0.27), *SE*=0.26) reported higher levels of QOL, *F* (1, 86.58) =4.93, *p*=0.03, compared to those who did not complete the study (*M*=0.88, *SE*=0.44). There were no significant changes across time for depression, *F* (2, 96.19) =0.03, *p*=0.97; anxiety, *F* (2, 112.81) =0.44, *p*=0.65; distress, *F* (2, 105.58) =1.16, *p*=0.32; QOL,

[2] Additional models with baseline measures as moderators were conducted on dummy variables of the patterns OMMM, OOMM, OOOM, OOOO. Models were also conducted with all four time points included as repeated factors. However, none of these models were significant, and therefore, for ease of results, are not presented.

F (2, 100.18) =0.01, *p*=0.99; or tobacco use, *F* (2, 113.24) =0.88, *p*=0.35 (Figures 3.7 and 3.8). There were no significant group by time interaction effects for depression, *F* (2, 96.10) =0.36, *p*=0.70; anxiety, *F* (2, 112.90) =0.13, *p*=0.88; distress, *F* (2, 105.71) =0.82, *p*=0.44; QOL, *F* (2, 100.44) =1.09, *p*=0.34; or tobacco use, *F* (2, 113.31) (Figures 3.13 and 3.14) =1.41, *p*=0.25 (Figures 1.8 and 1.9). There were no significant interaction effects between group and completers versus non-completers for depression, *F* (1, 97.50) =2.16, *p*=0.15; anxiety, *F* (1, 95.151) =1.13, *p*=0.29; distress, *F* (1, 116.19) =0.17, *p*=0.69; QOL, *F* (1, 84.00) =0.07, *p*=0.79; or tobacco use, *F* (1, 62.17) =0.99, *p*=0.33 (Figures 3.15 and 3.16). There were no significant interactions between time and completers versus non-completers for depression, *F* (2, 108.54) =2.41, *p*=0.10; anxiety, *F* (2, 122.80) =1.51, *p*=0.23; distress, *F* (2,124.69) =0.00, *p*=1.00; or tobacco use, *F* (2, 112.41) =0.50, *p*=0.61 (Figures 3.17 and 3.18). However, there was a significant time and completion status interaction for quality of life, *F* (2, 106.57) =5.43, *p*=0.006. Those who completed most of the time points reported higher levels of QOL at the six month follow-up (*M*=-0.22, *SE*=1.55) and compared to non-completers at the six month follow-up (*M*=1.55, *SE*=0.46; *p*=0.002). There were no significant three way interactions between time, group, and completers vs. non-completers for depression, *F* (2,109.79) =2.96, *p*=0.06; anxiety, *F* (2, 123.30) =1.25, *p*=0.29; distress, *F* (2, 124.69) =0.17, *p*=0.85; QOL, *F* (2, 108.01) =1.47, *p*=0.23; or tobacco use, *F* (2, 112.58) =1.13, *p*=0.33.

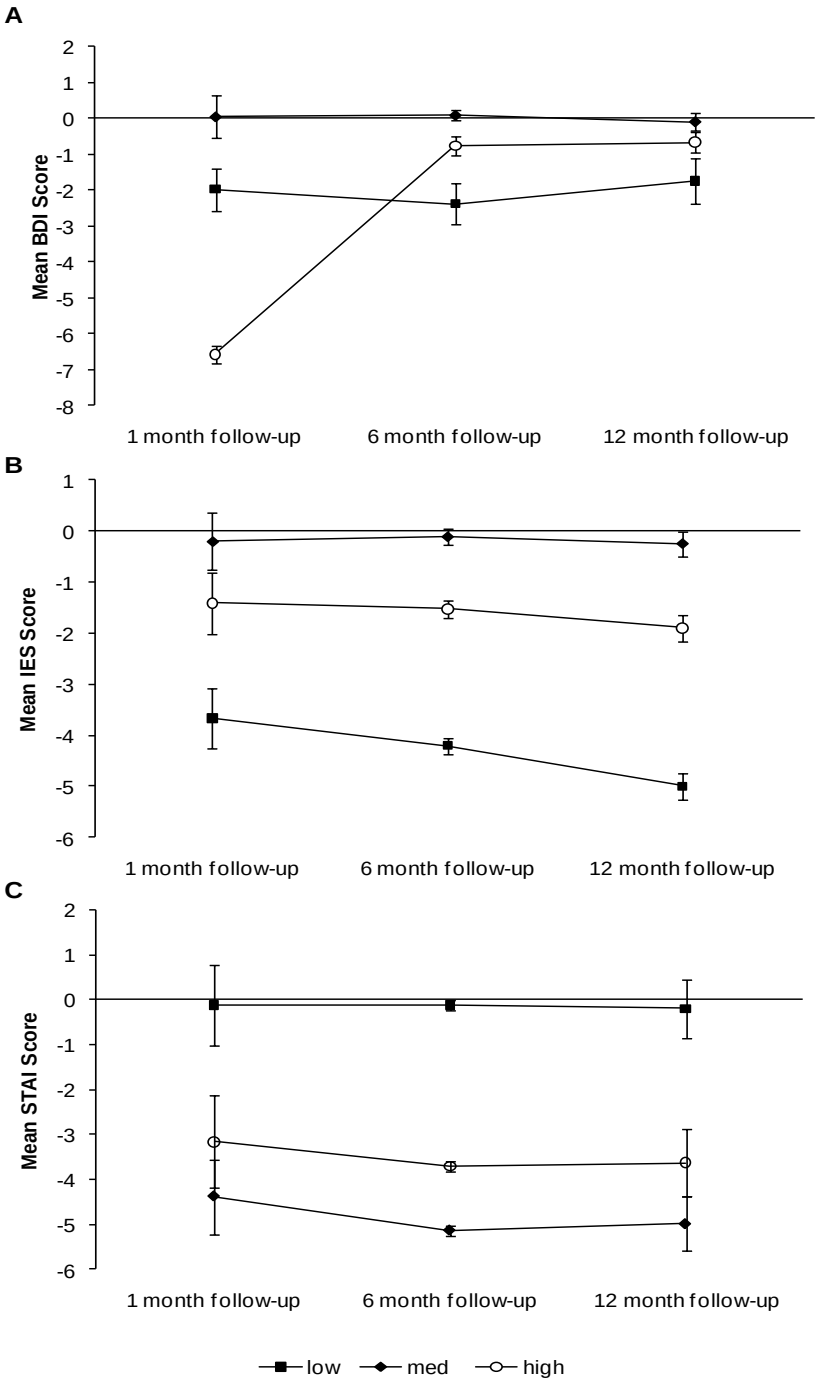

Figure 3.1. Marginal means and standard errors for the main effect for time for grand mean centered for the group, time and covariates (GTC) model for (A) BDI scores; (B) STAI scores; and (C) IES scores.

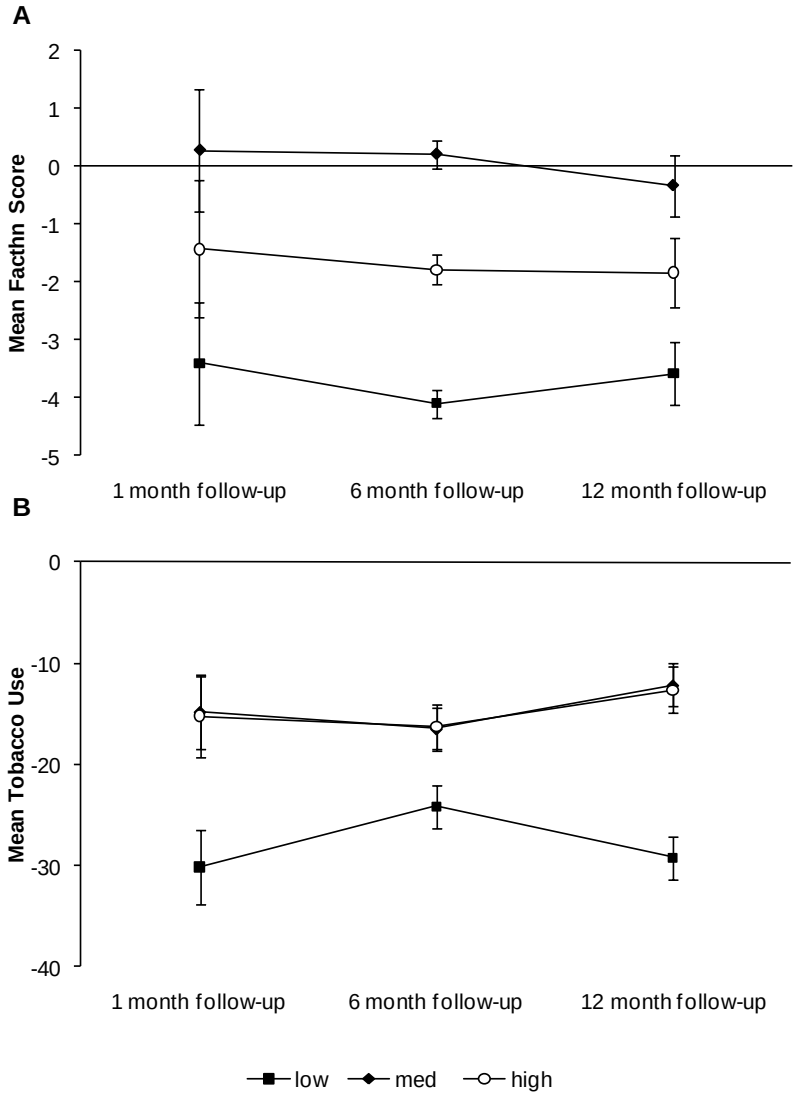

Figure 3.2. Marginal means and standard errors for the main effect for time for grand mean centered forthe group, time and covariates (GTC) model (A) FACT-HN scores; (B) Weekly tobacco use.

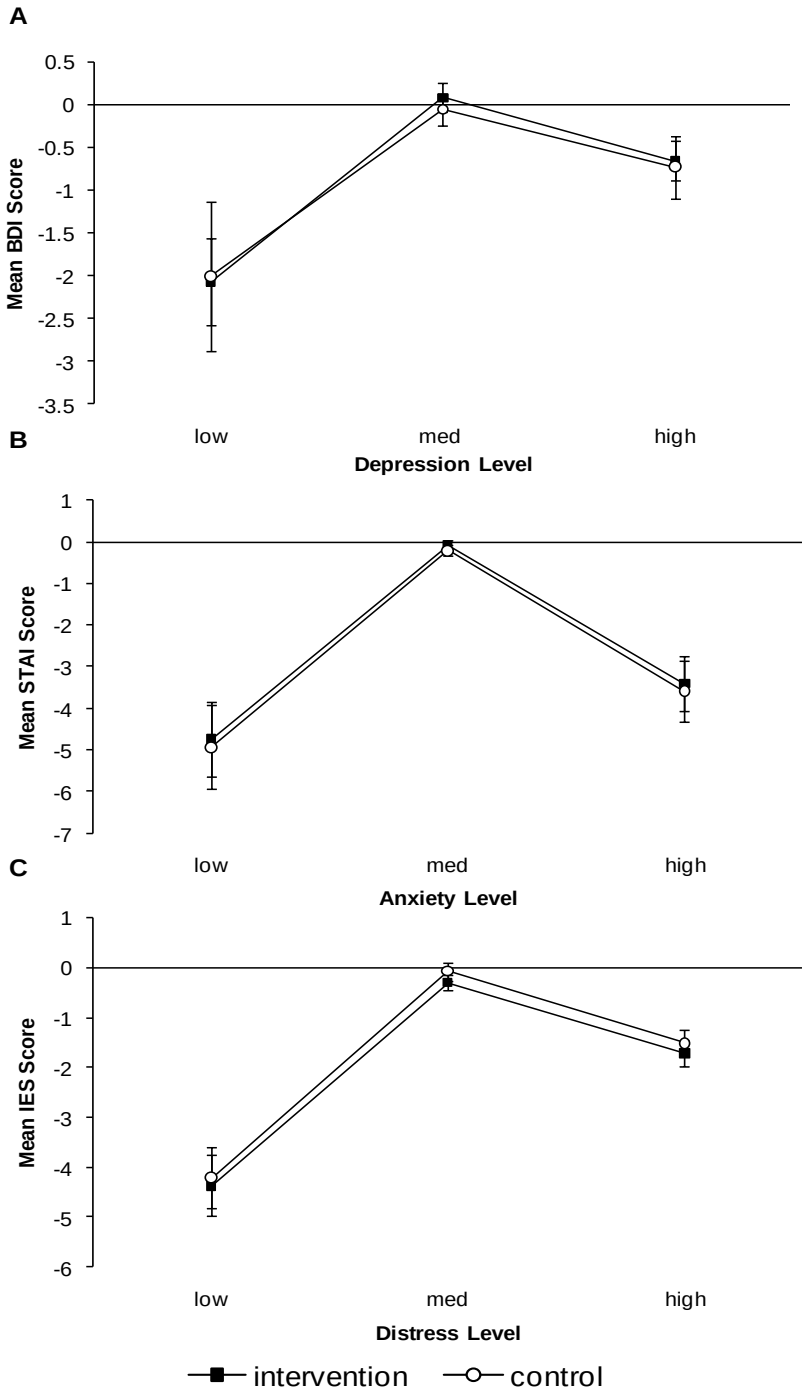

Figure 3.3 Marginal means and standard errors for the main effect for group for grand mean centered for the group, time and covariates (GTC) model for (A) BDI scores; (B) STAI scores; and (C) IES scores.

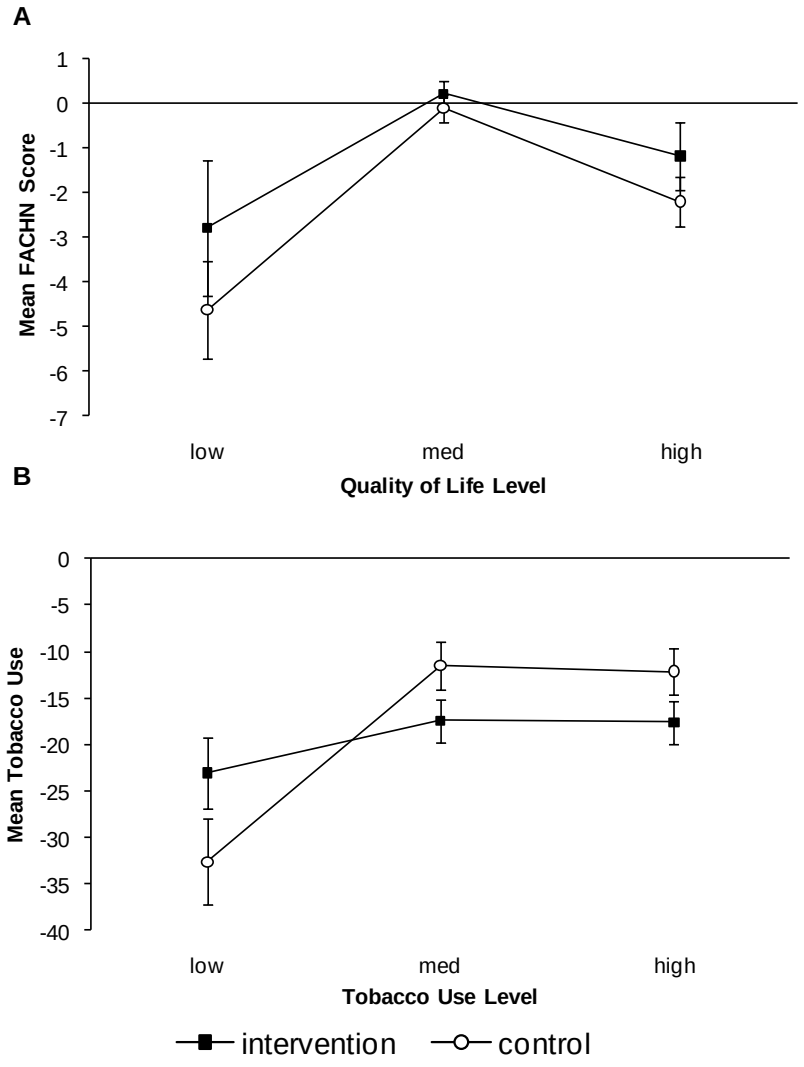

Figure 3.4. Marginal means and standard errors for the main effect for group for grand mean centered for the group, time and covariates (GTC) model for (A) FACT-HN scores; (B) Weekly tobacco use.

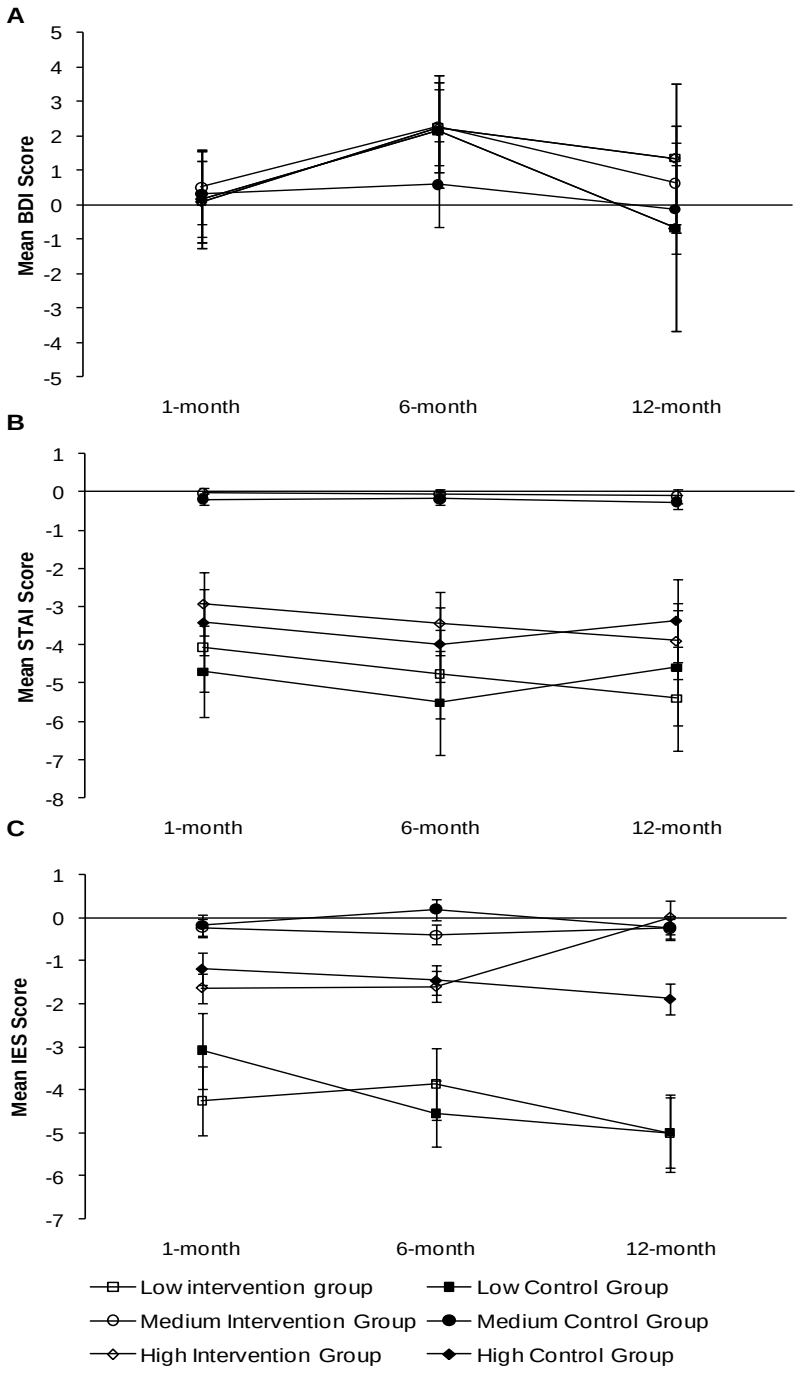

Figure 3.5. Marginal means and standard errors for the interaction effect for group and time for grand mean centered for the group, time and covariates (GTC) model for (A) BDI scores; (B) STAI scores; (C) IES scores.

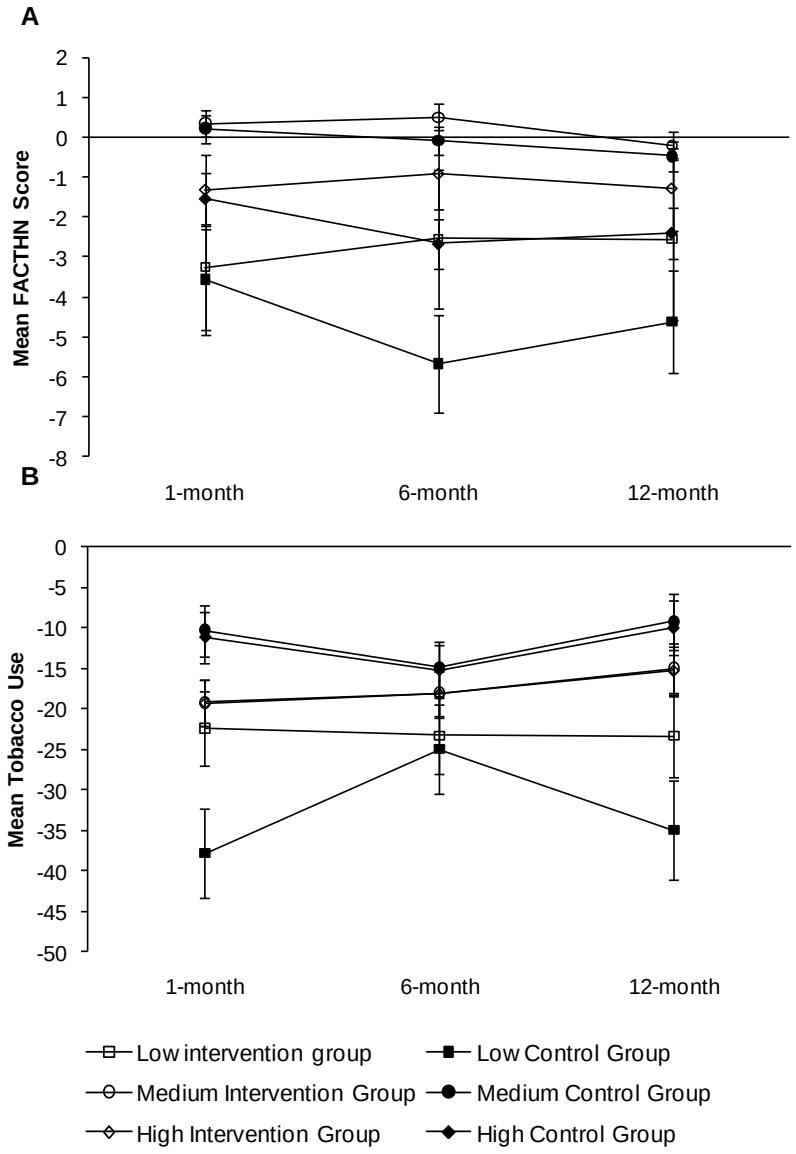

Figure 3.6. Marginal means and standard errors for the interaction effect for group and time for grand mean centered for the group, time and covariates (GTC) model for (A) FACT-HN scores; (B) Weekly tobacco use.

Table 3.5 Coefficients for Effects of the Intervention, Time and Completion Status for the BDI, STAI, and IES scores

	Model					
	BDI		STAI		IES	
Effect	*b*	*SE*	*b*	*SE*	*b*	*SE*
Gender	0.47	0.30	0.29	0.19	1.26***	0.29
Cancer Morphology	0.54	0.40	0.24	0.25	0.87**	0.38
Smoking Status	0.73*	0.29	0.10	0.20	0.65**	0.29
Cancer Stage	0.08	0..12	-0.03	0.08	0.23#	0.12
Education Level	-0.10	0.11	-0.09	0.07	-0.01	0.10
Baseline	0.23	0.25	0.57***	0.19	0.89***	0.16
Group	1.13	1.40	0.16	0.26	-0.07	1.48
Completion Status	1.43	0.93	0.58	0.51	-0.46	1.30
Time (1v12)	0.37	1.17	0.80	1.55	1.28	1.33
Time (6v12)	0.56	1.02	0.32	1.38	0.21	1.18
Time (1v12) X Baseline	0.23	0.26	0.00	0.22	-0.37	0.21
Time (6v12) X Baseline	0.44**	0.20	0.12	0.19	-0.02	0.17
Time (1v12) X Group	-0.57	1.39	0.45	2.06	-0.79	1.68
Time (6v12) X Group	-0.54	1.23	0.26	1.81	0.69	1.52
Time (1v12) X Completion Status	-0.80	0.92	-0.86	0.57	0.08	1.37
Time (6v12) X Completion Status	-1.78**	0.82	-1.23	0.51	0.30	1.31
Group X Baseline	0.36	0.29	0.16	0.26	00.01	0.23
Group X Completion Status	-2.23#	1.15	-1.10	0.74	-0.05	1.57
Time (1v12) X Group X Baseline	-0.34	0.30	-0.19	0.31	0.24	0.29
Time (6v12) X Group X Baseline	-0.51*	0.24	-0.21	0.27	-0.21	0.25
Time (1v12) X Group X Completion Status	1.46	1.14	0.83	0.81	-0.13	1.68
Time (6v12) X Group X Completion Status	2.24**	1.02	1.17	0.75	-0.60	1.62

Table 3.6 Coefficients for Effects of the Intervention, Time and Completion Status for FACT-HN scores and Tobacco Use

	Model			
	FACT-HN		Tobacco Use	
Effect	*b*	*SE*	*b*	*SE*
Gender	0.45	0.51	-3.79	4.03
Cancer Morphology	0.23	0.59	0.92	1.60
Smoking Status	0.54	0.45	-3.21	4.06
Cancer Stage	0.10	0.20	0.92	1.60
Education Level	-0.19	0.18	-0.97	1.61
Baseline	0.48	0.17***	0.23	0.04****
Group	1.37	2.35	15.24	9.83
Completion Status	-1.32	1.38	16.72	8.30*
Time (1v12)	0.20	1.56	3.62	8.96
Time (6v12)	0.32	1.37	12.52	7.69
Time (1v12) X Baseline	-0.09	0.16	0.01	0.05
Time (6v12) X Baseline	0.17	0.12	-0.15	0.04****
Time (1v12) X Group	-1.78	2.26	-6.42	11.09
Time (6v12) X Group	-0.54	1.90	-15.72	9.46
Time (1v12) X Completion Status	1.15	1.34	-5.57	9.43
Time (6v12) X Completion Status	-1.06	1.19	-11.66	7.98
Group X Baseline	-0.15	0.29	-0.16	0.05***
Group X Completion Status	-0.24	1.65	-14.62	10.51
Time (1v12) X Group X Baseline	0.27	0.28	-0.05	0.06
Time (6v12) X Group X Baseline	-0.08	0.22	0.12	0.05**
Time (1v12) X Group X Completion Status	0.11	1.60	7.21	11.96
Time (6v12) X Group X Completion Status	1.47	1.42	14.17	10.07

Note: Values represent unstandardized coefficients and standard errors for the estimate. *p<.05. **p.01. ***p<.005. ****p<.001.

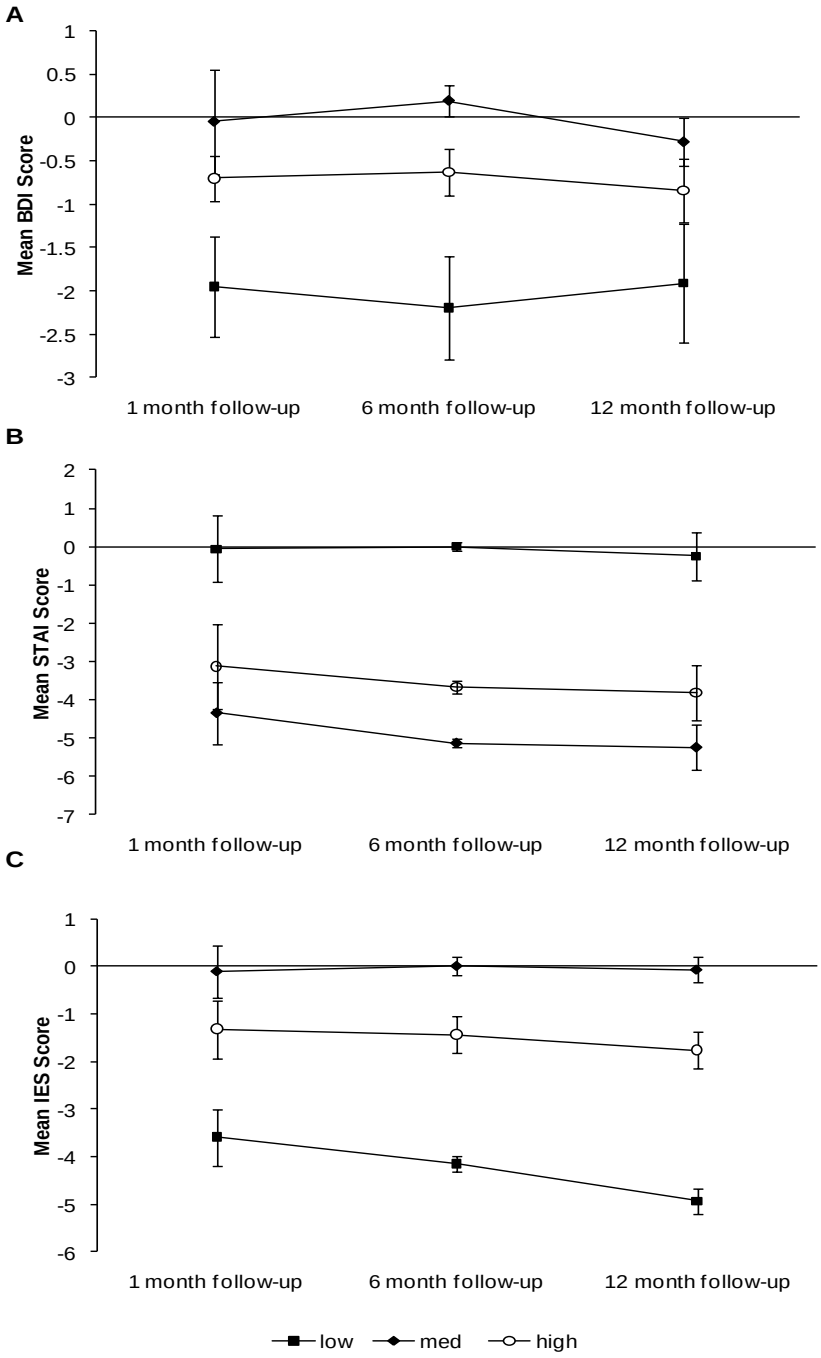

Figure 3.7. Marginal means and standard errors for the main effect for time for grand mean centered for the group, time, covariates, and completion status (GTCN) model for (A) BDI scores; (B) STAI scores; and .(C) IES scores.

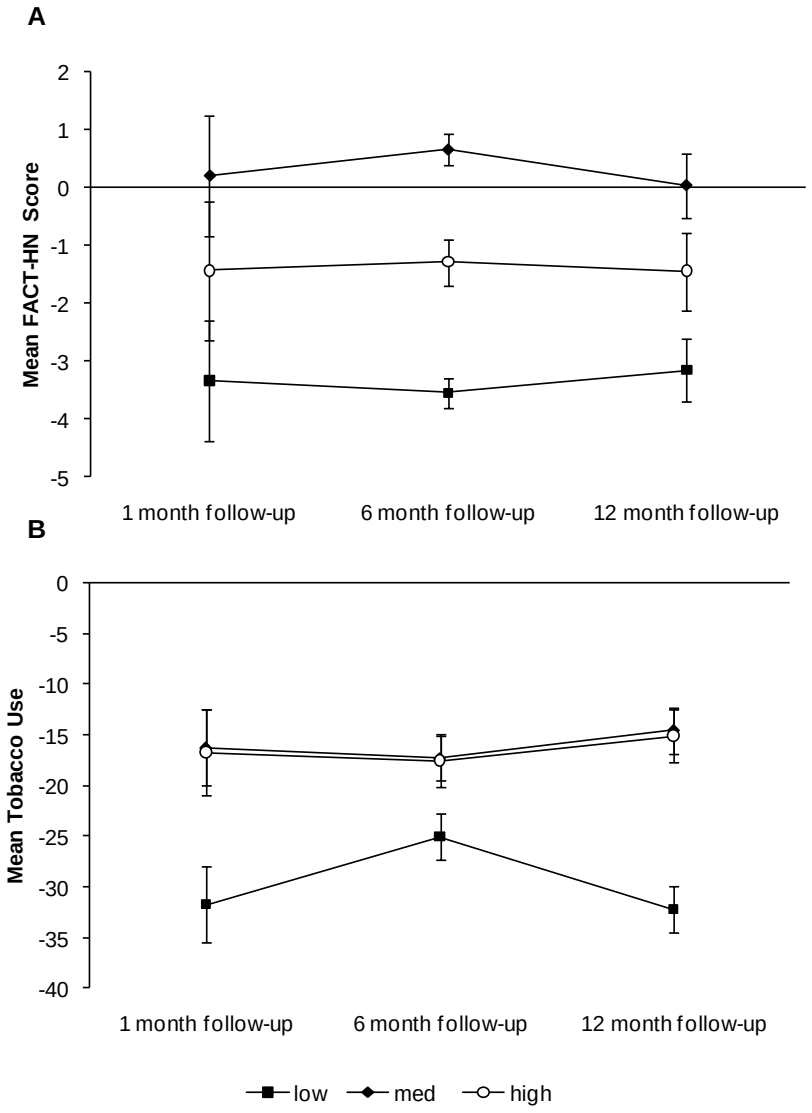

Figure 3.8. Marginal means and standard errors for the main effect for time for grand mean centered for the group, time, covariates, and completion status (GTCN) model for (A) FACT-HN scores; and (B) Weekly tobacco use.

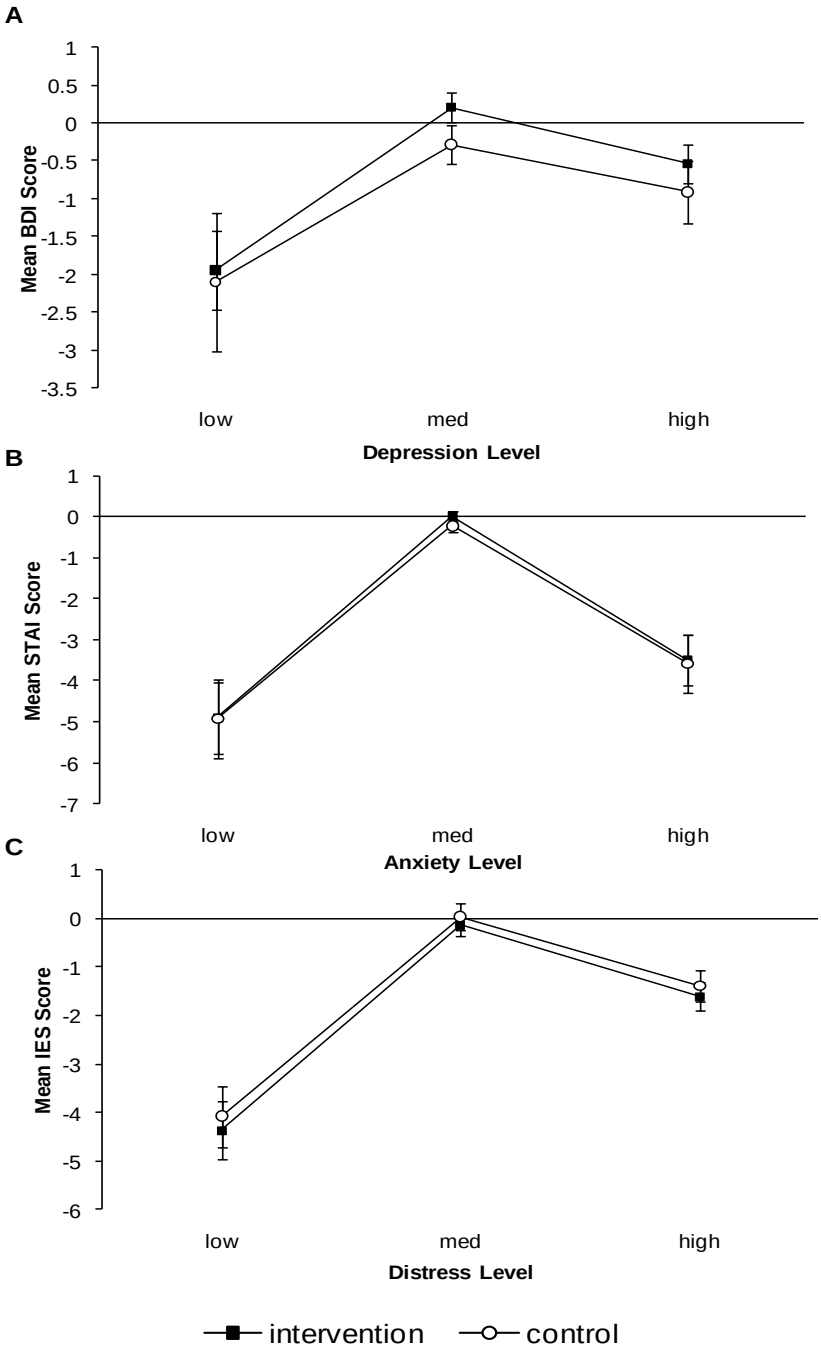

Figure 3.9. Marginal means and standard errors for the main effect for group for grand mean centered for the group, time, covariates, and completion status (GTCN) model for (A) BDI scores; (B) STAI scores; and (C) IES scores.

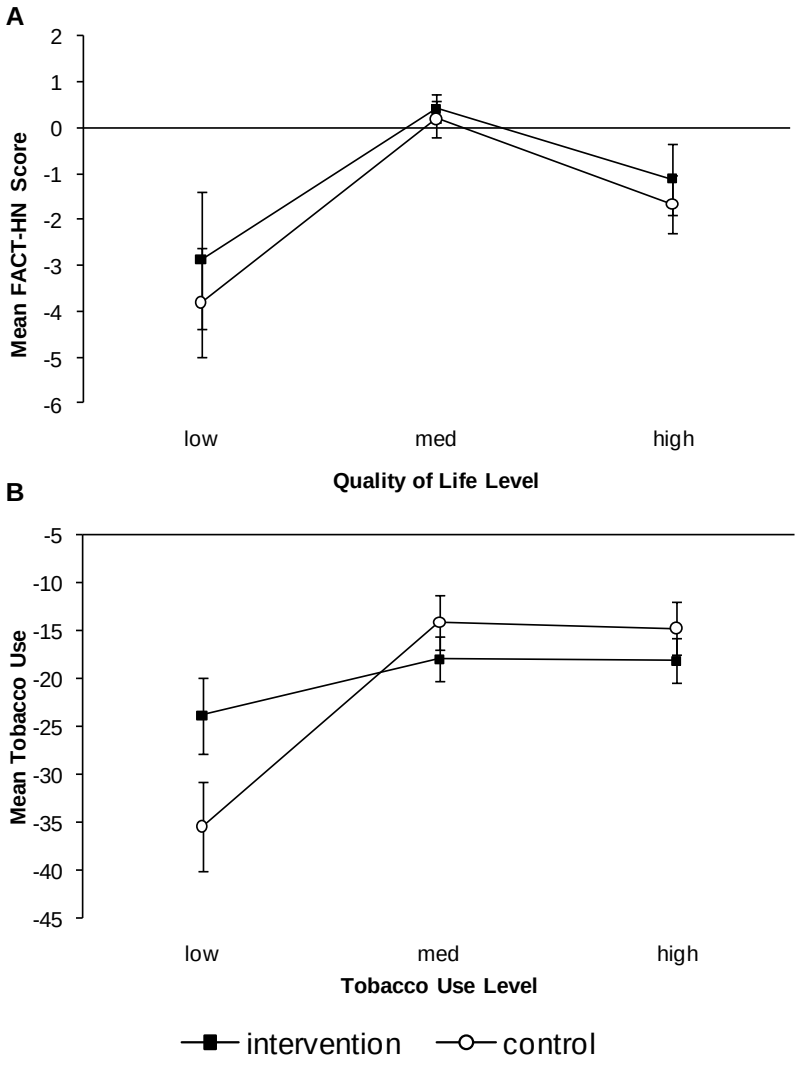

Figure 3.10 Marginal means and standard errors for the main effect for group for grand mean centered for the group, time, covariates, and completion status (GTCN) model for (A) FACT-HN scores; and (B) Weekly tobacco use.

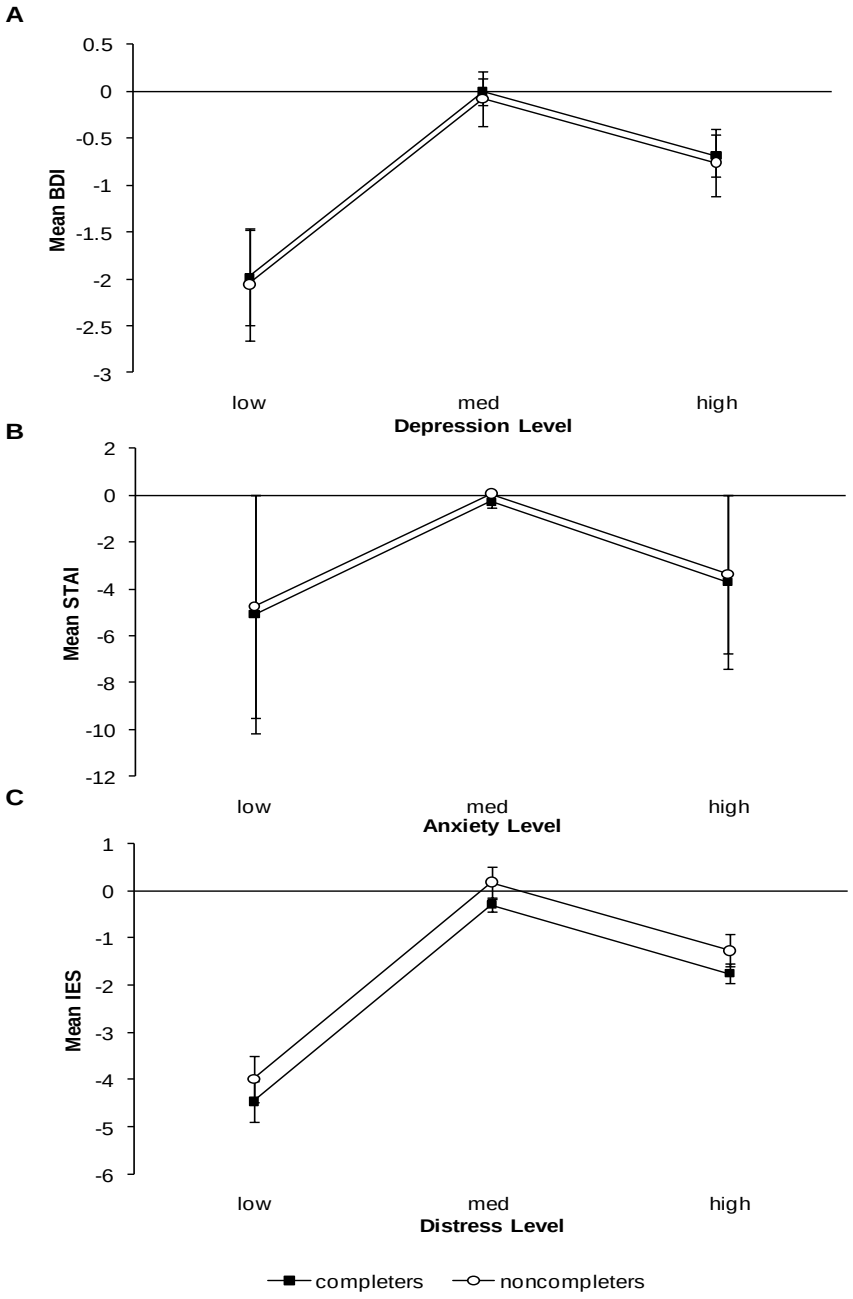

Figure 3.11. Marginal means and standard errors for the main effect for completion status for grand mean centered for the group, time, covariates, and completion status (GTCN) model for (A) BDI scores; (B) STAI scores; and (C) IES scores.

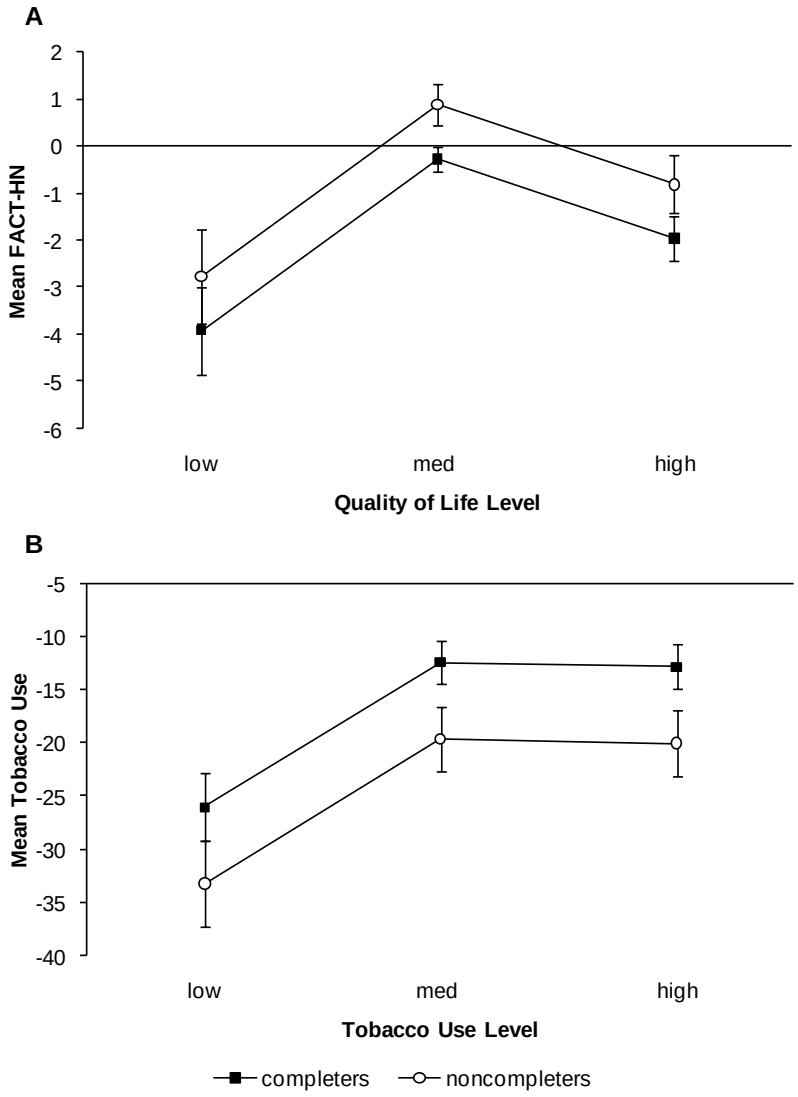

Figure 3.12. Marginal means and standard errors for the main effect for completion status for grand mean centered for the group, time, covariates, and completion status (GTCN) model for (A) FACT-HN scores; and (B) Weekly tobacco use.

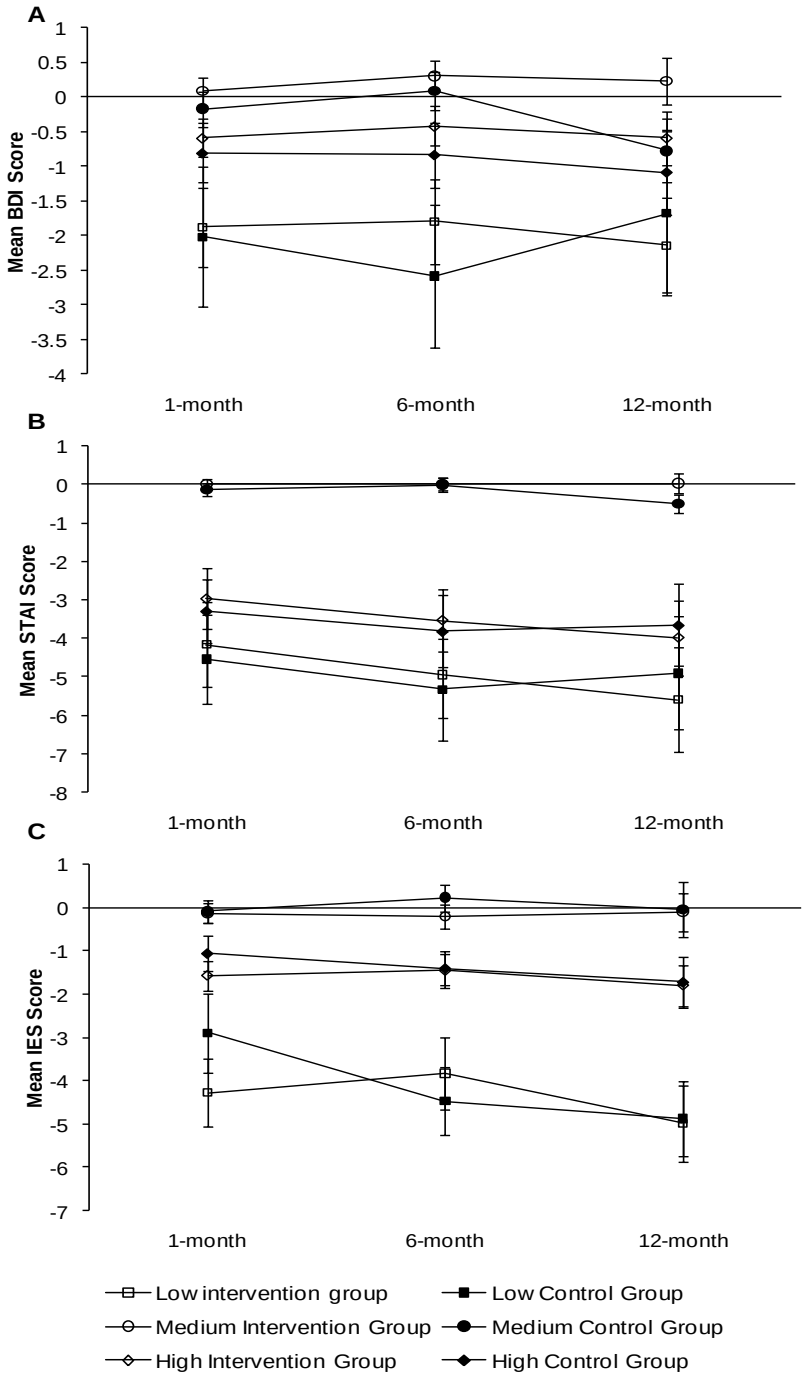

Figure 3.13. Marginal means and standard errors for the interaction effect of group and time for grand mean centered for the group, time, covariates, and completion status (GTCN) model for (A) BDI scores; (B) STAI scores; and (C) IES scores.

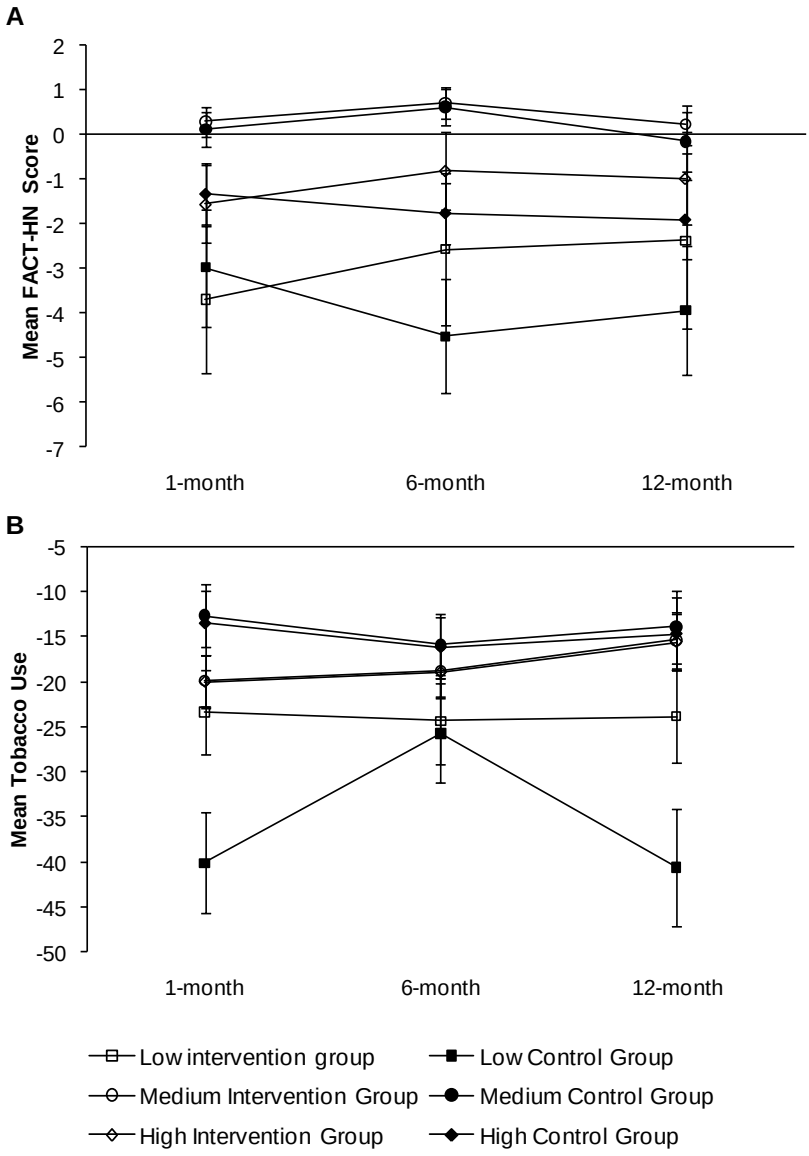

Figure 3.14. Marginal means and standard errors for the interaction effect of group and time for grand mean centered for the group, time, covariates, and completion status (GTCN) model for (A) FACT-HN scores; and (B) Weekly tobacco use.

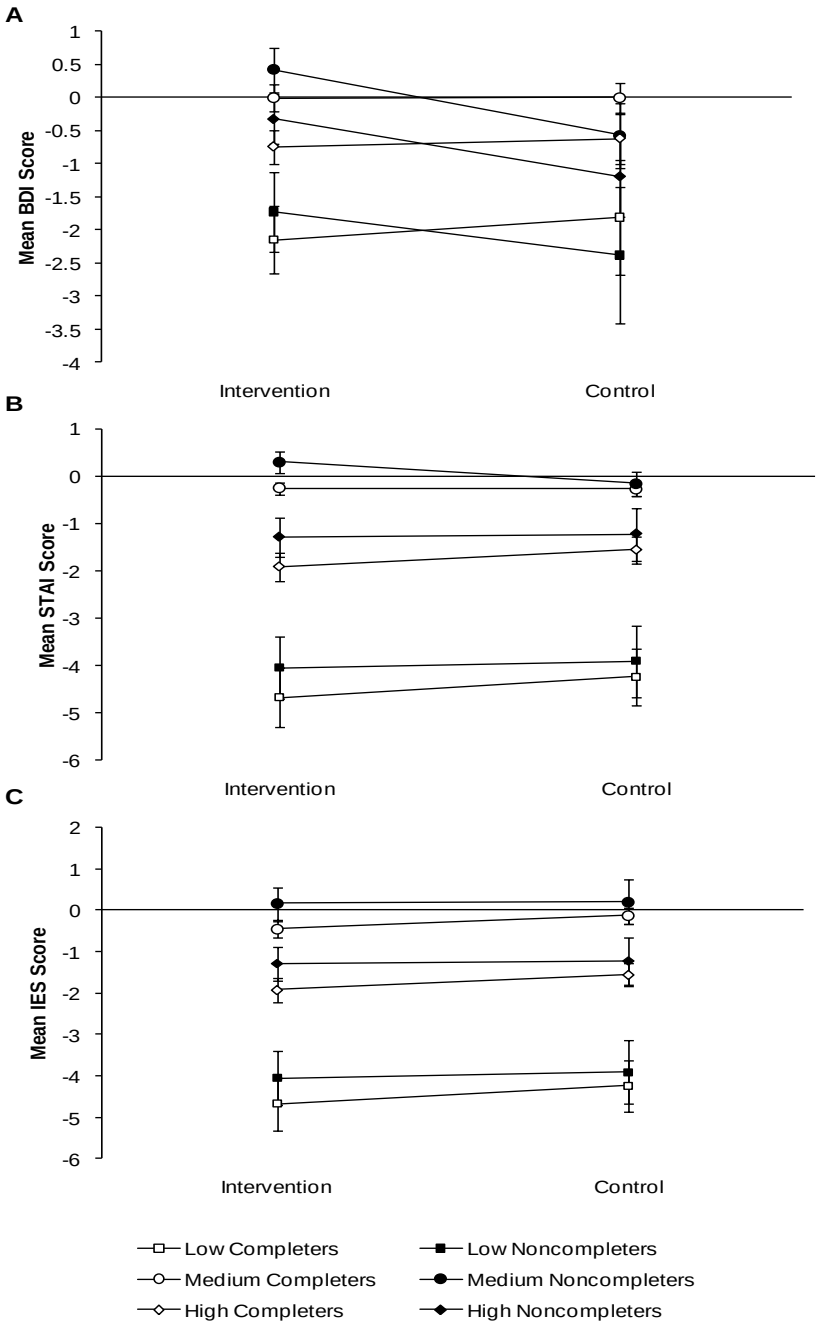

Figure 3.15. Marginal means and standard errors for the interaction effect of group and completion status for grand mean centered for the group, time, covariates, and completers versus non-completers (GTCN) model for (A) BDI scores; (B) STAI scores; and (C) IES scores.

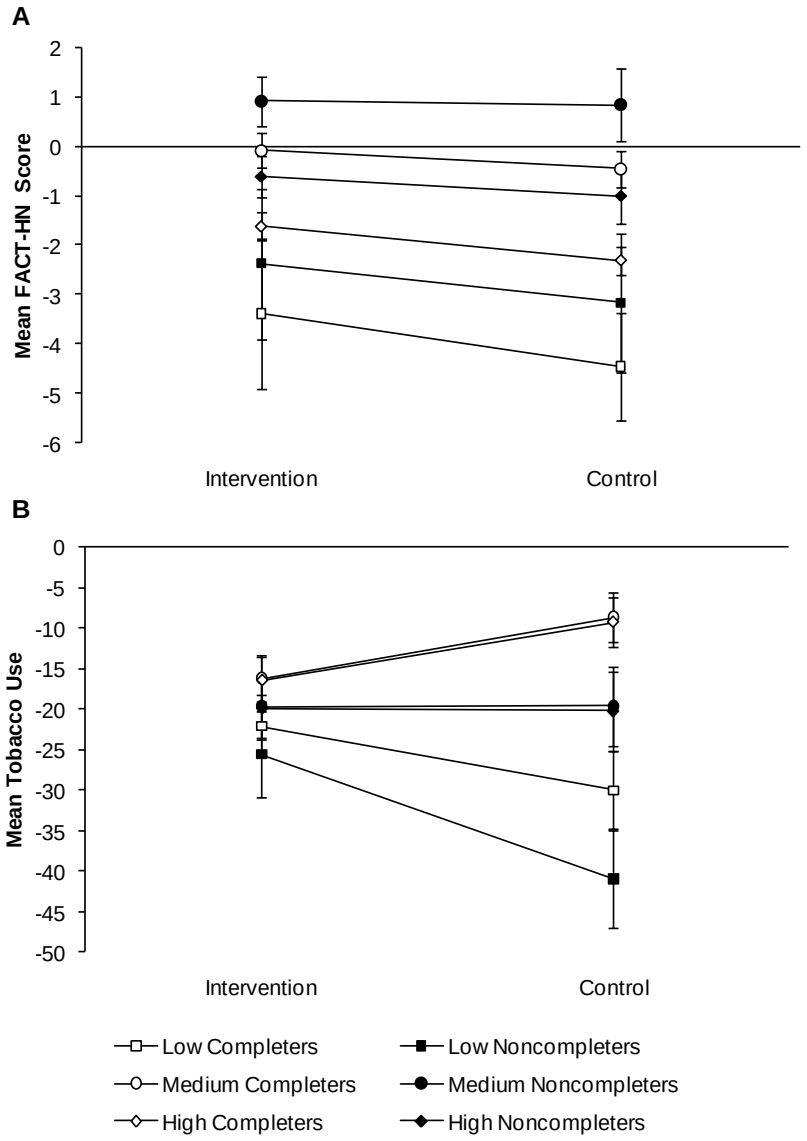

Figure 3.16. Marginal means and standard errors for the interaction effect of group and completion status for grand mean centered for the group, time, covariates, and completion status (GTCN) model for (A) FACT-HN scores; and (B) Weekly tobacco use.

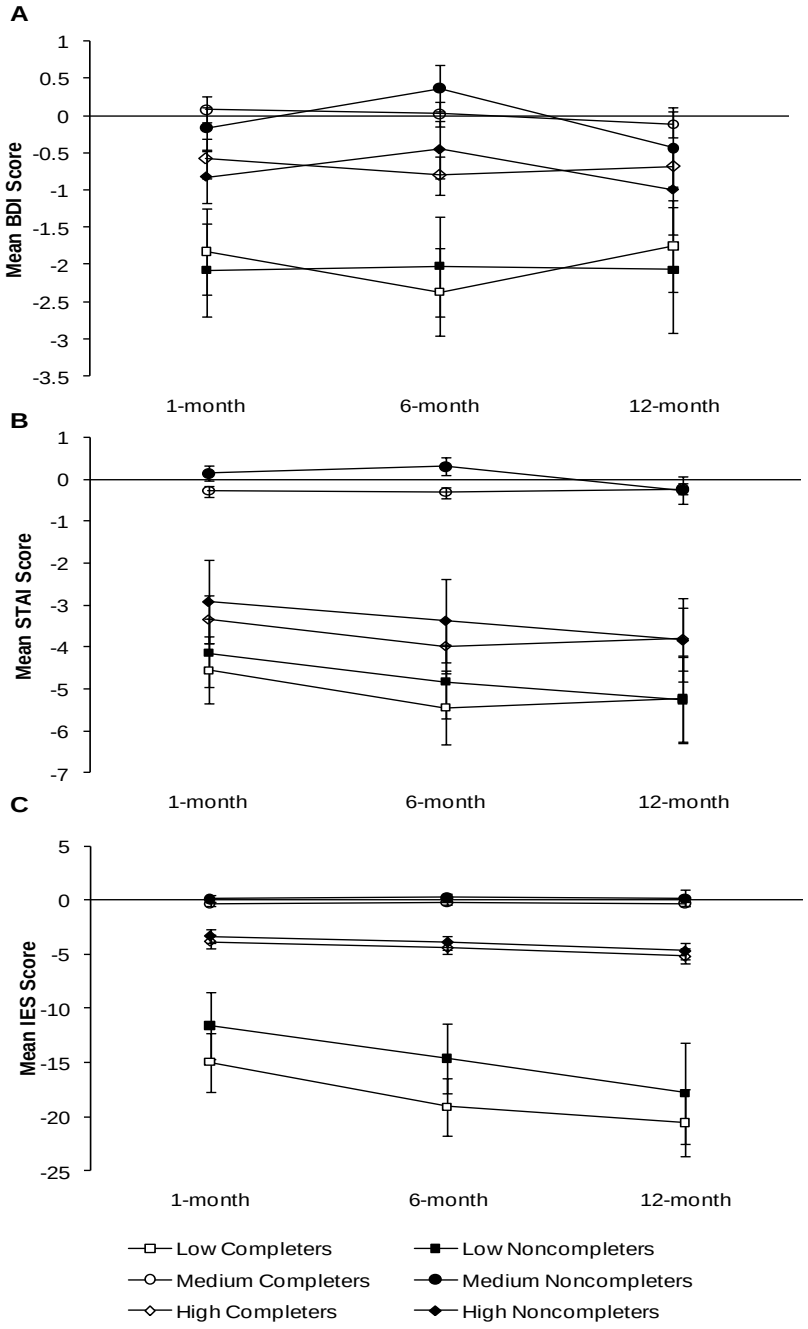

Figure 3.17. Marginal means and standard errors for the interaction effect of time and completion status for grand mean centered for the group, time, covariates, and completion status (GTCN) model for (A) BDI scores; (B) STAI scores; and (C) IES scores.

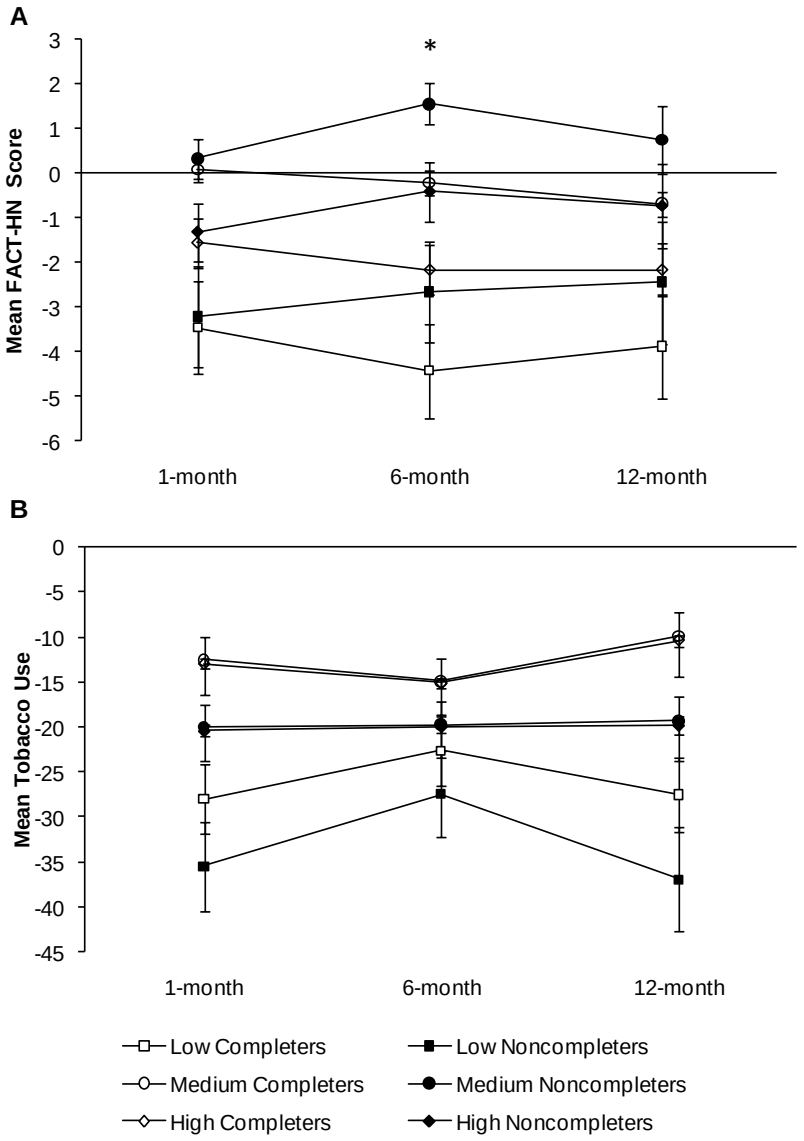

Figure 3.18. Marginal means and standard errors for the interaction effect of time and completion status for grand mean centered for the group, time, covariates, and completion status (GTCN) model for (A) FACT-HN scores; and (B) Weekly tobacco use.

3.2 Predictors of Survival and Progression

Due to the lower rate of death in the present sample, the planned structural equation models could not be performed. A chi-square goodness of fit test showed that our survival rate (Alive: 60; Dead: 31) was significantly higher than the national average (Alive: 39.1; Dead:

51.9), χ^2 (1) =19.53, p=0.00. However, exploratory Kaplan Meier and Cox regression survival analysis were performed in 12 month increments up to five years Kaplan Meier and Cox regression survival analysis were performed to assess the effects of baseline depression, anxiety, distress and quality of life on survival, progression, development of new primary tumors, and time to event after adjusting for the effects of smoking status, gender, education, morphology of cancer, and cancer stage. Due to the small number of events for these analyses, only results for five years are presented. Number of events and number of cases censored for each year are presented in Table 3.7.

Table 3.7 Number of Events and Censored Cases for the Cox Regression Analysis

	Time to Death		Time to Progression		Time to NPT		Time to Event	
	Event	Censored	Event	Censored	Event	Censored	Event	Censored
12 mos.	10	46	11	45	2	54	16	40
18 mos.	15	41	12	44	2	55	20	36
24 mos.	16	40	12	44	3	53	21	35
36 mos.	20	36	15	41	3	53	25	31
48 mos.	21	35	15	41	3	53	25	31
60 mos.	21	35	16	40	4	52	27	29

The log rank test was not statistically significant for group, smoking status, gender, education, cancer morphology, or cancer stage (Table 3.8). There was no statistically significant effect of baseline depression, anxiety, distress, quality of life, tobacco use or alcohol use on survival at 60 months after adjusting for the five covariates, G^2 (6) =5.83, p=0.44. Survival time was not significantly predicted by the set of covariates except cancer stage, R^2=-0.08 with a 95% confidence interval from 0 to 0.06 using Steiger and Fouladi's (1992) R2 software. None of the covariates, except cancer stage, reliably predicted survival time at 60 months at α=.05: Risk= 0.79 (cancer stage). Table 3.9 shows regression coefficients, degrees of freedom, p

values, and odds ratios for each covariate. At the mean of the covariates, the five year survival rate was just above 65%. Thus, survival time was predicted by cancer stage, and was not predicted by baseline depression, anxiety, distress or quality life scores after adjusting for the effects of smoking status, gender, education, and, morphology.

Table 3.8 Estimates from the Kaplan Meier Analysis of the Influence of Intervention, Sociodemographic and Medical Variables on Survival, Progression, Development of New Primary Tumors, and Event in Months

Variable	X^2	*df*	Prob.	Mean	Standard Error	Confidence Intervals
Survival						
Group	0.16	1	0.69	46.24	2.16	42.00-50.48
Smoking Status	0.96	1	0.33	46.23	2.21	41.91-50.55
Gender	0.87	1	0.35	46.24	2.16	42.00-50.48
Education	1.33	4	0.86	45.44	2.26	41.02-49.87
Morphology	0.00	1	1.0	46.63	2.15	42.42-50.85
Cancer Stage	5.26	3	0.15	41.62	2.20	41.62-50.25
Time to Progression (TTP)						
Group	1.85	1	0.17	46.47	2.34	41.88-51.07
Smoking Status	0.24	1	0.62	46.61	2.37	41.96-51.26
Gender	0.67	1	0.41	46.47	2.34	41.88-51.07
Education	5.08	4	0.28	45.69	2.45	40.88-50.50
Morphology	0.08	1	0.78	46.32	2.37	41.69-50.96
Cancer Stage	3.63	3	0.30	46.17	2.39	41.49-50.85
Time to Development of New Primary Tumors (TTNPT)						
Group	1.36	1	0.24	57.51	1.14	55.27-59.74
Smoking Status	2.77	1	0.10			
Gender	0.02	1	0.89	57.51	1.14	55.27-59.74
Education	2.21	4	0.70			
Morphology	0.01	1	0.92	57.48	1.15	55.22-59.74

Table 3.8-Continued

Variable	X^2	*df*	Prob.	Mean	Standard Error	Confidence Intervals
Cancer Stage	2.18	3	0.54			
Time to Event (TTE)						
Group	0.02	1	0.89	40.03	2.56	35.02-45.05
Smoking Status	0.08	1	0.78	39.96	2.60	34.86-45.05
Gender	0.03	1	0.86	40.03	2.56	35.02-45.05
Education	0.83	4	0.93	38.87	2.66	33.67-44.08
Morphology	0.26	1	0.61	40.36	2.57	35.32-45.39
Cancer Stage	5.04	3	0.17	39.58	2.60	34.50-44.67

Note: Blank spaces indicate that all cases were censored, and therefore no statistics were calculated.

Baseline depression, anxiety, distress and quality of life did not significantly predict progression at 60 months, however, weekly tobacco and alcohol use did predict time to progression after adjusting for the five covariates, G^2 (4) =5.133, p=0.27. Progression time was not significantly predicted by the set of covariates, R^2=-0.34 with a 95% confidence interval from 0 to 0.44 using the R2 software (Steiger & Fouladi, 1992). None of the covariates, except weekly tobacco and alcohol use reliably predicted progression time at 60 months at α=.05: Risk=.-1.06(tobacco use) + 0.86 (alcohol use) (Table 3.9). At the mean of the covariates, the five year progression rate was about 70%. Thus, progression time was predicted by weekly tobacco and alcohol use and was not predicted by baseline depression, anxiety, distress or quality life scores after adjusting for the effects of smoking status, gender, morphology, and cancer stage.

Due to the small number of cases and lack of convergence for the model, the effect of baseline depression, anxiety, distress, quality of life, tobacco use, and alcohol use on development of new primary tumors was not calculated. Time to the development of new

primary tumors was not significantly predicted by the set of covariates, R^2=-0.12 with a 95% confidence interval from 0 to 0.13 using R2 software (Steiger & Fouladi, 1992). None of the covariates reliably predicted time to development of new primary tumors at 60 months at α=.05 (Table 3.9). At the mean of the covariates, the five year rate of development of new primary tumors was just above 0.2%.

There was no statistically significant effect of baseline depression, anxiety, distress, quality of life, tobacco use, or alcohol use on time to event at 60 months after adjusting for the five covariates, G^2 (6) =2.48, p=0.83. Time to event was not significantly predicted by the set of covariates, R^2=-0.11 with a 95% confidence interval from 0 to 0.11 using R2 software (Steiger & Fouladi, 1992). None of the covariates reliably predicted time to event at 60 months at α=.05 (Table 3.9). At the mean of the covariates, the five year rate of time to event was just above 50%. Thus, time to event was not predicted by baseline depression, anxiety, distress or quality life scores after adjusting for the effects of smoking status, gender, education, morphology, and cancer stage.

Table 3.9 Estimates from the Cox Regression Analysis of Covariates, Outcomes, and Mediators on Survival, Progression, Development and Event of Head and Neck Cancer Patients

Covariate	*b*	df	Prob.	Hazard Ratio
Time to Death				
Smoking Status	-0.38	1	0.51	0.69
Gender	-0.11	1	0.85	0.90
Education	-0.08	1	0.72	0.92
Morphology	0.00	1	0.83	1.00
Cancer Stage	0.79	1	0.01*	2.20
BDI Score	0.34	1	0.37	1.41
STAI Score	0.57	1	0.17	1.77
IES Score	-0.14	1	0.48	0.87
Alcohol Use	0.01	1	0.36	0.97

Table 3.9-Continued

Covariate	*b*	df	Prob.	Hazard Ratio
Tobacco Use	-0.04	1	0.40	1.01
FACT-HN Score	-0.44	1	0.07	0.64
Time to Progression				
Smoking Status	0.33	1	0.61	1.38
Gender	0.89	1	0.22	2.44
Education	0.26	1	0.34	1.00
Morphology	-0.00	1	0.96	0.99
Cancer Stage	-0.01	1	0.98	1.18
BDI Score	0.09	1	0.83	1.09
STAI Score	-0.74	1	0.17	0.48
IES Score	0.16	1	0.48	1.18
Alcohol Use	0.86	1	0.02**	2.35
Tobacco Use	-1.06	1	0.02**	0.35
FACT-HN Score	-0.22	1	0.42	0.80
Time to Development of New Primary Tumors				
Smoking Status	13.04	1	0.98	460192.51
Gender	0.87	1	0.40	2.38
Education	0.69	1	0.08	1.99
Morphology	-0.01	1	0.91	1.00
Cancer Stage	0.19	1	0.75	1.21
BDI Score				
STAI Score				
IES Score				
FACT-HN Score				

Table 3.9-Continued

Covariate	*b*	df	Prob.	Hazard Ratio
Time to Event				
Smoking Status	-0.48	1	0.31	0.62
Gender	0.49	1	0.33	1.63
Education	0.16	1	0.40	1.17
Morphology	0.00	1	0.88	1.00
Cancer Stage	0.32	1	0.17	1.38
BDI Score	0.18	1	0.56	1.20
STAI Score	-0.02	1	0.57	1.22
IES Score	-0.03	1	0.90	0.98
Tobacco Use	0.00	1	0.96	1.00
Alcohol Use	-0.01	1	0.68	0.99
FACT-HN Score	-0.26	1	0.18	0.77

CHAPTER 4

DISCUSSION

The purpose of the present study was to evaluate the effects of a randomized clinical trial of a psychoeducational intervention on negative affect variables, quality of life and tobacco use in head and neck cancer patients. Additionally, negative affect variables, quality of life, tobacco and alcohol use were looked at as predictors of progression and survival in head and neck cancer. The first hypothesis was that patients with head and neck cancer who experienced depression, anxiety, and distress at baseline and completed the psychoeducational intervention would report lower levels of depression, anxiety and distress after the intervention compared to the control group, and to their pre-intervention levels. However, this hypothesis was not supported. The second hypothesis was that patients with head and neck cancer who completed the psychoeducational intervention would report significantly higher levels of quality of life compared to the control groups, or to their pre-intervention levels. This hypothesis was not supported. Controlling for patterns of missing data did not improve the results. The third hypothesis that patients with head and neck cancer who were smokers at baseline and completed the intervention would report higher smoking cessation rates compared to smokers in the control group across time was not supported. The fourth hypothesis was that the relationship between baseline depression, anxiety and distress would predict progression through the mediators, QOL and smoking and alcohol use (Figure 1.2). However, due to the small number of patients that had progression during the five year follow-up period and the number of variables in the model, this model was not tested. The final hypothesis was that the relationship between baseline depression, anxiety, and distress and survival would be mediated

by QOL and health behaviors (i.e. smoking and alcohol use) (Figure 1.3). The model was not tested due to the limited number of deaths in the sample and the large number of variables in the model.

Patients in the intervention group did not show significant improvements on the negative affect variables across time. The current literature does not support this finding for the psychosocial component of the present intervention. Hammerlid et al. (1999) conducted an intervention that consisted of several group therapy sessions where patients were encouraged to discuss their feelings regarding their diagnosis and treatment. Their intervention improved anxiety and depressive symptoms among head and neck cancer patients. The present intervention, given a larger sample size, may have seen significant improvements in anxiety and distress levels following the intervention due to the fact that the intervention was given shortly after diagnosis and at the start of treatment, when higher levels of these variables are reported (Hammerlid, Ahlner-Elmqvist, et al., 1999).However, Hammerlid et al.(1999) did not have an adequate control group that controlled for the interaction that the experimental group had with the psychologist or the other patients, whereas, participants in the control group in the present intervention had some interaction with the same clinician that administered the intervention. Given the lack of adequate controls in Hammerlid et al.'s study, the improvements they reported in anxiety and depressive symptoms in their intervention group may be attributed to the interaction with the psychologist and other patients, instead of the group therapy intervention, itself.

Patients did not report improvements in depressive symptoms across time. This finding did not follow the same pattern as other psychosocial interventions that have been effective in changing depression. For example, Allison et al.(2004) found improvements in depressive symptoms when teaching patients ways to cope with their cancer diagnosis. One possible explanation for the null findings in the present study could be due to differences in the focus of the intervention. The intervention by Allison et al.(2004) focused solely on teaching patients

ways of coping with their disease. The present intervention had several components, such as relaxation and smoking cessation techniques, in addition to coping skills training. The combination of psychosocial skills training and smoking cessation education in the intervention were not effective at improving depressive symptoms. The combination approach may not have allowed for enough emphasis on each of the parts of the intervention, thus, not effectively improving psychological outcomes. For example, the coping skills training in the intervention by Allison et al.(2004) was the sole focus of this study, and showed improvements in depressive symptoms. Given the different skills training in the present study, enough emphasis on coping skills may not have occurred, which may be why there was not an improvement in depressive symptoms in the present study. However, Allison et al.'s (2004)study was a preliminary study of their intervention and did not have a randomized design or adequate controls, so, therefore, their findings should be interpreted with caution. The findings of the present intervention on negative affect variables were not supported by what is found in the literature.

Improvements in quality of life following diagnosis have been reported in the literature(Morton, 2003; Ronis, et al., 2008); however, our results for quality of life did not show improvements across time. Ronis et al. (2008) found that quality of life improved in the one year following diagnosis, and that baseline quality of life was the best predictor of quality of life one year following diagnosis. Additionally, Hammerlid et al.(2001) found that changes in quality of life can occur up to three years following diagnosis; however, these changes are not different from one year to three years following diagnosis. Quality of life has been shown to be a significant predictor in survival(Karvonen-Gutierrez, et al., 2008; Mehanna, et al., 2008). The overall death rate in our sample was significantly lower compared to the national average, which could be due to the quality of care that patients receive at the University of Pittsburgh Medical Center. Since QOL is a predictor of survival in head and neck cancer patients and our death rate was low, it could be that they had higher levels of QOL due to the quality of care they received, and, therefore, they would not report significant improvements across time in QOL.

In the present study, patients who smoked prior to diagnosis did not report a reduction of tobacco use across time. However, the literature shows that tobacco use decreases following diagnosis, but at one year following diagnosis, tobacco use increases to that of pre-diagnosis levels (Gritz, et al., 1993). The present study did not support this finding. Additionally, continued tobacco use has been associated with reduced QOL. Duffy et al. (2002) reported reduced quality of life on physical functioning, general health, vitality, social functioning, and emotional health in head and neck cancer patients who continued to smoke following diagnosis. These findings indicated that continued tobacco use following the diagnosis of head and neck cancer could greatly affect a patient's physical functioning. Interestingly, Duffy et al. (2002) also found reduced quality of life on social and emotional functioning as well. This could be due to the fact that their continued tobacco use may impair their social relationships because of tobacco's relationship with developing this type of cancer. Impairments in their social relationships, therefore, might also impact their emotional functioning. These findings add importance to improving smoking cessation among this cancer demographic. However, our findings did not support this previous literature, and may indicate the need for with a larger sample sizes and improvements in patient attrition.

Progression was examined as time to first recurrence or metastasis, whichever came first. The exploratory analysis found that none of the baseline negative affect variables or QOL predicted time to progression. However, weekly tobacco and alcohol use following diagnosis did significantly predict time to progression in our sample. This finding is important because progression has been looked at on a limited basis, and predictors of progression have not been adequately identified. However, since this was an exploratory analysis with a smaller sample, this finding should be interpreted with caution.

Tobacco use has been looked at as a contributor to progression in head and neck cancer patients (Khuri, et al., 2001; Schantz, Byers, Goepfert, Shallenberger, & N., 1988). Schantz et al. (1988) found that young adults with head and neck cancer who had a history of

smoking were more likely than their non-smoking counterparts to experience progression. Additionally, they found that there were differences between smokers and non-smokers in terms of the site of their cancers, which has also been implicated as a predictor of survival (Brown, et al., 2003; Faye-Lund & Abdelnoor, 1996). Patients that did not have a history of smoking were more likely to have cancer of the tongue, tonsil or larynx. However, patients that had a history of smoking were more likely to have cancers of the pharynx (Khuri, et al., 2001; Schantz, et al., 1988), which fare worse with survival compared to cancers of the oral cavity or larynx (Brown, et al., 2003).

The impact of alcohol use in head and neck cancer patients on progression or recurrence, to my knowledge, has not been adequately examined. The finding that weekly alcohol use predicted progression is an important contribution to the literature, in that this finding has not been reported in terms of the effects that alcohol use may have on progression or recurrence. Alcohol use and its interaction with tobacco has been examined in terms of risk for developing head and neck cancer. Hashibe et al. (2009) found that the risk for developing head and neck cancer for alcohol use was about four percent, and the risk for developing head and neck cancer for tobacco use was about 33 percent. The risk for developing head and neck cancer for both alcohol and tobacco use was about 35 percent. Though alcohol may not be as large of a contributor for risk development of this cancer, it is a minor contributing factor that should not be overlooked when looking to improve recurrence or survival rates.

The model where survival would be predicted by baseline depression, distress, anxiety, through the mediators, QOL, and tobacco use or alcohol use was not tested due to the limited number of deaths in the sample and the number of variables in the model. The five year survival rate of our sample (48%) was significantly better than that of the national average (57%). Cancer stage was the only covariate that predicted survival in our sample of head and neck cancer patients. This indicated that advanced stages of cancer tended to fare worse with survival compared to earlier stages. The higher than expected survival rates could have been

due to the level of care received at University of Pittsburgh Medical Center, which is renowned for its quality of care for cancers. It could also be due to the fact that majority of our sample (97%) were white, which among the different ethnicities who are diagnosed with head and neck cancer, tend to fare better than their African American counterparts (Molina et al., 2008). Why there is a racial disparity among head and neck cancer patients in terms of prognosis has yet to be determined. It could be due to differences in access to health care or willingness to seek out health care (Molina, et al., 2008). The racial disparity could also be due to differences in the aggressiveness of the cancer, itself. Whites are more likely than African-Americans to develop this type of cancer, and therefore, African-Americans who develop head and neck cancer may develop more aggressive forms of the cancer, which results in reduced survival compared to whites who develop this cancer. The results of the present study emphasize the importance of having a more diverse sample size and may explain why our survival rate was slightly better than the national average.

4.1 Limitations and Future Directions

4.1.1 Limitations

The hypotheses for the present study were not supported. In relation to the hypotheses testing the effects of the intervention, there are several confounds that could have limited the effectiveness of the intervention. First, the study was not limited to smokers. Since the educational component of the intervention was related to how to achieve smoking cessation and avoid relapse, this information may not have been useful for individuals who had quit and maintained abstinence for several years, and most certainly did not benefit those who had never smoked at all. However, patients that were non-smokers reviewed topics from the previous sessions, when the sessions were related to smoking cessation. This allowed more emphasis on the coping skills and relaxation training, which may have improved the negative affect variables and QOL among this demographic. Including both smokers and non-smokers in this

study may improve our understanding of the interaction of negative affect outcomes, QOL of life, and smoking cessation among head and neck cancer patients

Improvements in the sampling biases that occurred in the present study may also improve effectiveness of the intervention. An overwhelming majority of patients in our sample were white (97.3%). This may be important to consider due to the findings of Duffy et al. (2006). In their study, they found that African American patients were more likely to seek out smoking cessation information than their white counterparts, indicating higher motivation to quit smoking. Though motivation to quit smoking was not measured in this study, including a more ethnically diverse sample may improve motivation to seek out information regarding smoking cessation, and therefore, improve the efficacy of the educational component of the intervention. The patients were all receiving treatment from the University of Pittsburgh Medical Center, which provides higher quality of care compared to other medical facilities. Recruitment at other medical facilities would improve this sampling bias and may demonstrate effectiveness of the present intervention. Additionally, the sample size was somewhat small, which limited the statistical power of the models. Increasing the sample size may also improve the effectiveness of the intervention.

4.1.2 Future Directions

Future directions for interventions with this cancer demographic should focus on improving smoking cessation rates among smokers. The relationship between smoking cessation and cancer diagnosis and treatment should be looked at in order to understand how or why some patients with head and neck cancer are not successful at maintaining abstinence from tobacco. Additionally, alcohol cessation and the relationship between smoking cessation and cancer diagnosis and treatment should also be considered. Though not all patients who drink are smokers, it is important to know the influence that alcohol may have among this cancer demographic.

The role of alcohol use in the progression and survival of head and neck cancer patients has not been extensively examined. Though the risk of developing head and neck cancer from alcohol use may be small, its contribution in conjunction with tobacco use may be important to consider. Predictors of progression and survival among those that do not drink, those that drink and those that smoke and drink should be looked at in order to better identify quality of life, demographic or treatment-related variables that may contribute to improvements in survival rates.

Smoking cessation has been linked to the development of major depression (Covey, Glassman, & Stetner, 1997; Tsoh et al., 2000). Covey et al. (1997) found that people who recently were treated for smoking cessation were at risk for developing major depression. This effect was intensified if these individuals had a previous history of depression. Therefore, history of depression may be important to consider when developing interventions for head and neck cancer patients. Anxiety, however, does not seem to change following treatment for smoking cessation (West & Hajek, 1997). Anxiety was shown to be highest immediately following elimination of smoking behaviors, but subsided one to two days following initial smoking cessation (West & Hajek, 1997). The studies that looked at the effects of smoking cessation on depression and anxiety included healthy individuals, and not cancer patients. The interaction between smoking cessation and cancer diagnosis and treatment, to my knowledge, has not been extensively considered. This may be an important relationship to consider in order to fully understanding the contributions of each of these variables to negative affective states and quality of life.

Future research should also look at differences between non-smokers and those that have a history of smoking in order to determine how these patients may fare with progression and survival. Most of the literature in head and neck cancer research focuses on patients who smoke, and on occasion, those that drink. Though these are both risk factors for developing head and neck cancer, not all cases of these cancers are related to smoking and alcohol use

(Koch, Lango, Sewell, Zahurak, & Sidransky, 1999). Distinctions between treatment-related variables, such as cancer site or morphology should be looked at to determine what differences there may be between head and neck cancer patients that smoke and drink and those that do not. The reason it is important for future research to examine predictors of progression in survival among smoking versus non-smoking head and neck cancer patients is because there may be differences in what factors predict progression and survival for each of these two demographics. Identification of specific predictors of progression and survival, such as quality of life, between these two demographics will lead to improvements in developing targeted psychosocial interventions to improve these variables. Identifying treatment-related and demographic factors that may impact negative affect and quality of life are important in order to develop targeted educational and psychosocial interventions for head and neck cancer patients that may ultimately improve progression, recurrence and survival rates among this demographic.

APPENDIX A

SELF-REPORT QUESTIONNAIRES FOR PSYCHOLOGICAL OUTCOMES, QUALITY OF LIFE AND TOBACCO USE OUTCOMES

OCC _____

Beck Inventory

On this questionnaire are groups of statements. Please read each group of statements carefully. Then pick out the one statement in each group which best describes the way you have been feeling in the past week, including today. Circle the number beside the statement you picked. Be sure to read all the statements in each group before making your choice.

1. 0 I do not feel sad.
   1 I feel sad.
   2 I am sad all the time and I can't snap out of it.
   3 I am so sad or unhappy that I can't stand it

2. 0 I am not particularly discouraged about the future.
   1 I feel discouraged about the future.
   2 I feel I have nothing to look forward to.
   3 I feel that the future is hopeless and that things cannot improve.

3. 0 I do not feel like a failure.
   1 I feel I have failed more than the average person.
   2 As I look back on my life all I can see is a lot of failures.
   3 I feel I am a complete failure as a person.

4. 0 I get as much satisfaction out of things as I used to.
   1 I don't enjoy things the way I used to.
   2 I don't get real satisfaction out of anything anymore.
   3 I am dissatisfied or bored with everything.

5. 0 I don't feel particularly guilty.
   1 I feel guilty a good part of the time.
   2 I feel quite guilty most of the time.
   3 I feel guilty all of the time.

6. 0 I don't feel I am being punished.
   1 I feel I may be punished.
   2 I expect to be punished.
   3 I feel I am being punished.

7. 0 I don't feel disappointed in myself.
   1 I am disappointed in myself.
   2 I am disgusted with myself.
   3 I hate myself.

8.
0 I don't feel I am any worse than anybody else.
1 I am critical of myself all the time for my faults.
2 I blame myself all the time for my faults.
3 I blame myself for everything bad that happens.

9.
0 I don't have any thoughts of killing myself.
1 I have thoughts of killing myself, but I would not carry them out.
2 I would like to kill myself.
3 I would kill myself if I had the chance.

10.
0 I don't cry anymore than usual.
1 I cry more now than I used to.
2 I cry all the time now.
3 I used to be able to cry, but now I can't cry even though I want to.

11.
0 I am no more irritated now than I ever am.
1 I get annoyed or irritated more easily than I used to.
2 I feel irritated all the time now.
3 I don't get irritated at all by the things that used to irritate me.

12.
0 I have not lost interest in other people.
1 I am less interested in other people now than I used to be.
2 I have lost most of my interest in other people.
3 I have lost all my interest in other people.

13.
0 I make decisions about as well as I ever could.
1 I put off making decisions more than I used to.
2 I have greater difficulty in making decisions than before.
3 I can't make decisions at all anymore.

14.
0 I don't feel I look any worse than I used to.
1 I am worried that I am looking old or unattractive.
2 I feel that there are permanent changes in my appearance and they make me look unattractive.
3 I believe that I am ugly or repulsive looking.

15.
0 I can work about as well as before.
1 It takes extra effort to get started at doing something.
2 I have to push myself very hard to do anything.
3 I can't do any work at all.

16.
0 I can sleep as well as usual.
1 I don't sleep as well as I used to.
2 I wake up 1-2 hours earlier than usual and find it hard to get back to sleep.
3 I wake up several hours earlier than I used to and cannot get back to sleep.

OCC _____

17. 0 I don't get more tired than usual.
1 I get tired more easily than I used to.
2 I get tired from doing almost anything.
3 I get too tired to do anything.

18. 0 My appetite is no worse than usual.
1 My appetite is not as good as it used to be.
2 My appetite is much worse now.
3 I have no appetite at all anymore.

19. 0 I haven't lost much weight, if any, lately.
1 I have lost more than 5 pounds.
2 I have lost more than 10 pounds.
3 I have lost more than 15 pounds.

* **Please circle**: I am purposely trying to lose weight by eating less.
0 = no 1 = yes

20. 0 I am no more worried about my health than usual.
1 I am worried about physical problems such as aches and pains or upset stomach or constipation.
2 I am very worried with physical problems and it's hard to think of much else.
3 I am so worried about my physical problems that I cannot think about anything else.

21. 0 I have not noticed any recent change in my interest in sex.
1 I am less interested in sex than I used to be.
2 I am much less interested in sex now.
3 I have lost interest in sex completely.

Impact of Event Scale

OCC _____

The following is a list of difficulties people sometimes have after stressful life events. Please read each item, and then indicate how distressing each difficulty has been for you **during the past 7 days** with respect to the medical symptoms you have been having. How much were you distressed or bothered by these difficulties?

	NOT AT ALL	A LITTLE BIT	MODERATELY	QUITE A BIT	EXTREMELY
1. Any reminder brought back feelings about it.					
2. I had trouble staying asleep.					
3. Other things kept making me think about it.					
4. I felt irritable and angry.					
5. I avoided letting myself get upset when I thought about it or was reminded of it.					
6. I thought about it when I didn't mean to.					
7. I felt as if it hadn't happened or wasn't real.					
8. I stayed away from reminders of it.					
9. Pictures about it popped into my mind.					
10. I was jumpy and easily startled.					
11. I tried not to think about it.					
12. I was aware that I still had a lot of feelings about it, but didn't deal with them.					
13. My feelings about it were kind of numb.					
14. I found myself acting or feeling like I was back at that time.					
15. I had trouble falling asleep.					
16. I had waves of strong feelings about it.					
17. I tried to remove it from my memory.					
18. I had trouble concentrating.					
19. Reminders of it caused me to have physical reactions, such as sweating, trouble breathing, nausea, or a pounding heart.					
20. I had dreams about it.					
21. I felt watchful and on guard.					
22. I tried not to talk about it.					

Note: Items 1, 2, 3, 5, 7, 11, 12, and 14 make up the Intrusion subscale. Items 4, 6, 8, 9, 10, 13, and 15 make up the Avoidance subscale

State/Trait Anxiety Inventory

DIRECTIONS:

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

	NOT AT ALL	SOMEWHAT	MODERATELY SO	VERY MUCH SO
1. I feel calm	1	2	3	4
2. I feel secure	1	2	3	4
3. I am tense	1	2	3	4
4. I feel strained	1	2	3	4
5. I feel at ease	1	2	3	4
6. I feel upset	1	2	3	4
7. I am presently worrying over possible misfortunes	1	2	3	4
8. I feel satisfied	1	2	3	4
9. I feel frightened	1	2	3	4
10. I feel comfortable	1	2	3	4
11. I feel self-confident	1	2	3	4
12. I feel nervous	1	2	3	4
13. I am jittery	1	2	3	4
14. I feel indecisive	1	2	3	4
15. I am relaxed	1	2	3	4
16. I feel content	1	2	3	4
17. I am worried	1	2	3	4
18. I feel confused	1	2	3	4
19. I feel steady	1	2	3	4
20. I feel pleasant	1	2	3	4

 STAIP-AD Test Form Y
Published by Mind Garden, Inc., Redwood City, CA.

Note: Items that were anxiety-absent items that were reverse coded were items 1, 2, 5, 8, 10, 11, 15, 16, 19, and 20. Items that were anxiety-present items were items, 3, 4, 6, 7, 9, 12, 13, 14, 17, and 18.

FACT-H&N (Version 4)

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

	PHYSICAL WELL-BEING	Not at all	A little bit	Some-what	Quite a bit	Very much
GP1	I have a lack of energy	0	1	2	3	4
GP2	I have nausea	0	1	2	3	4
GP3	Because of my physical condition, I have trouble meeting the needs of my family	0	1	2	3	4
GP4	I have pain	0	1	2	3	4
GP5	I am bothered by side effects of treatment	0	1	2	3	4
GP6	I feel ill	0	1	2	3	4
GP7	I am forced to spend time in bed	0	1	2	3	4

	SOCIAL/FAMILY WELL-BEING	Not at all	A little bit	Some-what	Quite a bit	Very much
GS1	I feel close to my friends	0	1	2	3	4
GS2	I get emotional support from my family	0	1	2	3	4
GS3	I get support from my friends	0	1	2	3	4
GS4	My family has accepted my illness	0	1	2	3	4
GS5	I am satisfied with family communication about my illness	0	1	2	3	4
GS6	I feel close to my partner (or the person who is my main support)	0	1	2	3	4
Q1	*Regardless of your current level of sexual activity, please answer the following question. If you prefer not to answer it, please check this box* ☐ *and go to the next section.*					
GS7	I am satisfied with my sex life	0	1	2	3	4

FACT-H&N (Version 4)

By circling one (1) number per line, please indicate how true each statement has been for you <u>during the past 7 days.</u>

	EMOTIONAL WELL-BEING	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
GE1	I feel sad	0	1	2	3	4
GE2	I am satisfied with how I am coping with my illness	0	1	2	3	4
GE3	I am losing hope in the fight against my illness	0	1	2	3	4
GE4	I feel nervous	0	1	2	3	4
GE5	I worry about dying	0	1	2	3	4
GE6	I worry that my condition will get worse	0	1	2	3	4

	FUNCTIONAL WELL-BEING	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
GF1	I am able to work (include work at home)	0	1	2	3	4
GF2	My work (include work at home) is fulfilling	0	1	2	3	4
GF3	I am able to enjoy life	0	1	2	3	4
GF4	I have accepted my illness	0	1	2	3	4
GF5	I am sleeping well	0	1	2	3	4
GF6	I am enjoying the things I usually do for fun	0	1	2	3	4
GF7	I am content with the quality of my life right now	0	1	2	3	4

FACT-H&N (Version 4)

By circling one (1) number per line, please indicate how true each statement has been for you during the past 7 days.

	ADDITIONAL CONCERNS	Not at all	A little bit	Some-what	Quite a bit	Very much
H&N 1	I am able to eat the foods that I like	0	1	2	3	4
H&N 2	My mouth is dry	0	1	2	3	4
H&N 3	I have trouble breathing	0	1	2	3	4
H&N 4	My voice has its usual quality and strength	0	1	2	3	4
H&N 5	I am able to eat as much food as I want	0	1	2	3	4
H&N 6	I am unhappy with how my face and neck look	0	1	2	3	4
H&N 7	I can swallow naturally and easily	0	1	2	3	4
H&N 8	I smoke cigarettes or other tobacco products	0	1	2	3	4
H&N 9	I drink alcohol (e.g. beer, wine, etc.)	0	1	2	3	4
H&N 10	I am able to communicate with others	0	1	2	3	4
H&N 11	I can eat solid foods	0	1	2	3	4

Note: All items on the physical well-being subscale, items 1, 3, 4, 5 and 6 on the emotional well-being subscale, and items 2, 3, and 6 on the additional concerns subscale are reverse coded.

Modified Daily Record Form

Subject # OCC _____ Date 10/27/02 To 11/2/02

On average, how many of each did you consume **each day** of this week:

Caffeinated Coffee (# of 8 oz cups)	____	Beer (# of 12 oz glasses)	____
Caffeinated Cola (# of 12 oz glasses)	____	Wine (# of 8 oz glasses)	____
Caffeinated Tea (# of 8 oz cups)	____	Other alcohol (# of shots or equiv)	____

How many cigarettes or ounces/tins/pouches of tobacco did you smoke/use this week? _____

If you are taking any medications, please list them here:

_____

_____

Circle NONE here if you are taking no medications.

1) If you have a job (including homemaker), did you work this week?	YES	NO	N/A

For Questions 2-10, circle the number on the scale from 1 to 7 that indicates how often something has happened or how you felt about something this week. For example, for question #2, if you felt very good, you might circle 1, if you felt very bad, you might circle 7, and if you felt somewhere in between, you would circle a 2, 3, 4, 5, or 6 depending on how good or bad you felt. Please keep in mind as you complete these questions that the words under 1 and 7 change from question to question and so each question should be evaluated separately.

2) Overall, how did you feel this week?	1 Very good	2	3	4	5	6	7 Very bad
3) Overall, how much did you enjoy your week?	1 Very much	2	3	4	5	6	7 Not at all

4) Think about the most stressful event that happened this week:

(a) List the event here: _____

(b) How stressful was this event?	1 Not at all	2	3	4	5	6	7 Extremely
(c) What was responsible for this event?	1 Totally due to me	2	3	4	5	6	7 Totally due to others or circumstances
5) Did you feel that you could control things that happened to you this week?	1 Not at all	2	3	4	5	6	7 Very much
6) This week, how often did you think of things that you had to accomplish?	1 Never	2	3	4	5	6	7 Very often
7) This week, how often did you feel nervous and "stressed"?	1 Never	2	3	4	5	6	7 Very often
8) This week, how often were you angered because of things that happened outside of your control?	1 Never	2	3	4	5	6	7 Very often

9) This week, did you feel as if you could cope with all the things that you had to do?	1 Yes, I could cope with everything	2	3	4	5	6	7 No, I couldn't

10) This week, were you able to control the way you spent your time?	1 Yes, I could	2	3	4	5	6	7 No, I couldn't

11) Circle any smoking cessation method that you are currently using:
NONE nicotine patch (Nicotrol, etc.) Zyban/Wellbutrin nicotine gum techniques learned during the intervention

List any other smoking cessation methods you are using _____

Please mark how much you have felt or experienced the following this week and for each, also mark whether this condition or symptom has been getting worse, (W), better (B), or has not changed (NC) this week.

	Not at all	A little bit	Moderately	Quite a bit	Extremely	**Worse (W) Better (B) or Not Changed (NC))**
Headache						
Sinus congestion						
Indigestion						
Back pain						
High energy						
Nausea						
Sore muscles						
Trouble concentrating						
Pain						
Loneliness						
Happiness						
Anxiety						
Sadness						
Overwhelmed						
Irritability						
Excitement						
Constipation/Diarrhea						
Dry Mouth						
Trouble Breathing						
Trouble Swallowing						
Communication Problems						

APPENDIX B

ALTERNATIVE MODEL WITHOUT BASELINE AS A MODERATOR FOR EFFECTS OF THE INTERVENTION

The following appendix includes results of the effect of the intervention within our sample. The models that were analyzed were similar to that of the models reported in the results section, with one exception. Baseline scores of the five outcome variables (BDI, STAI, IES, FACT-HN, and tobacco use) were not included as moderators, but rather were included in the time variable. The number of time points in this model was four, whereas, the models reported in the results section had three time points. The models presented in this appendix include a model that looks at the effects of the covariates, gender, education, smoking status, cancer stage, and cancer morphology on the five different outcomes. The model then included time, where the four time points (baseline, one month, six month and 12 month follow-ups) were included as repeated effects, and the variable, group, were added to the model to determine the effects of the intervention on the five outcome variables.

B.1 Covariates only model

Mixed linear models were conducted using the covariates gender, cancer morphology, smoking status, cancer stage, and education level. This was done for all five outcome variables (BDI score, STAI score, IES score, FACT-HN total score and tobacco use; see Tables B.1 and B.2). Depression levels (BDI scores) were predicted by smoking status, F (1, 241) = 11.32, p=0.001. Smokers (M=0.22, SE=0.15) reported significantly higher levels of depression than did non-smokers (M=-0.43, SE=0.19), p=0.001. Anxiety (STAI scores) was predicted by gender, F (1, 256) = 4.39, p=0.04 and education level, F (4, 256) = 3.00, p=0.02. Women (M=0.21, SE=0.15) reported significantly more anxiety than did men (M=-0.12, SE=0.12), p=0.04. Those who had some high school education (M=0.35, SE=0.18) reported significantly higher levels of anxiety than did those with some college education (M=-0.32, SE=0.17), p=0.02. There were no differences for high school graduates (M=-0.07, SE=0.13, p=0.31),

college graduates (*M*=0.01, *SE*=0.20, *p*=1.00), and those with some graduate work or graduate degrees (*M*=0.25, *SE*=0.23, *p*=1.00).

Distress levels in our sample were predicted by several of the covariates. Gender (*F* (1, 237) = 8.57, *p*=0.004), cancer morphology (*F* (1, 237) = 5.73, *p*=0.02), cancer stage (*F* (3, 237) = 2.938, *p*=0.03), and education level (*F* (4, 237) = 2.86, *p*=.02) were predictive of subsequent distress (IES scores). Females (*M*=0.83, *SE*=0.26) reported more distress than did their male counterparts (*M*=0.06, *SE*=0.20), *p*=0.004. Those with squamous cell carcinoma (*M*=0.05, *SE*=0.13) reported significantly less distress than did non-squamous cell patients (*M*=0.84, *SE*=0.32), *p*=0.02. Those with stage II cancer (*M*=-0.12, *SE*=0.29) reported marginally significantly less distress than did patients with stage IV (*M*=0.69, *SE*=0.26), *p*=0.052. There were no differences for stage I (*M*=0.51, *SE*=0.29, *p*=0.42), or stage III patients (*M*=0.70, *SE*=0.25, *p*=1.00). Those who had completed some high school (*M*=0.88, *SE*=0.30) reported significantly higher distress than did high school graduates (*M*=-0.07, *SE*=0.21), *p*=0.03. There were no differences for those who completed some college (*M*=0.28, *SE*=0.29, *p*=0.95), college graduates (*M*=0.81, *SE*=0.35, *p*=1.00), or those who had completed some graduate work or graduate degrees (*M*=0.33, *SE*=0.37, *p*=1.00).

Quality of life (FACT-HN scores) was predicted by smoking status (*F* (1, 245) = 4.19, *p*=0.04), cancer stage (*F* (3, 245) = 8.36, *p*=0.00), and education level *F* (4, 245) = 3.69, *p*=0.006). Non-smokers (*M*=-0.33, *SE*=0.0.27) reported higher QOL compared to smokers (*M*=0.26, *SE*=0.23), *p*=0.04. Those with stage II cancer (*M*=-1.29, *SE*=0.35) reported greater QOL compared to stage I (*M*=0.40, *SE*=0.33, *p*=0.001), stage III (*M*=0.39, *SE*=0.28, *p*=0.00), or stage IV (*M*=0.36, *SE*=0.30, *p*=0.00). There were no differences in QOL between stage I, stage III, and stage IV cancer patients. Those who had some high school education (*M*=0.88, *SE*=0.36) reported significantly lower levels of QOL compared to high school graduates (*M*=-0.29, *SE*=0.25; *p*=0.03) and those with some college education (*M*=-0.49, *SE*=0.32; *p*=0.01).

Those with some high school education had marginally significant lower levels of QOL compared to those with some graduate work or graduate degree (*M*=-0.57, *SE*=0.44), *p*=0.057. There were no differences for college graduates (*M*=0.30, *SE*=0.38). Tobacco use was predicted by smoking status (*F* (1, 267) = 10.57, *p*=0.001) and education level (*F* (4, 267) = 2.52, *p*=0.04). Smokers (*M*=3.56, *SE*=6.24) reported significantly higher tobacco use than did non-smokers (*M*=-20.93, *SE*=7.54), *p*=0.001. There were no significant differences in tobacco use for those with some high school education (*M*=13.31, *SE*=9.09), high school graduates (*M*=-4.71, *SE*=6.65), those who had completed some college (M=-13.79, *SE*=8.62), college graduates, (*M*=-17.19, *SE*=11.05) and those who had completed some graduate work (*M*-21.03, *SE*=12.82).

B.2The Effect of the Intervention and Time

The effects of time and the intervention were added to the covariates model. The subsequent model was a significantly better fit for all five outcomes: depression (-2 Log likelihood=790.57 for covariates only vs. 709.53 for group and time, *df*=3, *p*<.05), anxiety (-2 Log likelihood=732.17 for the covariates only model vs. 653.96 when including group and time, *df*=3, *p*<.05), distress (-2 Log likelihood=1020.49 for the covariates only model vs. 831.22 when including group and time, *df*=3, *p*<.05), quality of life (-2 Log likelihood=1377.05 for the covariates only model vs. 938.31 when including group and time, *df*=3, *p*<.05), and tobacco use (-2 Log likelihood= 2889.81 for covariates only vs. 2826.75 when including group and time, *df*=3, *p*<.05).

There was not a significant change across time in depression levels, F (3, 164.18) =1.34, *p*=0.26 (baseline: *M*=-0.09, *SE*=0.15; one month: *M*=0.09, *SE*=0.15; six month: *M*=0.13, *SE*=0.16; 12 months: *M*=-0.11, *SE*=0.17). However, there was a significant change across time for anxiety levels, *F* (3, 178.78) =0.36, *p*=0.001 (baseline: *M*=0.30, *SE*=0.12; one month: *M*=-0.14, *SE*=0.12; six month: *M*=-0.13, *SE*=0.13; 12 months: *M*=-0.19, *SE*=0.14). Baseline anxiety

was significantly higher than the one month (p=0.001), six month (p=0.02), or 12 month follow up periods (p=0.02). There were no differences between any of the other time points. There was also a significant effect across time for distress, F (3, 166.02) =3.32, p=0.02. Baseline distress (M =0.34, SE=0.20) was significantly higher than the one month follow-up (M =-0.20, SE=0.20), p=0.02.

There were no differences between the six month follow-up (M =-0.13, SE=0.21, p=0.27) or the 12 month follow-up (M =-0.25, SE=0.23, p=0.18). There was also a significant effect across time for QOL, F (3, 168.12) =2.86, p=0.04. However, post-hoc tests (Bonferroni) showed no significant differences between baseline (M =-0.06, SE=0.24), one month follow-up (M =0.33, SE=0.24, p=0.37), six month follow-up (M =0.20, SE=0.25, p=1.00) or the 12 month follow-up (M =-0.32, SE=0.27, p=1.00). Tobacco use also changed significantly across time, F (3, 140.96) =24.32, p=0.00. Tobacco use was significantly higher at baseline (M =39.00, SE=5.57) than at the one month follow-up (M =-15.55, SE=6.08, p=0.00), the six month follow-up (M =-16.65, SE=6.10, p=0.00), and the 12 month follow-up (M =-12.38, SE=6.68, p=0.00).

There were no differences between the control group and the intervention group for depression, F (1, 84.23) =0.00, p=0.95 (control: M=0.01, SE=0.18; intervention: M=0.00, SE=0.17); anxiety, F (1, 84.28) =0.98, p=0.33 (control: M=-0.13, SE=0.14; intervention: M=0.06, SE=0.13); distress, F (1, 80.12) =0.02, p=0.89 (control: M=-0.04, SE=0.24; intervention: M=-0.08, SE=0.23); QOL, F (1, 81.89) =1.12, p=0.29 (control: M=-0.20, SE=0.30; intervention: M=0.25, SE=0.27); or tobacco use, F (1, 52.40) =0.26, p=0.61 (control: M=0.51, SE=5.16; intervention: M=-3.30, SE=4.91). There were no significant group by time interaction effects for depression, F (3, 164.59) =0.54, p=0.66; anxiety, F (3, 178.78) =0.36, p=0.79; distress, F (3, 166.25) =1.14, p=0.33; QOL, F (23, 168.52) =0.50, p=0.68; or tobacco use, F (3, 140.74) =0.45, p=0.72 (Figures 1.22 and 1.23). The unstandardized coefficients and standard errors for the outcome measures and covariates are presented in Table B.3 and B.4.

Table B.1 Unstandardized Coefficients for BDI, STAI, and IES for the covariates only model

	Model					
	BDI Score		STAI Score		IES Score	
Effect	*b* (SE)	*t*(241)	*b* (SE)	*t*(256)	*b* (SE)	*t*(237)
Gender	-0.24 (0.20)	-1.23	-0.32 (0.15)	-2.10*	-0.77 (0.26)	-2.928***
Cancer Morphology	-0.10 (0.25)	0.41	0.01 (0.19)	0.03	-0.78 (0.33)	-2.39**
Smoking Status	-0.65 (0.19)	-3.37**	-0.22 (0.15)	-1.46	-0.02 (0.25)	-0.09
Cancer Stage (I)	-0.04 (0.26)	-0.17	0.35 (0.20)	1.81	-0.17 (0.34)	-0.51
Cancer Stage (II)	-0.48 (0.24)	-1.99*	-0.19 (0.19)	-0.99	-0.81 (0.31)	-2.65**
Cancer Stage (III)	0.08 (0.23)	0.35	0.15 (0.18)	0.81	0.02 (0.31)	0.05
Education (SHS)	0.52 (0.34)	1.53	0.10 (0.27)	0.38	0.55(0.43)	1.27
Education (HSG)	-0.04 (0.31)	-0.12	-0.32 (0.24)	-1.29	-0.39 (0.40)	0.97
Education (SC)	-0.00 (0.33)	-0.01	-0.57 (0.25)	-2.25	-0.05 (0.42)	-0.11
Education (CG)	0.09 (0.35)	0.79	-0.24 (0.28)	-0.87	0.49 (0.46)	1.05

Note: SHS-Some high school; HSG-High school graduate; SC-Some college; CG-College graduate. *p<.05; **p<.01; ***p<.005; ****p<.0001.

Table B.2 Unstandardized Coefficients for FACT-HN and Tobacco use for the covariates only model

	Model			
	FACT-HN Total Score		Tobacco Use	
Effect	*b* (SE)	*t*(245)	*b*(SE)	*t*(267)
Gender	0.13 (0.31)	0.42	3.57 (8.23)	0.43
Cancer Morphology	-0.62 (0.36)	-1.72	7.16 (9.93)	0.72
Smoking Status	-0.59 (0.29)	-2.05*	-24.49 (7.53)	-3.25***
Cancer Stage (I)	0.04 (0.39)	0.11	-4.06 (10.67)	-0.38
Cancer Stage (II)	-1.64 (0.38)	-4.35****	17.61 (9.83)	1.79
Cancer Stage (III)	0.03 (0.36)	0.09	3.14 (9.90)	0.32
Education (SHS)	1.45(0.52)	2.79****	34.34 (14.44)	2.38*
Education (HSG)	0.28 (0.48)	0.59	16.32 (13.68)	1.19
Education (SC)	0.08 (0.53)	0.17	7.24 (13.94)	0.52
Education (CG)	0.87 (0.53)	1.62	3.84 (15.73)	0.24

Note: SHS-Some high school; HSG-High school graduate; SC-Some college; CG-College graduate. *p<.05; **p<.01; ***p<.005; ****p<.0001.

B.3 The Effect of the Intervention and Time with Completers vs. Non-completers

A dichotomous variable of whether participants had completed all time points or not was created and added to the group, time and covariates (GTC) model. The resulting group, time, covariates, and non-completers vs. completers model (GTCN) was not a significantly better fit for depression (-2 Log likelihood= 709.53 for the GTC model vs. 702.60 for the GTCN model, *df*=8, *p*>.05), anxiety (-2 Log likelihood= 653.96 for the GTC model vs. 642.04 for the GTCN model, *df*=8, *p*>.05), distress (-2 Log likelihood= 831.22for the GTC model vs. 825.35 for the GTCN model, *df*=8, *p*>.05), quality of life (-2 Log likelihood= 938.31 for the GTC model vs. 825.35 for the GTCN model, *df* =8, *p*<.05) or tobacco use (-2 Log likelihood= 2826.75 for the GTC model vs. 2821.70 for the GTCN model, *df*=8, *p*>.05). [3]

There were no differences between the control group and the intervention group for depression, *F* (1, 130.13) =0.28, *p*=0.60 (control: *M*=-0.08, *SE*=0.23; intervention: *M*=0.08, *SE*=0.18); anxiety, *F* (1, 103.30) =0.51, *p*=0.48 (control: *M*=-0.08, *SE*=0.16; intervention: *M*=0.07, *SE*=0.14); distress, *F* (1, 123.54) =0.04, *p*=0.85 (control: *M*=-0.07, *SE*=0.30; intervention: *M*=-0.15, *SE*=0.25); QOL, *F* (1, 119.74) =0.14, *p*=0.71 (control: *M*=0.24, *SE*=0.37; intervention: *M*=0.42, *SE*=0.28); or tobacco use, *F* (1, 58.62) =0.02, *p*=0.89 (control: *M*-2.21, *SE*=6.11; intervention: *M*=-3.32, *SE*=5.04). There were no differences between completers and non-completers for depression, *F* (1, 128.29) =0.32, *p*=0.57 (completers: *M*=-.09, *SE*=0.15; non-completers: *M*=0.09, *SE*=0.26); anxiety, *F* (1, 101.46) =0.87, *p*=0.35 (completers: *M*=-0.11, *SE*=0.12; non-completers: *M*=0.09, *SE*=0.18); distress, *F* (1, 119.76) =0.08, *p*=0.78 (completers: *M*=-0.05, *SE*=0.20; non-completers: *M*=-0.17, *SE*=0.36); or tobacco use, *F* (1,

[3] Additional models were conducted on dummy variables of the patterns OMMM, OOMM, OOOM, OOOO. However, none of these models were significant, and therefore, for ease of results, are not presented.

57.70) =0.09, *p*=0.77 (completers: *M*=-1.54, *SE*=4.56; non-completers: *M*=-3.99, *SE*=6.64). However, completers (*M*=-0.28, *SE*=0.24) reported significantly higher QOL than did non-completers (*M*=0.94, *SE*=0.41), *F* (1, 117.92) =0.14, *p*=0.01.

There were no significant changes across time for depression, *F* (3, 178.66) =1.83, *p*=0.14 (baseline: *M*=--0.079, *SE*=0.15; one month: *M*=0.07, *SE*=0.17; six month: *M*=0.27, *SE*=0.19; 12 months: *M*=-0.28, *SE*=0.32); or distress, *F* (3, 182.95) =2.13, *p*=0.10 (baseline: *M*=0.31, *SE*=0.20; one month: *M*=-0.08, *SE*=0.22; six month: *M*=-0.06, *SE*=0.25; 12 months: *M*=-0.60, *SE*=0.44). There were significant changes across time for anxiety, *F* (3, 191.03) =4.90, *p*=0.003; tobacco use, *F* (3, 149.53) =24.07, *p*=0.00; and a marginally significant change across time for QOL, *F* (3, 183.70) =2.58, *p*=.055. Patients reported significantly higher anxiety at baseline (*M*=0.32, *SE*=0.12) than the one month follow up (*M*=-0.06, *SE*=0.13, *p*=0.006) and the 12 month follow-up (*M*=-0.29, *SE*=0.19, *p*=0.03). There were no differences between baseline and the six month follow-up for anxiety (*M*=-0.00, *SE*=0.14, *p*=0.20). Baseline tobacco use (*M*=39.29, *SE*=5.72) was significantly higher compared to one month (*M*=-17.61, *SE*=6.51, *p*=0.00), six months (*M*=-17.74, *SE*=6.43, *p*=0.00), and the 12 months: (*M*=-15.01, *SE*=7.69, *p*=0.00) following completion of the intervention.

There were no significant group by time interaction effects for depression, *F* (3, 179.17) =1.30, *p*=0.28; anxiety, *F* (2, 116.52) =0.00, *p*=0.70; distress, *F* (3, 183.07) =0.29, *p*=0.83; QOL, *F* (3, 184.39) =0.13, *p*0.94; or tobacco use, *F* (3, 148.99) =0.32, *p*=0.81 (Figures 1.24 and 1.25). There were no significant interactions between time and completers versus non-completers for depression, *F* (3, 178.59) =0.88, *p*=0.45; distress, *F* (3, 182.79) =1.67, *p*=0.18; QOL, *F* (3, 183.62) =2.38, *p*=0.07; or tobacco use, *F* (3, 149.31) =0.83, *p*=0.48 (Figures 1.26 and 1.27). There was a significant interaction effect between time and completion status for anxiety, *F* (3, 190.94) =2.78, *p*=0.04. Completers (*M*=-0.29, *SE*=0.15) at the six month follow-up reported significantly lower levels of anxiety compared to non-completers (*M*=0.28, *SE*=0.23), *p*=0.04.

There were no significant interaction effects between group and completers versus non-completers for depression, *F* (1, 133.17) =0.48, *p*=0.49; anxiety, *F* (1, 104.44) =0.57, *p*=0.45; distress, *F* (1, 124.88) =0.19, *p*=0.67; QOL, *F* (1, 120.59) =1.42, *p*=0.25; or tobacco use, *F* (1, 59.48) =1.22, *p*=0.27. There were no significant three way interactions between time, group, and completers vs. non-completers for depression, *F* (3, 179.10) =1.522, *p*=0.21; anxiety, *F* (3, 19113) =0.57, *p*=0.64; distress, *F* (3, 183.08) =0.17, *p*=0.92; QOL, *F* (3, 184.47) =0.37, *p*=0.78; or tobacco use, *F* (3, 149.30) =0.17, *p*=0.92. The unstandardized coefficients and standard errors for the outcome measures and covariates are presented in Table B.5 and B.6.

Table B.3 Coefficients for BDI, STAI, and IES scores for the Intervention and Time model

	Model					
	BDI		STAI		IES	
Effect	*b*	*SE*	*b*	*SE*	*b*	*SE*
Gender	0.33	0.28	0.43*	0.21	0.90**	0.37
Cancer Morphology	-0.06	0.33	-0.20	0.26	0.37	0.45
Smoking Status	0.49	0.27	0.04	0.21	-0.17	0.36
Cancer Stage	0.07	0.11	-0.07	0.09	0.10	0.15
Education	-0.11	0.11	-0.03	0.08	0.01	0.14
Group	0.04	0.35	0.31	0.28	0.18	0.47
Time (0v12)	0.17	0.29	0.63**	0.24	0.70	0.39
Time (1v12)	0.20	0.27	0.10	0.22	0.10	0.36
Time (6v12)	0.18	0.22	0.10	0.18	0.42	0.29
Group x Time (0v12)	-0.30	0.39	-0.29	0.33	-0.21	-.54
Group x Time (1v12)	-0.02	0.37	-0.11	0.30	-0,60	0.49
Group x Time (6v12)	0.11	0.30	-0.08	0.25	-0.60	0.40

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

Table B.4 Coefficients for FACT-HN scores and Tobacco Use for the Intervention and Time model

	Model			
	FACT-HN		Tobacco Use	
Effect	*b*	*SE*	*b*	*SE*
Gender	0.16	0.45	-4.18***	8.45
Cancer Morphology	0.34	0.53	-14.54	10.27
Smoking Status	0.10	0.44	28.37	7.99
Cancer Stage	0.22	0.18	-1.68	3.42
Education	-0.22	0.17	-10.15**	3.17
Group	0.43	0.55	-6.87	13.39
Time (0v12)	0.28	0.46	44.91***	12.95
Time (1v12)	0.75	0.41	-1.62	13.13
Time (6v12)	0.38	0.33	-5.46	11.80
Group x Time (0v12)	-0,05	0.61	12.94	17.27
Group x Time (1v12)	-0.21	0.56	-3.11	17.50
Group x Time (6v12)	0.27	0.45	2.40	15.79

**p<.002; ***p<.001.

Table B.5 Coefficients for BDI, STAI, and IES scores for GTCN Model

	Model					
	BDI		STAI		IES	
Effect	*b*	*SE*	*b*	*SE*	*b*	*SE*
Gender	0.32	0.28	0.40	0.22	0.87*	0.37
Cancer Morphology	-0.09	0.35	-0.28	0.26	0.38	0.47
Smoking Status	0.53#	0.27	0.05	0.21	-0.24	0.36
Cancer Stage	0.07	0.11	-0.07	0.09	0.11	0.15
Education Level	-0.08	0.11	-0.02	0.08	-0.01	0.14

Table B.5-Continued

	Model					
	BDI		STAI		IES	
Effect	*b*	*SE*	*b*	*SE*	*b*	*SE*
Group	1.81	1.24	0.44	0.72	0.26	1.69
Completion Status	1.13	1.06	0.17	0.56	0.71	1.42
Time (0v12)	1.46	1.03	-0.71	0.76	1.37	1.39
Time (1v12)	1.32	1.03	-0.39	0.74	1.40	1.39
Time (6v12)	1.97*	0.96	-0.69	0.69	1.38	1.30
Time (0v12) X Group	-2.03	1.26	-0.71	0.76	-0.62	1.73
Time (1v12) X Group	-1.63	1.27	-0.39	0.74	-0.71	1.73
Time (6v12) X Group	-2.12	1.17	-0.69	0.69	-0.70	1.65
Time (0v12) X Completion Status	-1.33	1.08	-0.37	0.61	-0.58	1.46
Time (1v12) X Completion Status	-1.12	1.07	-0.71	0.58	-1.45	1.44
Time (6v12) X Completion Status	-1.92#	0.98	-1.06	0.51*	-1.04	1.33
Group X Completion Status	-1.85	1.30	-0.10	0.78	-0.01	1.77
Time (0v12) X Group X Completion Status	1.74	1.33	0.63	0.85	0.56	1.84
Time (1v12) X Group X Completion Status	1.62	1.33	0.34	0.81	0.76	1.81
Time (6v12) X Group X Baseline	2.37#	1.21	0.73	0.74	0.11	1.70

*p<.05; **p<.01; ***p<.001; # p<.06

Table B.6 Coefficients for FACT-HN scores and Tobacco Use for GTCN Model

	Model			
	FACT-HN		Tobacco Use	
Effect	*b*	*SE*	*b*	*SE*
Gender	-0.04	0.45	-3.01	8.56
Cancer Morphology	-0.03	0.54	-13.16	10.46
Smoking Status	0.30	0.43	29.03	8.05***
Cancer Stage	0.20	0.18	-1.84	3.43
Education Level	-0.12	0.17	-10.30	3.24
Group	0.31	1.82	8.12	26.80
Completion Status	-1.57	1.63	18.84	24.75**
Time (0v12)	-0.07	1.58	58.26	25.77
Time (1v12)	0.65	1.58	2.06	26.94
Time (6v12)	1.57	1.46	2.81	24.42
Time (0v12) X Group	-0.75	1.85	14.40	31.74
Time (1v12) X Group	-0.90	1.85	-8.17	33.20
Time (6v12) X Group	-1.15	1.72	-7.27	30.19
Time (0v12) X Completion Status	0.44	1.65	-16.71	29.84
Time (1v12) X Completion Status	0.08	1.64	-3.42	30.80
Time (6v12) X Completion Status	-1.39	1.49	-9.60	27.85
Group X Completion Status	0.27	1.92	-19.17	31.08
Time (0v12) X Group X Completion Status	1.00	1.98	-11.19	37.97

Table B.6-Continued

	Model			
	FACT-HN		Tobacco Use	
Effect	*b*	*SE*	*b*	*SE*
Time (1v12) X Group X Completion Status	0.88	1.94	4.57	39.09
Time (6v12) X Group X Baseline	1.58	1.78	11.60	35.43

*p<.05; **p<.01; ***p<.001; # p<.06

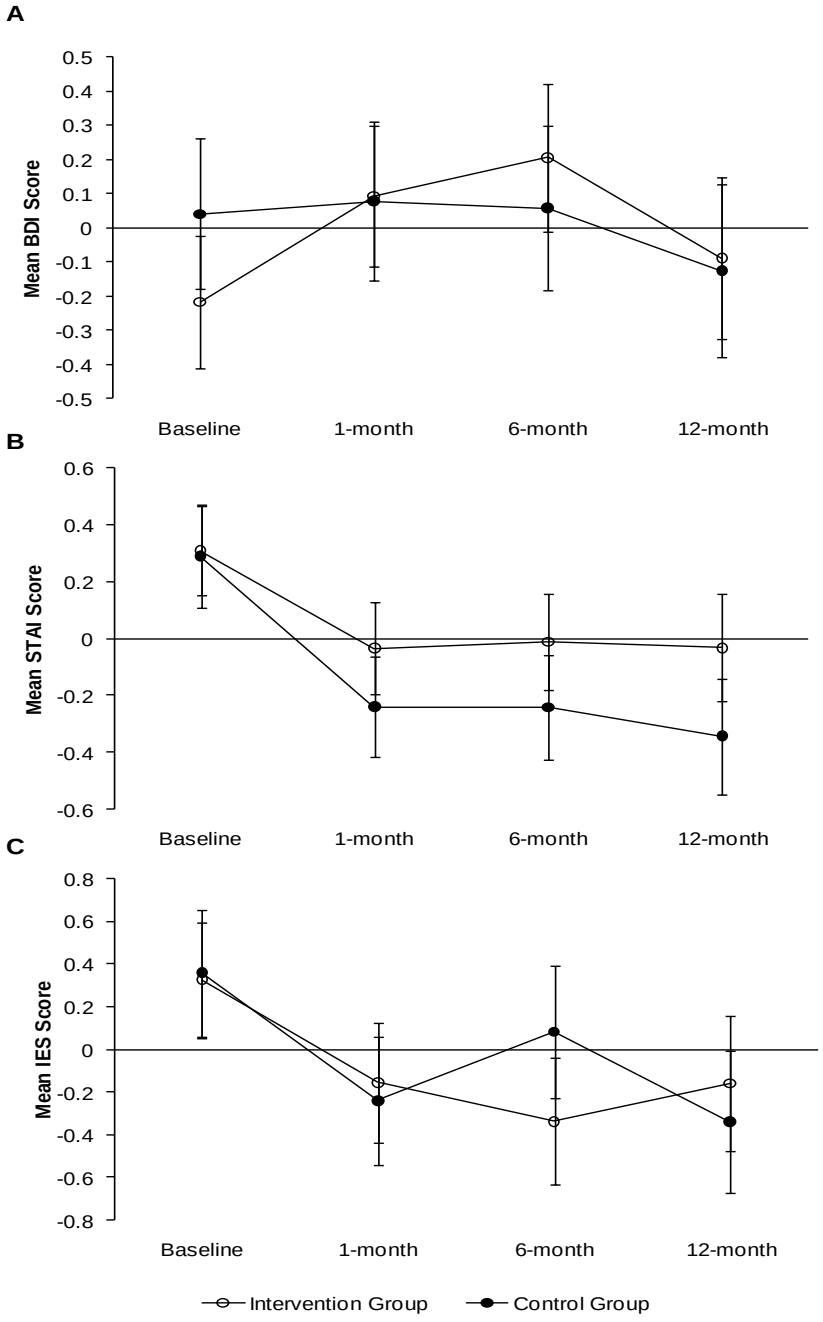

Figure B.1. Marginal means and standard errors for group and time for the group, time and covariates model for the (A) BDI scores; (B) STAI scores; (C) IES scores.

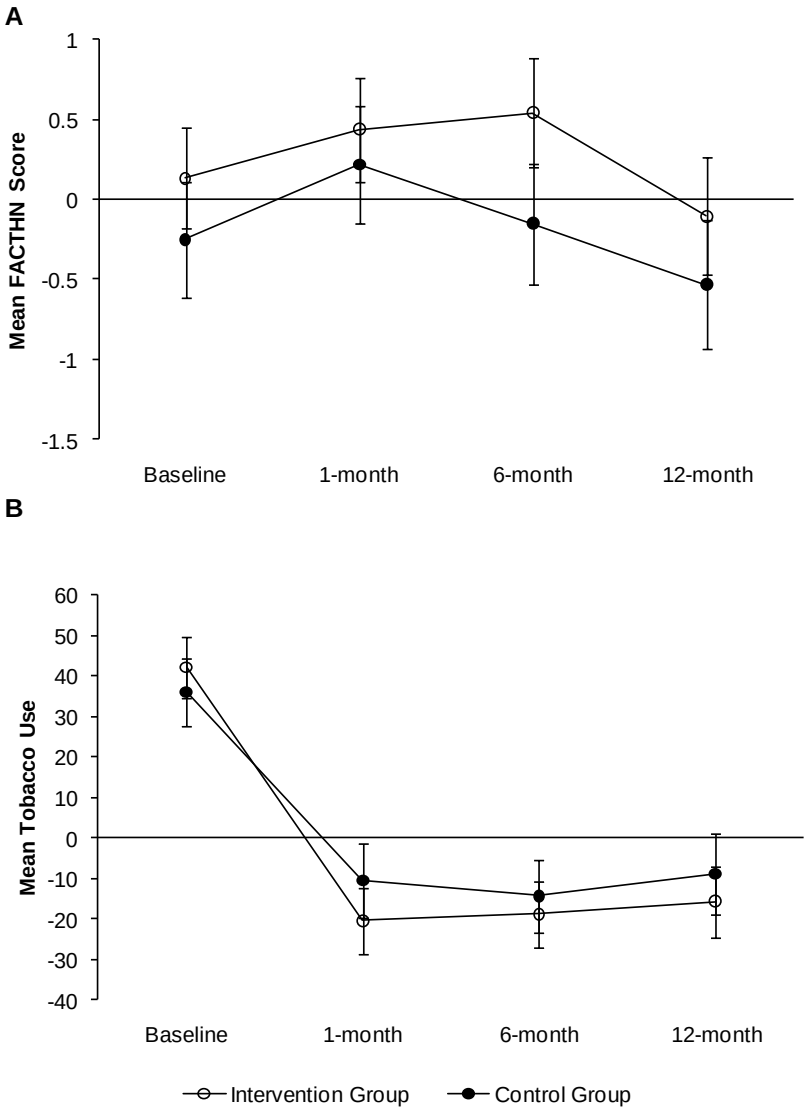

Figure B.2. Marginal means and standard errors for group and time for the group, time and covariates model for the (A) FACT-HN scores and (B) Weekly tobacco use.

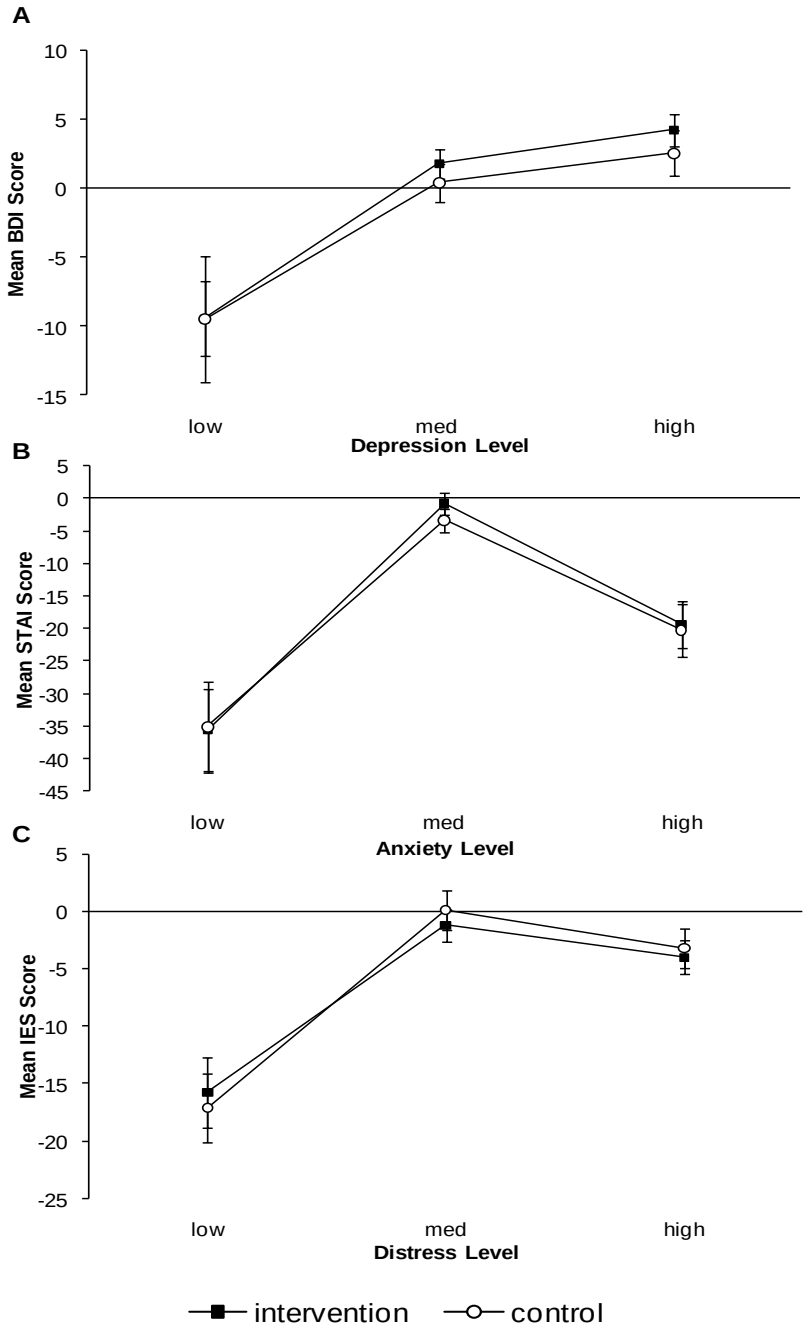

Figure B.3. Marginal means and standard errors for group and time for the group, time, covariates, and completion status model for the (A) BDI scores; (B) STAI scores; (C) IES scores.

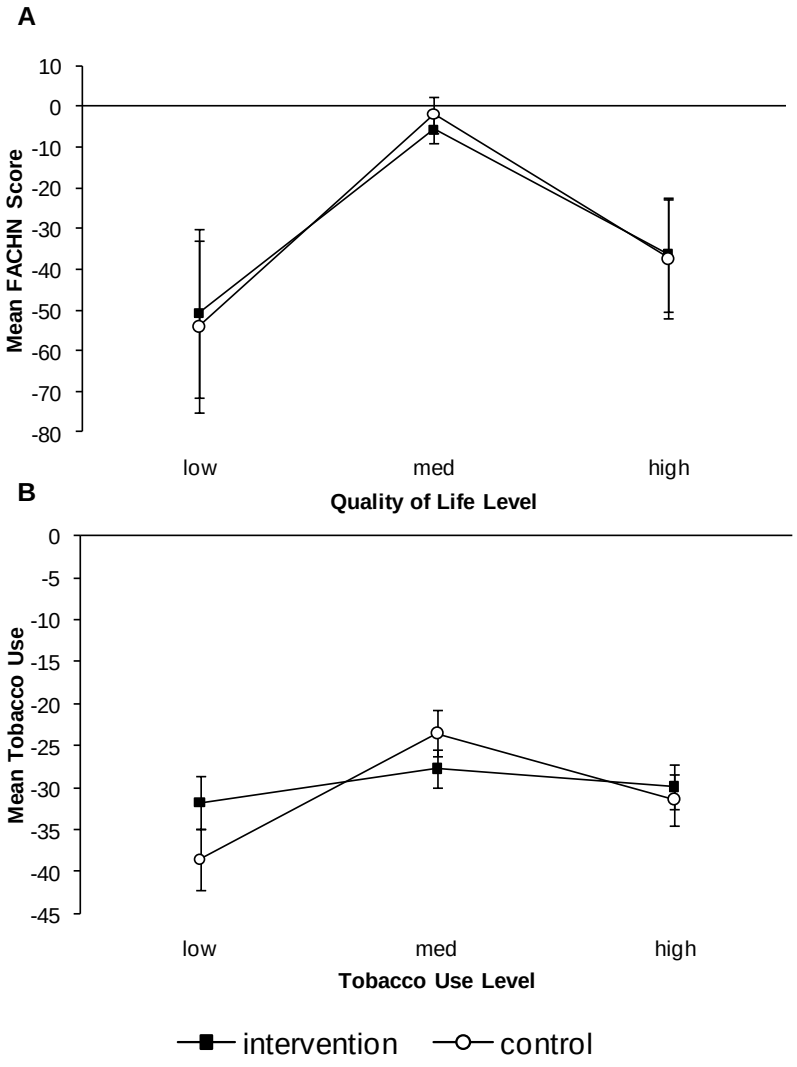

Figure B.4.Marginal means and standard errors for group and time for the group, time, covariates, and completion status model for the (A) FACT-HN scores and (B) Weekly tobacco use.

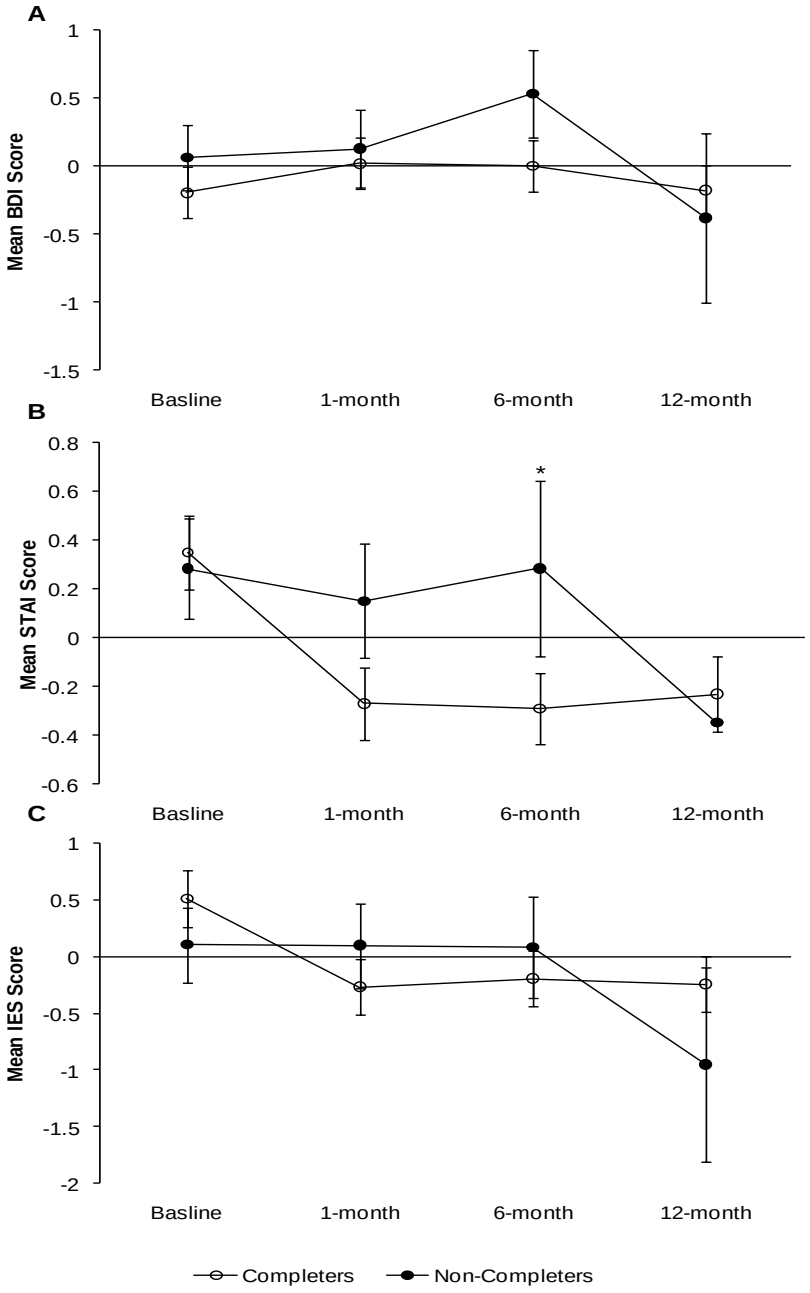

Figure B.5. Marginal means and standard errors for completion status and time for the group, time, covariates, and completion status model for the (A) BDI scores; (B) STAI scores; (C) IES scores. *p<.05 between completers and non-completers.

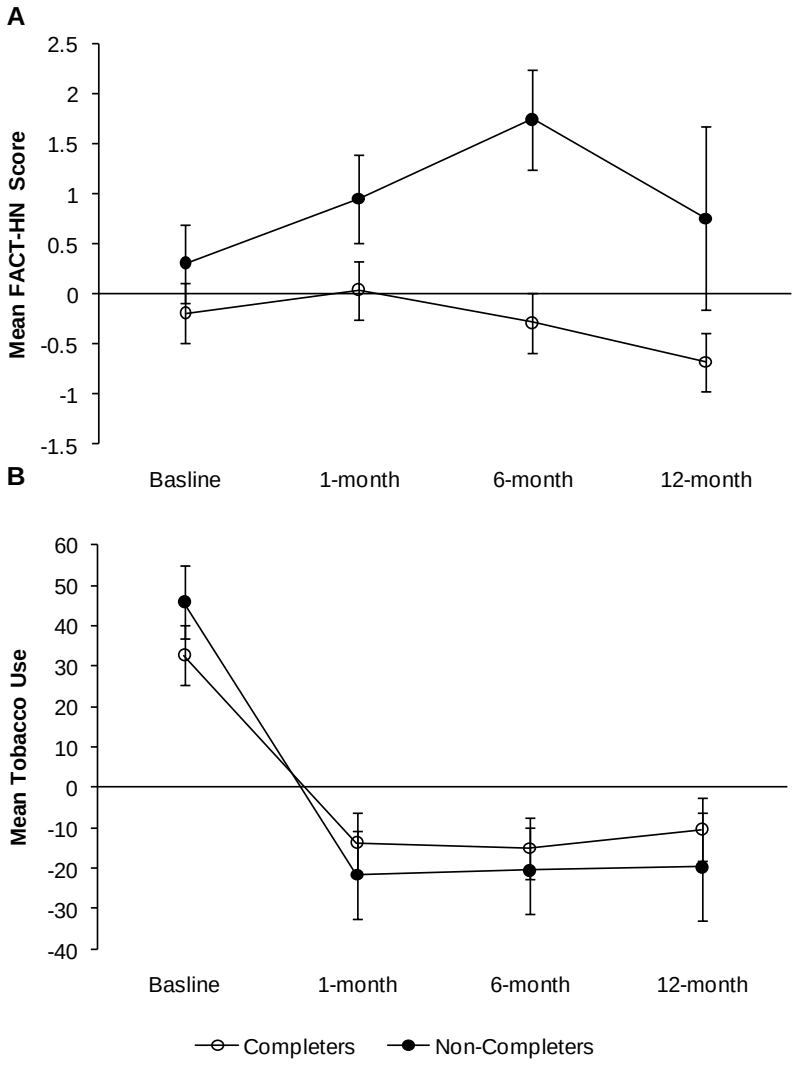

Figure B.6. Marginal means and standard errors for completion status and time for the group, time, covariates, and completion status model for the (A) FACT-HN scores and (B) Weekly tobacco use.

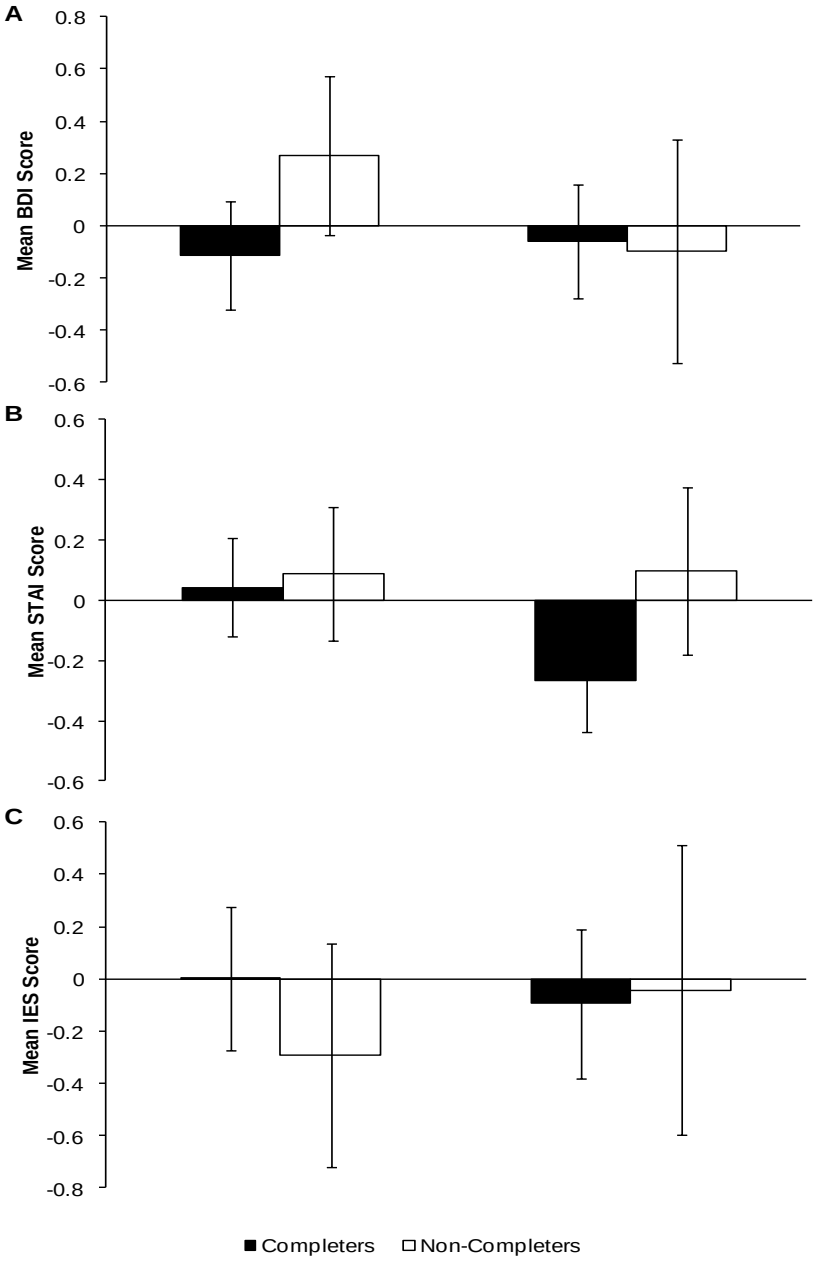

Figure B.7. Marginal means and standard errors for completion status and group for the group, time, covariates, and completion status model for the (A) BDI scores; (B) STAI scores; (C) IES scores.

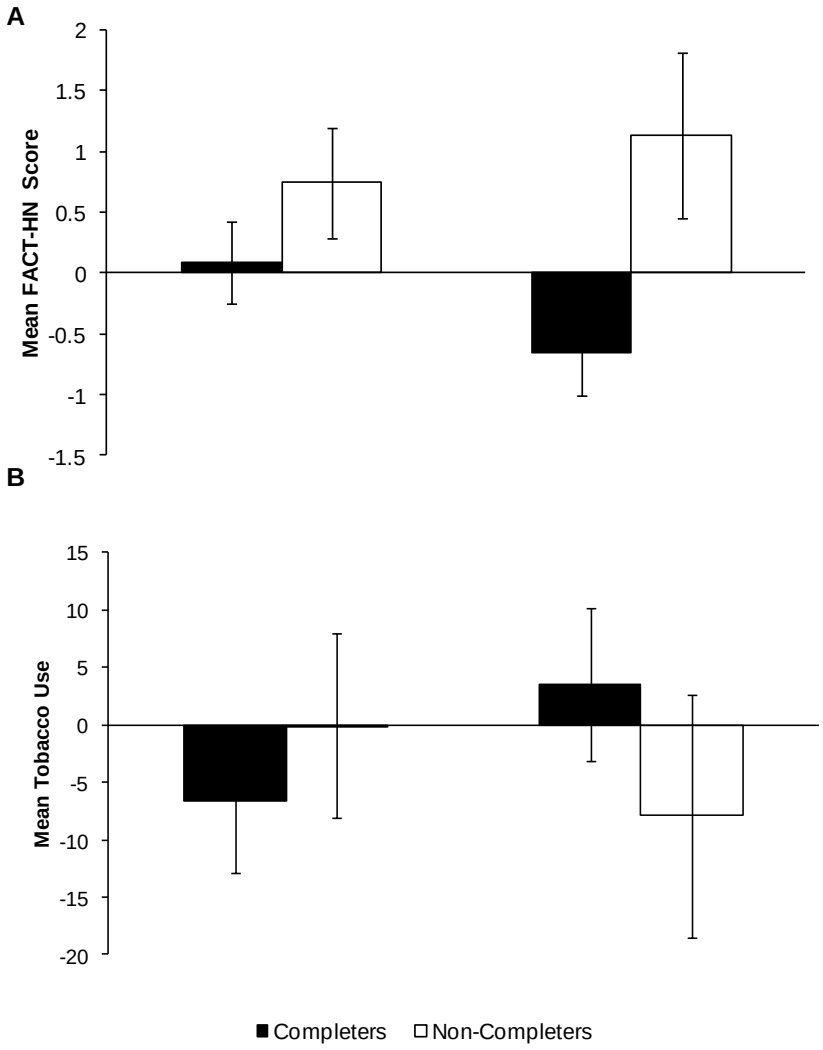

Figure B.8. Marginal means and standard errors for completion status and group for the group, time, covariates, and completion status model for the (A) FACT-HN scores and (B) Weekly tobacco use.

REFERENCES

Allison, P. J., Edgar, L., Nicolau, B., Archer, J., Black, M., & Hier, M. (2004). Results of a feasibility study for a psycho-educational intervention in head and neck cancer. *Psycho-Oncology, 13*(7), 482-485. doi: 10.1002/pon.816

Allison, P. J., Nicolau, B., Edgar, L., Archer, J., Black, M., & Hier, M. (2004). Teaching head and neck cancer patients coping strategies: Results of a feasibility study. *Oral Oncology, 40*, 538-544. doi: 10.1016/j.oraloncology.2003.11.008/c

American Cancer Society. (2010). Cancer facts and figures 2010. In A. C. Society (Ed.). Atlanta.

Andersen, B. L., Kiecolt-Glaser, J. K., & Glaser, R. (1994). A biobehavioral model of cancer stress and disease course. *American Psychologist, 49*(5), 389-404.

Baum, A., Breslin, F. C., O'Keefe, M., Raliff-Crain, J., & Burrell, L. (1994). The daily record form: A brief measure of daily perceived stress and psychosomatic complaints. *Anxiety, Stress, and Coping, 7*, 375-384.

Baum, A., Trevino, L. A., & Dougall, A. L. (2011). Stress and the Cancers. In R. J. Contrada & A. Baum (Eds.), *The Handbook of Stress Science: Biology, Psychology, and Health* (pp. 411-423). New York: Springer Publishing Company.

Beck, A., Ward, C., & Mendelson, M. (1961). An inventory for measuring depression. *Archives of General Psychiatry, 4*, 561-571.

Bjordal, K., & Kaasa, S. (1995). Psychological distress in head and neck cancer patients 7-11 years after curative treatment. *British Journal of Cancer, 71*, 592-597.

Browman, G. P., Wong, G., Hodson, I., Sathya, J., Russell, R., McAlpine, L., . . . Levine, M. N. (1993). Influence of cigarette smoking on the efficacy of radiation therapy in head and neck cancer. *The New England Journal of Medicine, 328*, 159-163.

Brown, K. W., Levy, A. R., Zeev, R., & Edgar, L. (2003). Psychological Distress and Cancer Survival: A Follow-Up 10 Years After Diagnosis. *Psychosomatic Medicine, 65*(4), 636-643. doi: 10.1097/01.psy.0000077503.96903.a6

Campbell, B., Marbella, A., & Layde, P. M. (2000). Quality of life and recurrence concern in survivors of head and neck cancer. *Laryngoscope, 110*, 895-906.

Carvalho, A. L., Nishimoto, I. N., Califano, J. A., & Kowalski, L. P. (2005). Trends in incidence and prognosis for head and neck cancer in the United States: A site-specific analysis of the SEER database. *International Journal of Cancer, 114*, 806-816.

Cella, D., Tulsky, D., Gray, G., Sarafian, B., Linn, E., Bonomi, A., & al., e. (1993). The functional assessment of cancer therapy scale: Development and validation of the general measure. *Journal of Clinical Oncology, 11*, 555-572.

Chida, Y., Hamer, M., Wardle, J., & Steptoe, A. (2008). Do stress-related psychosocial factors contribute to cancer incidence and survival? *Nature Clinical Practice Oncology, 5*(8), 466-475. doi: 10.1038/ncponc1134

Christensen, A. J., Moran, P. J., Ehlers, S. L., Raichle, K., Karnell, L., & Funk, G. (1999). Smoking and drinking behavior in patients with head and neck cancer: Effects of behavioral self-blame and perceived control. *Journal of Behavioral Medicine, 22*(5), 407-418

Cooper, J. S., Pajak, T. F., Rubin, P., Tupchong, L., Brady, L. W., Leibel, S. A., . . . Cox, J. D. (1989). Second malignancies in patients who have had head and neck cancer: Incidence, effect on

survival and implications based on the RTOG experience. *International Journal of Radiation Oncology, Biology, Physics, 17*(3), 449-456.

Covey, L. S., Glassman, A. H., & Stetner, F. (1997). Major depression following smoking cessation. *The American Journal of Psychiatry, 154*(2), 263-265.

Coyne, J. C., Pajak, T. F., Harris, J., Konski, A., Movsas, B., Ang, K., & Watkins Bruner, D. (2007). Emotional well-being does not predict survival in head and neck cancer patients. *Cancer, 110*(11), 2568-2575. doi: 10.1002/cncr.23080

D'Antonio, L. L., Long, S. A., Zimmerman, G. J., Peterman, A. H., Petti, G. H., & Chonkich, G. D. (1998). Relationship between quality of life and depression in patients with head and neck cancer. *Laryngoscope, 108*, 806-811.

de Graeff, A., de Leeuw, J. R. J., Ros, W. J. G., Hordijk, G. J., Blijham, G. H., & Winnubst, J. A. M. (2000). Pretreatment factors predicting quality of life after treatment for head and neck cancer. *Head & Neck, 22*, 398.

De Graeff, A., De Leeuw, J. R. J., Ros, W. J. G., Hordijk, G. J., Blijham, G. H., & Winnubst, J. A. M. (2001). Sociodemographic factors and quality of life as prognostic indicators in head and neck cancer. *European Journal of Cancer 37*, 332-339.

Deleyiannis, F. W. B., Thomas, D. B., Vaughan, T. L., & Davis, S. (1996). Alcoholism: Independent predictor of survival in patients with head and neck cancer. *Journal of the National Cancer Institute, 88*(8), 542-549.

Duffy, S. A., Ronis, D. L., & Valenstein, M. (2006). A tailored smoking, alcohol, and depression intervention for head and neck cancer patients. *Cancer Epidemiology, Biomarkers and Prevention, 15*, 2203-2208.

Duffy, S. A., Terrell, J. E., Valenstein, M., Ronis, D. L., Copeland, L. A., & Connors, M. (2002). Effect of smoking, alcohol, and depression on the quality of life of head and neck cancer patients. *General Hospital Psychiatry, 24*, 140-147.

Fang, F.-M., Liu, Y.-T., Tang, Y., Wang, C.-J., & Ko, S.-F. (2004). Quality of life as a survival predictor for patients with advanced head and neck carcinoma treated with radiotherapy. *Cancer, 100*(2), 425-432. doi: 10.1002/cncr.20010

Faye-Lund, H., & Abdelnoor, M. (1996). Prognostic factors of survival in a cohort of head and neck cancer patients in Oslo. *European Journal of Cancer Care with Oral Oncology, 32B*(2), 83-90.

Feldman, J. G., Hazan, M., Nagarajan, M., & Kissin, B. (1975). A case-control investigation of alcohol, tobacco, and diet in head and neck cancer. *Preventive Medicine, 4*, 444-463.

Freedman, N. D., Abnet, C. C., Leitzmann, M. F., Hollenbeck, A. R., & Schatzkin, A. (2007). Prospective investigation of the cigarette smoking–head and neck cancer association by sex. *Cancer, 110*(7), 1593-1601. doi: 10.1002/cncr.22957

Funk, G. F., Karnell, L. H., Robinson, R. A., Zhen, W. K., Trask, D. K., & Hoffman, H. T. (2002). Presentation, treatment, and outcome of oral cavity cancer: A national cancer data base report. *Head & Neck, 24*, 165-180.

Goldfried, M. R., & Davison, G. (1994). *Clinical behavior therapy*. New York: Wiley.

Gritz, E. R. (2000). Facilitating smoking cessation in cancer patients. *Tobacco Control, 9*(S1), 150.

Gritz, E. R., Carmack, C. L., de Moor, C., Coscarelli, A., Schacherer, C. W., Meyers, E. G., & Abemayor, E. (1999). First year after head and neck cancer: Quality of life. *Journal of Clinical Oncology, 17*, 352-360.

Gritz, E. R., Carr, C. R., Rapkin, D. A., Abemayor, E., Chang, L. J. C., Wong, W. K., . . . Ward, P. H. (1993). Predictors of long-term smoking cessation in head and neck cancer patients. *Cancer Epidemiology, Biomarkers and Prevention, 2*, 261-270.

Hammerlid, E., Ahlner-Elmqvist, M., Bjordal, K., Biorklund, A., Evensen, J., Boysen, M., . . . Westin, T. (1999). A prospective multicentre study in Sweden and Norway of mental distress and psychiatric morbidity in head and neck cancer patients. *British Journal of Cancer, 80*(5/6), 766-774.

Hammerlid, E., Persson, L. O., Sullivan, M., & Westin, T. (1999). Quality-of-life effects of psychosocial intervention in patients with head and neck cancer. *Otolaryngology-Head and Neck Surgery, 120*, 507-516.

Hammerlid, E., Silander, E., Homestam, L., & Sullivan, M. (2001). Health-related quality of life three years after diagnosis of head and neck cancer: A longitudinal study. *Head & Neck, 23*, 113-125.

Hammerlid, E., & Taft, C. (2001). Health-related quality of life in long-term head and neck cancer survivors: A comparison with general population norms. *British Journal of Cancer, 84*(2), 149-156. doi: 10.1054/

Hashibe, M., Brennan, P., Chuang, S. C., Boccia, S., Castellsague, X., Chen, C., . . . Boffetta, P. (2009). Interaction between tobacco and alcohol use and the risk of head and neck cancer: Pooled analysis in the international head and neck cancer epidemiology consortium. *Cancer Epidemiology, Biomarkers and Prevention, 18*, 541-550.

Hassanein, K., Musgrove, B., & Bradbury, E. (2001). Functional status of patients with oral cancer and its relation to style ofcoping, social support and psychological status. *British Journal of Oral and Maxillofacial Surgery, 39*(5), 340-345. doi: 10.1054/bjom.2001.0652

Hedeker, D., & Gibbons, R. D. (1997). Application of random-effects pattern-mixture models for missing data in longitudinal studies. *Psychological Methods, 2*, 64-78.

Hodges, L. J., & Humphris, G. M. (2009). Fear of recurrence and psychological distress in head and neck cancer patients and their carers. *Psycho-Oncology, 18*(8), 841-848. doi: 10.1002/pon.1346

Horowitz, M., Wilner, N., & Alvarez, W. (1979). Impact of event scale: A measure of subjective stress. *Psychometric Medicine, 41*, 209-218.

Hutton, J., & Williams, M. (2001). An investigation of psychological distress in patients who have beentreated for head and neck cancer. *British Journal of Oral and Maxillofacial Surgery, 39*(5), 333-339. doi: 10.1054/bjom.2001.0645

Jenewein, J., Zwahlen, R. A., Zwahlen, D., Drabe, N., Moergeli, H., & BÜChi, S. (2008). Quality of life and dyadic adjustment in oral cancer patients and their female partners. *European Journal of Cancer Care, 17*(2), 127-135. doi: 10.1111/j.1365-2354.2007.00817.x

Karvonen-Gutierrez, C. A., Ronis, D. L., Fowler, K. E., Terrell, J. E., Gruber, S. B., & Duffy, S. A. (2008). Quality of Life Scores Predict Survival Among Patients With Head and Neck Cancer. *Journal of Clinical Oncology, 26*(16), 2754-2760. doi: 10.1200/jco.2007.12.9510

Katz, M. R., Irish, J. C., Devins, G. M., Rodin, G. M., & Gullane, P. J. (2003). Psychosocial adjustment in head and neck cancer: The impact of disfigurement, gender and social support. *Head & Neck, 25*(2), 103-112. doi: 10.1002/hed.10174

Katz, M. R., Kopek, N., Waldron, J., Devins, G. M., & Tomlinson, G. (2004). Screening for depression in head and neck cancer. *Psycho-Oncology, 13*(4), 269-280. doi: 10.1002/pon.734

Khuri, F. R., Kim, E. S., Lee, J. J., Winn, R. J., Benner, S. E., Lippman, S. M., . . . Hong, W. K. (2001). The impact of smoking status, disease stage, and index tumor site on second primary tumor indicidence and tumor recurrence in the head and neck retinoid chemoprevention trial. *Cancer Epidemiology, Biomarkers and Prevention, 10*, 823-829.

Koch, W. M., Lango, M., Sewell, D., Zahurak, M., & Sidransky, D. (1999). Head and neck cancer in nonsmokers: A distinct clinical and molecular entity. *The Laryngoscope, 109*, 1544-1551.

Kohda, R., Otsubo, T., Kuwakado, Y., Tanaka, K., Kitahara, T., Yoshimura, K., & Mimura, M. (2005). Prospective studies on mental status and quality of life in patients with head and neck cancer treated by radiation. *Psycho-Oncology, 14*(4), 331-336. doi: 10.1002/pon.892

Kugaya, A., Akechi, T., Okamura, H., Mikami, I., & Uchitomi, Y. (1999). Correlates of depressed mood in ambulatory head and neck cancer patients. *Psycho-Oncology, 8*, 494-499.

Kugaya, A., Tatsuo, A., Okuyama, T., Nakano, T., Mikami, I., Okamura, H., & Uchitomi, Y. (2000). Prevalence, predictive factors, and screening for psychologic distress in patients with newly diagnosed head and neck cancer. *Cancer, 88*, 2817-2823.

León, X., Venegas, M. d. P., Orús, C., López, M., García, J., & Quer, M. (2008). Influence of the persistence of tobacco and alcohol use in the appearance of second neoplasm in patients with a head and neck cancer. A case–control study. *Cancer Causes & Control, 20*(5), 645-652. doi: 10.1007/s10552-008-9277-8

Liu, H.-E. (2008). Changes of satisfaction with appearance and working status for head and neck tumour patients. *Journal of Clinical Nursing, 17*(14), 1930-1938. doi: 10.1111/j.1365-2702.2008.02291.x

Llewellyn, C., Weinman, J., McGurk, M., & Humphris, G. (2008). Can we predict which head and neck cancer survivors develop fears of recurrence? *Journal of Psychosomatic Research, 65*(6), 525-532. doi: 10.1016/j.jpsychores.2008.03.014

Mehanna, H. M., De Boer, M. F., & Morton, R. P. (2008). The association of psycho-social factors and survival in head and neck cancer. *Clinical Otolaryngology, 33*, 83-89.

Mehanna, H. M., & Morton, R. P. (2006). Deterioration in quality-of-life of late (10-year) survivors of head and neck cancer. *Clinical Otolaryngology, 31*, 204-211.

Mehanna, H. M., & Morton, R. P. (2006). Does quality of life predict long-term survival in patients with head and neck cancer? *Archives of Otolaryngology-Head and Neck Surgery, 132*, 27-31.

Molina, M. A., Cheung, M. C., Perez, E. A., Byrne, M. M., Dido, F., Moffat, F. L., . . . Koniaris, L. G. (2008). African American and poor patients have a dramatically worse prognosis for head and neck cancer: An examination of 20,915 patients. *Cancer, 113*(10), 2797-2806.

Morton, R. P. (2003). Studies in the quality of life of head and neck cancer patients: Results of a two-year longitudinal study and a comparative cross-sectional cross-cultural survey. *Laryngoscope, 113*, 1091-1103.

Pandey, M., Devi, N., Thomas, B. C., Vinod Kumar, S., Krishnan, R., & Ramdas, K. (2007). Distress overlaps with anxiety and depression in patients with head and neck cancer. *Psycho-Oncology, 16*(6), 582-586. doi: 10.1002/pon.1123

Peugh, J. L., & Enders, C. K. (2005). Using the SPSS mixed procedure to fit cross-sectional and longitudinal multilevel models. *Educational and Psychological Measurement 65*, 717-741.

Piccirillo, J. F., Costas, I., & Reichman, M. E. (2007). Cancers of the Head and Neck. In L. A. Gloeckler Ries, J. Young, J. L., G. E. Keel, M. P. Eisner, Y. D. Lin & M. J. D. Horner (Eds.), Cancer Survival Among Adults: U.S. SEER Program, 1988-2001: Patient and Tumor Characteristics (pp. 7-22). Bethesda: National Cancer Institute.

Reiche, E. M. V., Nunes, S. O. V., & Morimoto, H. K. (2004). Stress, depression, the immune system, and cancer. *Lancet Oncology, 5*, 617-625.

Ronis, D. L., Duffy, S. A., Fowler, K. E., Khan, M., & Terrell, J. E. (2008). Changes in quality of life over 1 year in patients with head and neck cancer. *Archives of Otolaryngology-Head and Neck Surgery, 134*(3), 241-248.

Satin, J. R., Linden, W., & Phillips, M. J. (2009). Depression as a predictor of disease progression and mortality in cancer patients. *Cancer, 115*(22), 5349-5361. doi: 10.1002/cncr.24561

Schantz, S. P., Byers, R. M., Goepfert, H., Shallenberger, R. C., & N., B. R. (1988). The implication of tobacco use in the young adult with head and neck cancer. *Cancer, 62*(7), 1374-1380.

Schnoll, R. A., Rothman, R. L., Wielt, D. B., Lerman, C., Pedri, H., Wang, H., . . . Cheng, J. (2005). A randomized pilot study of cognitive-behavioral therapy versus basic health education for smoking cessation among cancer patients. *Annals of Behavioral Medicine, 30*(1), 1-11.

Spiegel, D., & Kraemer, H. C. (2008). Emotional well-being does not predict survival in head and neck cancer patients. *Cancer, 112*(10), 2326-2327. doi: 10.1002/cncr.23435

Spielberger, C. (1983). *Manual for the state-trait anxiety inventory*. Palo Alto, CA: Consulting Psychologists Press.

Stanislaw, A. E., & Wewers, M. E. (1994). A smoking cessation intervention with hospitalized surgical cancer patients: A pilot study. *Cancer Nursing, 17*(2), 81-86.

Steiger, J. H., & Fouladi, R. T. (1992). R2: A computer program for interval estimation, power calculation, and hypothesis testing for the squared multiple correlation. *Behavior Research Methods, Instruments, and Computers, 4*, 581-582.

Sturgis, E. M., & Cinciripini, P. M. (2007). Trends in head and neck cancer incidence in relation to smoking prevalence. *Cancer, 110*(7), 1429-1435. doi: 10.1002/cncr.22963

Tadbi, A. A., Mehrabani, D., & Heydari, S. T. (2009). Sociodemographic and Etiologic Differences of Malignant Orofacial Tumors in Iran. *Journal of Craniofacial Surgery, 20*(3), 837-840. doi: 10.1097/SCS.0b013e3181a2d62a

Terrell, J. E., Nanavati, K., Esclamado, R. M., Bradford, C. R., & Wolf, G. T. (1999). Health impact of head and neck cancer. *Otolaryngology-Head and Neck Surgery, 120*, 852-859.

Terrell, J. E., Ronts, D. L., Fowler, K. E., Bradford, C. R., Chepeha, D. B., Prince, M. E., . . . Duffy, S. A. (2004). Clinical predictors of quality of life in patients with head and neck cancer. *Archives of Otolaryngology-Head and Neck Surgery, 130*, 401-408.

Tsoh, J. Y., Humfleet, G. L., Munoz, R. F., Reus, V. I., Hartz, D. T., & Hall, S. M. (2000). Development of major depression after treatment for smoking cessation. *The American Journal of Psychiatry, 157*(3), 368-374.

Verdonck-de Leeuw, I. M., Eerenstein, S. E., Van der Linden, M. H., Kuik, D. J., de Bree, R., & Leemans, C. R. (2007). Distress in spouses and patients after treatment for head and neck cancer. *Laryngoscope, 117*.

Vickery, L. E., Latchford, G., Hewison, J., Bellew, M., & Feber, T. (2003). The impact of head and neck cancer and facial disfigurement on the quality of life of patients and their partners. *Head & Neck, 25*, 289-296.

West, R., & Hajek, P. (1997). What happens to anxiety levels on giving up smoking? *The American Journal of Psychiatry, 154*(11), 1589-1592.

BIOGRAPHICAL INFORMATION

Lara A. Trevino was born in Tyler, Texas and spent most of her childhood in Lindale, Texas. She graduated from the University of Texas at Arlington with a B.S. in Biology with a minor in Psychology. During her undergraduate career, she had the opportunity to work with Dr. Perry Fuchs. She completed her Masters of Science in Psychology under the mentorship of Dr. Yuan Bo Peng at the University of Texas at Arlington. Following completion of her Masters in August of 2008, she began working towards her PhD in Health Psychology at the University of Texas at Arlington under the mentorship of Drs. Andrew Baum and Angela Liegey Dougall. Her general research interests include the impact of stress and physiological responding on health outcomes. Following completion of her PhD, she will begin a National Cancer Institute Postdoctoral Fellowship in the Department of Radiation Oncology at the University of Rochester.