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Level Of Demoralization As A Predictor Of Stage Of Change In Patients With Gastrointestinal And Colorectal Cancer

Cheryl Anne Cockram
University of South Florida

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by

Cheryl Anne Cockram

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Major Professor: Mary E. Evans, Ph.D.
Jason W. Beckstead, PhD.
Judith F. Karshmer, PhD.
Michael A. Weitzner, MD

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Dedication

This dissertation is dedicated to the three people who most profoundly impacted my life. First to my mother, Olive Henderson, who taught me the merit of a sense of humour. The memory of her laughter sustained me through this long and arduous process. Then to my father, Norval H. Henderson, who instilled in me the value of knowledge, a deep respect for books and who let me ask the never ending question "why?" Finally to my husband Robert (Eddie) Cockram who taught me to be optimistic, to persevere and to always hit the save button. Without his unconditional support this dissertation would not have happened.

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Level of Demoralization as a Predictor of Stage of Change in Patients with Gastrointestinal Cancer

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ABSTRACT

Demoralization is a concept that evolved out of the study of individuals under stress. It is defined as the combination of distress and subjective incompetence in the presence of inadequate social bonds. When patients with alcohol abuse problems are diagnosed with cancer they may become demoralized and be unable to summons adequate resources to address issues associated with changing their addictive behavior. The Stage of Change Model (SOC), one of the primary approaches in addiction therapy, is used to guide individuals through the process of behavioral change.

This two phase study examined the relationship between demoralization and stage of change. The fist phase was a retrospective chart review (N =112) intended to establish the psychometrics of a new instrument measuring the subjective incompetence component of demoralization. The twelve item Subjective Incompetence Scale (SIS) demonstrated strong internal consistency (.92) and strong indices of being a reliable and valid measure. As expected there was a weak relationship in a positive direction with pain and confusion, a moderate and positive relationship with avoidant coping, and a strong and positive relationship depression, anger and fatigue. There was a moderate and negative correlation with apathy which was also in the direction expected. Phase two was a correlational study using a survey research design, aimed at examining the relationship between alcohol use, depression, level of demoralization and stage of change. The study was done on a convenience sample of patients in colorectal and gastrointestinal clinics at H. Lee Moffitt Cancer Center (N=71). Depression and demoralization were found to be distinct but related constructs. Level of alcohol consumption was not correlated with SOC. The components of demoralization were regressed on Stage of Change to determine

their predictive value. Social support (ISELSF), perceived stress (IES) and subjective incompetence (SIS) resulted in a significant increment in variance explained (R^2). The whole model produced R^2 =.284, F (7, 53) = 2.847, p =.013 which explained a significant portion of the variance in stage of change. Implications for practice and directions for future research are discussed.

CHAPTER ONE

Introduction

There were 7,114,896 cancer-related deaths reported world wide in 2001. Of those 2,306,330 were attributed gastrointestinal cancers (http://www.who.int/health_topics/). Cancer kills an estimated 526,000 Americans yearly, second only to heart disease. Cancers of the lung, large bowel, and breast are the most common in the United States. Considerable evidence suggests a connection between heavy alcohol consumption and increased risk for cancer, with an estimated 2 to 4 percent of all cancer cases thought to be caused either directly or indirectly by alcohol (Rothamn, 1980). Understanding how alcoholism impacts the oncology population is of substantial concern to healthcare providers.

The prevalence of alcoholism in the United States has been determined to be approximately 16%, or 40 million people in the general population (Helzer & Pryzbeck; 1991). Alcohol consumption is measured in liters of pure alcohol according to the alcohol content of beer (4.5%), wine (14%) and spirits (42%). World Health Organization statistics show a fluctuation in alcohol consumption in the United States from a low in 1961 of 6.78 liters of pure alcohol per adult (15 years and older) to a high of 10.51 in 1980 and an estimate of 9.08 in 2000 (http://www3.who.int/whosis/alcohol/alcohol). The use of alcohol contributes to an annual occurrence of approximately 100,000 deaths, and the related health, social, and economic consequences from alcohol use results in additional costs of approximately $100 billion a year (http://www.niaaa.nih.gov/databases/cost.htm). Alcohol use and alcoholism has contributed to 3% to 5% of cancer-related deaths in the under 65 year old population in United States (Doll & Peto; 1981, Higginson & Muir, 1979; Milo, 1981, Doll, Forman, La Vecchia & Wouteersen, 1999). The cancers most commonly associated with alcohol consumption include upper aerodigestive tract cancers, gastric cancer, and small and large bowel cancers. The reason for the increased cancer risk associated with increasing alcohol consumption is not completely

understood (Harris, 1997). It may be due to the carcinogenic effect of the first metabolite of ethanol, acetaldehyde (Harris, 1997, Harty et al., 1997). High intake of beer and spirits has been found to be a risk factor for small bowel adenocarcinomas with an odds ratio of 3.5 for beer and 3.4 for spirits (Kaerlev et al., 2000). Heavy drinkers (mean daily alcohol intake 117 (SD 4) g/day for a mean duration of 22 (SD 0.6) years have a risk factor of developing high-risk adenomas or cancer at an odds ratio of 1.6. (Bardou et al., 2002). The combination of alcohol abuse and a cancer diagnosis may have serious negative consequences for patient outcomes.

At the time of their cancer diagnosis, alcohol abusing patients are not only challenged with a distressing medical illness but often it is the first time they must confront the implication that their addiction to a substance has had dire health implications. They may come into treatment having abstained from alcohol for less than twenty-four hours. This combination of recent abstinence and stress of diagnosis and treatment put the patient at risk for delirium and relapse.

Delirium was recognized as far back as the 16th century (Lipowski, 1991). Its clinical features included a disturbance of consciousness, changes in attention, cognition and perception, with rapid onset and a waxing and waning course (American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders, 1994). Delirium is more likely to occur in those with vulnerable nervous systems, young children, geriatric populations and patients in withdrawal from alcohol. A recent study estimates that delirium impacts lengths of stay for more than 2.3 million geriatric patients each year thus increasing health care dollar expenditures dramatically (Rizzo, Bogardus, Leo-Summers, et al., 2001). Patients developing delirium while hospitalized have poorer outcomes including longer lengths of stay, increased mortality both during hospitalization and post discharge, require high levels of care at discharge and frequently require re-hospitalization or institutionalization (Francis & Kapor, 1992). Further, those who develop delirium while hospitalized are at greater risk for developing dementia (relative risk 3.23, 95 % confidence interval 1.86-5.63) (Rookwood, Cosway & Carver et al., 1999).

Patients who are hospitalized with cancer frequently develop delirium due to the physical challenges of their therapies, the impact of their cancer and pre-existing addictions. Recent studies have found that 28-44% of cancer patients are delirious on admission to the hospital and 68-88% develop delirium before death (Massie, Holland, & Glass, 1983, Minagawa, Uchitomi, Yamawaki, & Ishitani, 1986, Bruera, Miller, McCallion, et al., 1992, Pereira, Hanson, & Bruera, 1997).

Studies of clinical subsets of delirium and associated pathophysiology reveal that metabolic encephalopathy is associated with hypoactive delirium, and withdrawal syndromes induce hyperactive delirium (O'Keefe, & Lavan, 1999). Since delirium in an oncology population is frequently multifactorial, it can be indicative of poor prognosis and shortened survival times (Caraceni, Nanni, & Maltoni, et al., 2000).

Delirium negatively impacts several features of palliative care of cancer patients including pain and symptom management, quality of life and caregiver stress. Since appropriate polypharmacy, paraneoplastic syndromes, dehydration and pre-existing addictions cloud the picture of delirium in cancer patients, it is not surprising that delirium is under recognized and undertreated (Breitbart, Rosenfeld, Roth, et al., 1997).

Addictive behaviors including alcohol abuse have been clearly linked to demoralization (Prochaska, DiClemente & Norcross, 1992). Demoralization has been defined as the combination of distress and subjective incompetence in the presence of inadequate social bonds (Frank, 1974).

Most major theories of addiction postulate a correlation between increasing stress, motivation to use, and relapse (Marlatt & Gordon, 1985; Koob & LeMoal, 1997). Acute stress in the newly abstinent patient may result in a regulation failure that initiates the patterns of behavior which reinforce negative affect and result in relapse. This failure to maintain abstinence results in subjective incompetence and increases the risk of the patient becoming demoralized. Demoralization impedes the patient's perceived ability to initiate change in his or her addictive behaviors.

How people change and what motivates change behavior has been the subject of intense study. Psychotherapeutic approaches focus on patients' efforts to understand and change their behavior and most produce favorable and equivalent outcomes (Luborsky, 1975). More recently researchers have focused on developing a guiding theory of change (Prochaska, DiClemente, & Norcross, 1992). Since the model included primary change processes gleaned from all of the major psychotherapies the authors called it the Stage of Change (SOC). SOC has become one of the primary approaches in addiction therapy and has been used to help patients change negative behaviors as well as initiate positive health related behaviors.

The Stage of Change (SOC) serves as a guide to understanding how demoralization affects patients' efforts to abstain. The model posits that change involves progression through six stages: precontemplation, contemplation, preparation, action, maintenance and termination. Patients in the precontemplation stage are described as "so demoralized they are resigned to remaining in a situation they consider their fate "(Prochaska, 1994, p. 75). The social-emotional and physical consequences of addictive behaviors are stressful. Patients in the precontemplation stage of change may deny their addictive behavior to themselves and others because they feel overwhelmed and helpless. Previous failed attempts to master their addiction may result in subjective incompetence. Since addicted patients tend to associate with addicted peers they may also have inadequate social supports. The triad of stress, subjective incompetence and inadequate social bonds result in demoralization. As the patient moves from precontemplation to contemplation they begin to gather their resources to mount an attempt to change. If the patient takes the risk of acknowledging addiction and meets with support from others they begin to develop a sense of competence. If they meet with failure or inadequate support their subjective sense of incompetence is reinforced. Although each stage of change carries with it the risk of failure and relapses the success of negotiating the previous stage reinforces the patient's sense of mastery and shields them from subjective incompetence. Success is cumulative and failure at a later stage may be a temporary set back until the patient can marshal the needed energy to try

again. Demoralization is seen as an impediment to change and a core concept to designing interventions aimed at promoting change. Since the author postulates that levels of demoralization decrease as patients master each stage, the focus in this study was on the first two stages of precontemplation and contemplation.

Statement of the Problem

Ongoing addictive behaviors negatively impact chemotherapy, pain management, palliation, and end of life care. Practitioners may believe that it is inappropriate to expect patients to give up the comfort or pleasure of his or her addiction at the traumatic time of their diagnosis and initial treatment (Passik & Theobald, 2000). On the contrary, during the time of diagnosis and early treatment the patient may be most open to acknowledgement of his or her addiction and support of their effort to abstain. Understanding demoralization and the role it plays in maintaining the patient's denial of his or her alcohol dependency or reluctance to attempt to abstinence is imperative to the development of interventions for this vulnerable population.

The purpose of this study was to determine the extent to which the level of demoralization can be used to predict stage of change. It is the first step in developing interventions directed at decreasing demoralization and supporting patients' efforts to change behaviors that impact treatment outcomes and quality of life.

The goal of this study is to enhance the understanding of potential psychological processes that influence alcohol abusing patients' acknowledgement of and readiness to address their addiction. This area has been neglected in the oncology research literature. Studying the concept of demoralization in an alcohol abusing cancer population as one of those psychological mechanisms will significantly advance the field and provide important evidence that will lead to the development of specific empirically based interventions directed at improving quality of care. Interventions aimed at reducing appraised stress, increasing social support and challenging subjective incompetence would support patients' efforts to change addictive behaviors. The

development of timely assessments and interventions targeted to an at risk population at the time of admission could significantly reduce patient and family distress, the care burden of nursing staff, hospital costs and patient outcomes. In order to appreciate the development of the concept of demoralization and recent work done in the area a review of literature across the social sciences was undertaken and is described in Chapter Two.

CHAPTER TWO

Review of Literature

Demoralization

The impact of stress on chronic illness and disease outcomes has been the subject of intense study (Selye, 1973; Tache & Selye, 1985; Difede, Ptacek et al., 2002). Coping style, locus of control, hardiness, social support and health promoting behaviors impact how an individual copes with stress (Agrawal & Pandey, 1998; Meijer, Sinnema, Bijstra, Mellenbergh, Wolters, 2002; Moos 2002). Demoralization has been identified as a factor that negatively impacts coping (Clarke, Mackinnon, Smith, Mackenzie and Herrman, 2000; Kearney, 2001). Demoralization, in fact, is a construct that has been applied in a variety of contexts and bears exploration as a concept that accounts for unique variance to overall emotional distress.

Demoralization has been defined as depriving a person of spirit, courage or discipline, destroying their morale and causing confusion and bewilderment (Webster's College Dictionary, 1991). Demoralization appears in the sociological and anthropological literature in reference to society and culture. It is used in psychology, psychiatry and nursing to describe an individual's experience and it is seen again in the medical literature in a physiological context. Clarifying the concept of demoralization is the first step in developing a consistent distinct definition and a working model that will potentially lead to the development of a measurement instrument.

Demoralization in Sociology

Sociology is the study of the origin, development, organization and functioning of human society. In this context demoralization is seen as a social phenomenon with its roots in social dysfunction. Demoralization is described as a state of panic and fear that ranges from discouragement to despair and is used as an offensive strategy employed during warfare to immobilize the enemy (Suarez-Orozoco, 1990). It involves the destruction of faith, loss of

meaning in life, disorganization of governing structure and eventually the disintegration of community fabric (Sullivan, 1941). Approaches to thwart demoralization involve communication, solidarity, and realistic distribution of roles. Based on an assessment of the impact of propaganda and infiltration on the morale of people during wartime, demoralization occurs when there is a threat to one's happiness under circumstances that prohibit rational analysis. In this state of affairs, people begin to believe that they are no longer capable of improving their lot and that they cannot prevent others from making the situation worse.

A number of authors have studied how social stressors impact demoralization in immigrant populations (Westermeyer, Neider & Vang, 1984; Tsvang, 1991; Zilber & Lerner, 1996). These studies have documented that immigrants, whether by choice or by circumstance, experience high levels of psychological stress during the process of social reintegration and that many factors affect the level of demoralization experienced. Work and religious affiliation were found to reduce demoralization by providing social contact and financial resources (Tsvang, 1991). Previous mental health problems, lack of social support, living alone and subjective fears of danger increased levels of demoralization (Zilber & Lerner, 1996).

Demoralization as a Concept in Anthropology

From an anthropological perspective, with its focus on the origin and development of cultures, demoralization is viewed as a societal ill and attributed to state mandated or condoned violence (Scherper-Hughes, 1992). Demoralization is understood as de-moralization or the breakdown of the moral fabric of a culture. When violence is supported by a state against its own populace it serves to subjugate, separate and weaken resistance. By creating an atmosphere of unpredictable, irrational violence, the state engenders chaos and fear, which may prevent its own demise (Desjarlais & Kleinman, 1994). The common thread of demoralization between these two social science disciplines is the sense of disbelief or discomfirmation of what is considered normative and the resulting inability to affect change.

Demoralization as a Concept in Psychology and Psychiatry

In psychology and psychiatry, demoralization evolved out of the concept of hope. In fact, at the midpoint of the last century, demoralization was the condition for which hope was prescribed (Menninger, 1959). Hope was described as a movement forward and a confident search. When one is deprived of hope one gives up, whereas the restoration of hope leads to energetic efforts to survive. It was suggested that apathy results from the withdrawal of hope in chronic mental facilities (Menninger, 1959). The link between hope and demoralization was eventually made in the psychotherapy literature when the practice of encouraging realistic hope was introduced as a means of combating demoralization by reducing perceptual ambiguity (Frank, 1968). Demoralization is associated with the temporary loss of hope; however, it is not hopelessness, which is despair. It is at this point in the evolution of the concept that the contributions from sociology, anthropology and the social sciences merge, leading to a refinement of the construct. Sociology contributed the context in which demoralization develops and anthropology established the discomfirmation of what the patient perceives as normative. The integration of these different views led to the conclusion that demoralization was the combination of distress and subjective incompetence in the presence of inadequate social bonds and the common goal for all psychotherapies was the relief of demoralization (Frank, 1974). Distress is caused by a discomfirmation of the person's expectations of the world as it relates to his or her. Subjective incompetence is a state of self-perceived failure to act in response to a distressing situation in a certain preconceived way according to an internalized standard. An individual might cope effectively with one of these issues, but in combination, they overwhelm and demoralize the person. Social bonds, a sense of community with shared common assumptions about the world, generally prevent the individual from becoming inundated and demoralized. For example, epidemiological studies of individuals and communities under acute stress such as immigration, natural disaster, or economic strain, confirmed that social integration and sense of community act as buffers against demoralization (Fenig & Levav, 1991).

The subjective experience of demoralization has been described as a low mood with pessimistic thinking that may become suicidal at times, passive behavior and sleep and appetite disturbance (Slavney, 1999). Clearly depression and demoralization share some common features.

In the past five years the literature on demoralization in psychology and psychiatry has focused on distinguishing demoralization from depression. Of note, several alternative terms were used across studies to refer to demoralization. This lack of a definitive label has hampered the use of the concept for diagnostic and research purposes. Several authors focus on the difference between major depression and demoralization (Dohrenwend, Shrout, Egri, & Mendelsohn, 1980; Angelino & Treisman, 2001). They use the terms "adjustment disorder", "grief reaction" and "situational or reactive depression" in reference to demoralization. They differentiate between the two concepts saying that the depressive cluster of symptoms that signals demoralization is a normative reaction to severe stressors and does not involve physiological changes. Major depression on the other hand is a physiological disorder that requires intervention with medications and supportive treatments. The authors conceptualize demoralization as responding more effectively to"supportive therapy, hope, therapeutic optimism and time, than to medication" (Angelino & Treisman, 2001). They suggest that demoralization is a minor depression that will resolve in time with supportive therapy.

Clarke, Mackinnon, Smith, Mackenzie and Herrman (2000) enhanced the description of demoralization by studying a diversified population which included all patients admitted to a general medical ward in the Monash Medical Center during the study period. In order to approximate the type of sample most often referred to in previous literature, the authors used a 20/21 cutoff score on the General Health Questionnaire (GHQ). Patients were excluded who could not complete the questionnaire due to mental or physical incapacity or inadequate fluency in English. Of the 2927 patients were screened, 988 scored above the cutoff point and 312 of these patients were randomly selected. Data were gathered using the Monash interview for liaison

psychiatry (Clarke, Smith, Herrman, et al., 1998). The interrater reliability was high (Kappa = 0.83). The data were analyzed using the multidimensional latent trait model and the result was a four dimensional solution that accounted for 34% of the variance. The authors labeled the first dimension, accounting for 12% of the variance, demoralization. The symptoms included in this dimension were: dysphoria, flattened mood, low self-esteem and self-confidence anxiety, and feelings of loss of control and inability to cope. The other dimensions were labeled anhedonia, anxiety and somatic symptoms. Further data were gathered and the authors were able to provide evidence for a fifth dimension of grief reaction. These empirical data supported the idea that grief reaction and demoralization cannot be used interchangeably.

Demoralization in the Nursing Literature

Although the term demoralization has frequently been used in nursing literature (Weiden, 1994; Nayeri, 1995; Sayre, 2001), the concept has not been defined or used in empirical work until recently. Nursing has identified demoralization in various populations that share the common characteristic of overwhelming stress. The concept has been offered as a relevant diagnosis in palliative care and includes increased feelings of dependency relating to subjective incompetence and the perception of being a burden. Demoralization in this population is seen as a significant predictor of desire to die or suicidal ideation (Kissane & Street, 2001).

Demoralization has been used to describe a theme that emerges from a woman's experience of domestic violence, as they give up their notion of romantic commitment to their abusive partner (Kearny, 2001). Demoralization in this context is due to social and emotional isolation and involves immobilization and a sense of having lost control and sanity.

More recently a model of demoralization has been proposed with demoralization as one anchor and depression as the other on a continuum of depressogenic disorders (Rickleman, 2002). In this model cognitive factors including attritional styles, helplessness/hopelessness, pessimism, rigidity, and avoidance of responsibility interact with the situational variable of social isolation to

contribute to a person's vulnerability to demoralization.

Demoralization as a Concept in Pathophysiology

Given that demoralization appears to be a response to a *dist*ressing situation, there may be underlying physiological changes associated with demoralization that underscore the need for early intervention. It has been proposed that stressors might leave their biochemical mark at the level of gene expression and render the individual vulnerable to further occurrences of affective disorders, with an eventual malignant transformation to rapid cycling, spontaneous episodes (Post, 1992).

It is well understood that stress impacts the hypothalmic-ptiuitary-adrenocortical (HPA) axis. A recent study focused on the relationship between the HPA axis, stress and demoralization in a sample of elderly married couples (Jacob, et al., 1997). Sixty-seven dyads of elderly subjects and their spouses were identified. The stressor was an admission of their spouse to hospital for a life threatening illness. The participants were interviewed six times during the 25-month study period using a structured interview. Urine samples were collected and blood samples were drawn to assess neuroendocrine function. Outcomes included depressive symptomology using the Center for Epidemiologic Studies Depression (CES-D), anxiety using the Psychiatric Epidemiology Research Interview – Anxiety (PERI –A), demoralization was measured with the Psychiatric Epidemiology Research Interview – Hopelessness/Helplessness (PERI –HH) and a sense of well being using a single item measure of self rated health. An inverse relationship was found between urinary free cortisol and scores on the Peri-HH at 13 and 25 months. Higher urinary epinephrine output was consistently associated with higher demoralization scores. Although this study was limited by a relatively small sample size the finding of an inverse correlation between urinary free cortisol and demoralization supports the idea that elevated adrenocortical functioning during the acute phase of a stressor might be adaptive to long range recovery.

Apathy

The concept of apathy shares with demoralization a lack of drive or motivation to cope. Apathy is an aspect of a number of neurological and psychiatric disorders and is often considered a presenting feature rather than a single diagnosis. Apathy is distinguished from other disorder of motivation in that it is not attributable to a diminished level of consciousness, an intellectual deficit or emotional distress (Marin, 1990). Apathy is described as a dulled emotional tone associated with detachment or indifference (Kaplan, Sadock & Grebb, 1994). In general, apathy may be seen in response to overwhelming situations such as natural catastrophes, personal loss or tragedy or sudden social and role changes. Apathy may also be associated with certain medical conditions such as frontal lobe injuries or tumors, cerebrovascular traumas or hypoxic brain damage. Apathy is not a simple lack of motivation or emotional blandness, for although patients with frontal lobe injuries may present as apathetic, they are capable of violence and irritability (Marin, 1990). Apathetic states may be seen as a component of some motivational disorders such as hypoactive delirium, dementia, abulia and depression; however, they share only the surface qualities of passivity or compliance but lack the affective indifference that is the hallmark of apathy. Marin (1991) clarified the definition as reduced goal-directed activity in the behavioral, cognitive and emotional domains. In further work, Marin (1997) differentiated apathy from depression saying, "apathy is a syndrome of diminished motivation whereas depression is by definition a disorder of mood".

Andersson, Krogstad and Finset (1999) assessed 72 individuals with brain injuries, who were engaged in rehabilitation for apathy and depression. Apathy was measured using the Apathy Evaluation Scale (AES) developed by Marin (1997). Depression was measured with the Montgomery and Asberg Depression Rating Scale (MADRS) (Montgomery & Asberg, 1979). Psychophysiological data were gathered using heart rate and skin conductance levels (SCL). The individuals were exposed to mental stressors designed to produce psychophysiological reactivity. Apathy was most severe in those individuals with subcortical damage and right hemisphere

damage, regardless of the cause. Apathy and depression had overlapping presentations, in that those individuals who were depressed were more likely to be apathetic. There was an inverse relationship between apathy and physiological reactivity that the authors attributed to emotional indifference.

Fones (1998) warned that apathy and depression, although clinically different, might be symptoms of other syndromes and as a result apathy may be misdiagnosed as depression. He points out that apathy does not respond to antidepressant or supportive therapy and suggests instead that it should be treated with stimulants and dopamine antagonists.

Refer to Table 1 for a comparison of the diagnostic criteria for demoralization and apathy (Marin, 1997).

Table 1
Comparison of the Diagnostic Criteria for Demoralization and Apathy

Demoralization	Apathy
• Affective symptoms of existential distress, including hopelessness or loss of meaning and purpose in life • Cognitive attitudes of pessimism, helplessness, sense of being trapped , personal failure or a lack of a worthwhile future • Conative absence of drive or motivation to cope differently • Associated features of social alienation or isolation and lack of support • Allowing for fluctuation in emotional intensity these phenomenon persist across more that two weeks • A major depressive episode or other psychiatric disorder is not present as the primary condition	• A profound lack of emotional tone with a general impairment of the capacity for encoding and transforming emotional information • Reduced emotional tone does not preclude irritability or violence • The patient is able to verbalize and identify affective states in others • There are deficits in overt behavioral, cognitive and emotional concomitants of goal directed behavior • Lack of motivation that is not attributable to a diminished level of consciousness, an intellectual deficit or emotional distress

Depression

Unlike apathy, depression shares some features with demoralization. Endogenomorphic depression is an un-reactive pervasive impairment of the capacity to experience pleasure or to anticipate pleasure. This inhibition of pleasure results in a lack of interest and investment in the environment (Klein, 1974). Two criteria distinguish demoralization from depression: 1) the presence of subjective incompetence and 2) the magnitude and direction of the patient's motivation (de Figuiredo, 1993). In depression there is a loss of both consummatory and anticipatory pleasure, while in demoralization the patient cannot anticipate pleasure but can experience it. Depressed individuals have decreased motivation to act, while those who are demoralized similarly lack motivation, not due to the loss of drive but to a loss of the self-confidence to act in a manner suited to the solution of their problem. One of the main features of depression anhedonia, or a loss of pleasure or interest in daily activities, does not occur in demoralization (Kissane & Street, 2001). Demoralization is less severe and pervasive than depression. Cognitively the person who is demoralized will be rigid, helpless, uncertain and pessimistic, presenting with anxiety, discouragement and frustration (Rickleman, 2002).

A comparison of the diagnostic criteria for depression as found in the DSM-IV and demoralization as proposed by Kissane and Street (2001), shows the difference in the depth of cognitive impairment, engagement and somatic features (See Table 2).

Adjustment Disorder

Adjustment disorder is the term most similar to demoralization. The DSM-IV states that adjustment disorder is the principal diagnosis for 5 to 20% of adults in outpatient mental health treatment (*DSM-IV*, 1994 fourth edition). Prior to this the term, transient situational disturbance and reactive depression were used to refer to a depressive disorder that resolved without aggressive intervention. Adjustment disorders, like demoralization, are precipitated by a stressor or stressors that overwhelm the individual's capacity to cope.

Table 2
Comparison of the Diagnostic Criteria for Depression and Demoralization

Depression	Demoralization
• depressed mood most of the day, nearly every day, as indicated by either subjective report (e.g. feels sad or empty) or observation made by others • Markedly diminished interest or pleasure in all or almost all activities most of the day, nearly every day • Significant weight loss when not dieting or weight gain or decreased appetite nearly every day • Insomnia or hypersomnia • Psychomotor agitation or retardation nearly every day • Fatigue or loss of energy every day • Feelings or worthlessness or excessive or inappropriate guilt • Diminished ability to think or concentrate or indecisiveness nearly every day • Recurrent thoughts of death, recurrent suicidal ideation without a suicidal plan or a suicide attempt or a specific plan for committing suicide • Five or more of the criteria must be meet during the same two week period and represent a change from previous functioning and at lest one of the symptoms must be criteria 1 or 2	• Affective symptoms of existential distress, including hopelessness or loss of meaning and purpose in life • Cognitive attitudes of pessimism, helplessness, sense of being trapped , personal failure or a lack of a worthwhile future • Conative absence of drive or motivation to cope differently • Associated features of social alienation or isolation and lack of support • Allowing for fluctuation in emotional intensity these phenomenon persist across more that two weeks • A major depressive episode or other psychiatric disorder is not present as the primary condition

The most apparent differences between the two concepts lie in the premorbid personality of the individual and the experience of subjective incompetence. Factors that render a person more susceptible to an adjustment disorder include intellectual impairments that negatively impact the learning of coping skills, rigidity in personality style that isolated the person from peer support or loss of a parent during infancy (Kaplan, Sadock & Grebb, 1994). Subjective incompetence, the hallmark of demoralization, occurs when an individual experiences a stressor that disconfirms their assumptions and expectancies about themselves and others (de Figueiredo,

1982). The stressor threatens the person's self esteem and leads them to question their capacity to cope. If social supports are inadequate and the individual is unable to "check their reality" or validate their experience with peers they become demoralized. A review of the diagnostic criteria for adjustment disorder and demoralization reveals less specific affective symptoms in adjustment disorder and no sense of personalization that occurs with demoralization. Refer to Table 3 for a comparison of the diagnostic criteria that delineate adjustment disorders from depression.

Having determined what demoralization is not, it is now important to determine exactly what it is by defining the concept and offering a model of the interaction of the composite variables.

Demoralization

As proposed in deFiguiredo's 1992 work, demoralization occurs when a person experiences a disconfirming event or stressor in the presence of inadequate social bonds. The person's self-schema is challenged and without the buffering effect of social support a sense of subjective incompetence evolves and the individual becomes demoralized.

Social Support

Social support serves as an emotional buffer and safety net during time of stress. It has been described as social therapy for life's incongruities, a safe haven and a network of others who accept us complete with our imperfections (Moss, 1974). The adequacy of an individual's support system is subjective. What may be adequate for one is insufficient for another and what may be sufficient in one circumstance may seem inadequate when stressors become overwhelming or chronic.

Table 3
Comparison of the Diagnostic Criteria for Adjustment Disorder and Demoralization

Adjustment Disorder	Demoralization
• The development of emotional or behavioral symptoms in response to an identifiable stressor(s) occurring within 3 months of the onset of the stressor. • These symptoms or behaviors are clinically significant as evidenced by either of the following: a. marked distress in excess of what would be expected from exposure to the stressor b. significant impairment in social or occupational functioning • The stress-related disturbance does not meet the criteria for another specific Axis I disorder and is not merely an exacerbation of a preexisting axis I or II disorder • The symptoms do not represent bereavement • Once the stressor or its consequences has terminated the symptoms do not persist for more than an additional 6 months.	• Affective symptoms of existential distress, including hopelessness or loss of meaning and purpose in life • Cognitive attitudes of pessimism, helplessness, sense of being trapped , personal failure or a lack of a worthwhile future • Conative absence of drive or motivation to cope differently • Associated features of social alienation or isolation and lack of support • Allowing for fluctuation in emotional intensity these phenomenon persist across more that two weeks • A major depressive episode or other psychiatric disorder is not present as the primary condition

Stress

It is useful to consider Cohen and Wills' (1985) definition and description of stress. Stress arises when one appraises a situation as threatening or otherwise demanding and believes that it is important to respond, but does not have sufficient coping resources to effect an appropriate response. Feelings of helplessness increase with the individual's subjective inability to cope. If the person has a self-schema of competence and the stress disconfirms that self-perception then self-esteem may be damaged or lost (de Figueiredo, 1982).

Subjective Incompetence

Subjective incompetence occurs when one's self-concept is challenged by a disconfirming event. This discomfirmation engenders feelings of confusion, helplessness, anxiety, uncertainty and social estrangement. As a result of inadequate social bonds the individual has insufficient resources and opportunities to challenge this self perceived failure. When challenged by a new stressor, the individual loses the capacity to act at some minimal level according to some internalized standard (de Figueiredo, 1982). Subjective incompetence accounts for the inability to anticipate pleasure because the individual can no longer see a way out of his or her dilemma.

Figure 1 depicts the proposed model of demoralization in which stress and inadequate social supports interact in the presence of feelings of subjective incompetence and result in demoralization.

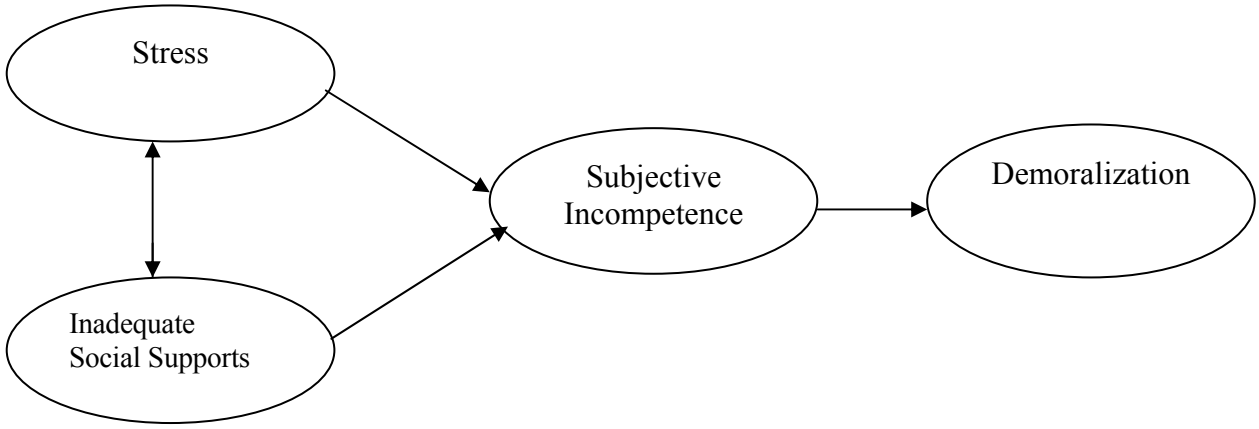

Fig. 1 Proposed Model of Demoralization

The model shows that perceived stress in the presences of inadequate social supports in a subject with a sense of subjective incompetence results in demoralization.

Summary

In reviewing the literature on demoralization, conceptual and methodological difficulties become apparent. The first is the lack of a consensus in the terminology surrounding and the definition of demoralization. Too often the term is used inconsistently or terms such as grief reaction, minor depression, and reactive depression are substituted within the same article. The component variables of demoralization are not clearly labeled. The lack of a consistent clear definition and a working model of demoralization have hampered the development of a measurement instrument. The instruments that are currently available include questions specific to depression, lack sufficient items for subjective incompetence and do not take into account the effect of social support.

Using De Figueiredo's (1982) concept of subjective incompetence and the diagnostic criteria for demoralization proposed by Kissane and Clarke (2001) the above model is proposed to combine features of measurement instruments for the three variables in order to develop a working instrument to measure demoralization.

If, as Post (1992) predicts, affective disorders that occur under stress potentially plant the seeds for future depression, then early, focused, intervention at the beginning of the process may offset the effect or mitigate the outcome. Nursing is in a particularly germane position to intervene. The contact that nurses have with patients provides the opportunity to assess social supports, coping skills, stressors and feelings of subjective incompetence. The therapeutic relationship that is an integral part of nursing care of a patient is an appropriate arena for cognitive therapy. Understanding the components of demoralization may facilitate future research and focused intervention.

De Figueiredo (personal communication, March 29, 2000) developed the Subjective Incompetence Scale (SIS). The first phase of this study was undertaken to validate the SIS. The second phase used the SIS, along with other well established instruments measuring social support and perceived stress, to determine if demoralization could be used to predict stage of

change in a sample of patients with colorectal or gastrointestinal cancer. Chapter three will describe the methodology for both phases.

CHAPTER THREE

This chapter has two integral parts. The first component includes the methods for the first phase of the study. Since phase two of the study is predicated on the outcome of phase one, the results will be described in this chapter prior to the methods for phase two.

Phase One

Definitions

The following section describes the definitions used in phase one. Refer to the Instruments section on p. 25 for the operationalization of these concepts.

Depression

Depression is defined using the criteria for a Major Depressive Episode. The patient experiences symptoms most of the day for more that two weeks at a time. One of two criteria symptoms is present, low mood or loss of interest or pleasure and four of the secondary symptoms: significant weight loss when not dieting, insomnia or hypersomnia, psychomotor agitation or retardation, loss of energy, feelings of worthlessness, diminished ability to think or concentrate, and recurrent thoughts of death (DSM-IV 2001). In this phase of the study depression was operationalized using the Profile of Mood States (POMS).

Subjective Incompetence

Subjective incompetence is a state of self-perceived incapacity to act at some minimal level according to an internalized standard in a specific stressful situation (de Figueiredo & Frank 1982). This concept was operationalized using the Subjective Incompetency Scale (SIS) developed by de Figueiredo (2002).

Apathy

Apathy is dulled emotional tone associated with detachment or indifference (Kaplan & Saddock, 1994). The diagnosis of apathy depends on detecting simultaneous diminution in goal related action, though and emotional responses (Marin, 1997). Apathy was operationalized with the Apathy Evaluation Scale (AES).

Alexithymia

Alexithymia is inability or difficulty in identifying, describing or being aware of one's emotions or moods (Kaplan & Saddock, 1994). The patient may have difficulty discriminating between physical sensations and emotions. Alexithymia was operationalized using the Toronto Alexithymia Scale (TAS).

Purpose of the Study

de Figueiredo (1982) described subjective incompetence as the hallmark of demoralization. During the literature review no instruments were found that included the concept of subjective incompetence. The purpose of the study was to establish the psychometrics of the new scale and enhance the study of demoralization.

Hypotheses

Hypothesis #1

It was hypothesized that subjective incompetence, depression, apathy and alexithymia are distinct but related variables. Bivariate analysis involved computing correlations between scores on the SIS, the POMS, the TAS and the AES. The researcher determined that the presence of a correlation (r = 0.8) or smaller would provide support for the hypothesis that these were distinct but related variables.

Methodology

Research Design

The Phase One study was a descriptive correlational design intended to determine convergent and divergent validity of the Subjective Incompetence Scale (SIS). Subjects were compared on measures of depression (POMS), subjective incompetence (SIS), apathy (AES) and alexithymia (TAS).

Methods

Patients with cancer pain who were treated in the Palliative Care Clinic at H. Lee Moffitt Cancer Center from March through August 2003 were included in the study. Data were collected through retrospective chart review. When patients registered to be seen in the pain clinic they are routinely given an information package to complete prior to their appointment. The information package becomes a portion of their medical record and contains: The General Background Information (GBI), Moffitt Interdisciplinary Pain Program (MIPP) Patient Pain Assessment Guide, the modified Brief Pain Inventory (BPI) the Profile of Mood States (POMS), Brief COPE Scale, the Subjective Incompetence Scale (CIS), the Toronto Alexithymia Scale (TAS), the Apathy Evaluation Scale (AES). The information contained in that portion of the patient's medical record was used to determine baseline and subsequent pain, demoralization and affective scores in the retrospective analysis. This data was routinely collected in the patient record at the initial visit.

Prior to the initiation of the study, approval was sought from the Scientific Review Board at H. Lee Moffitt Cancer Center and the Institutional Review Board at the University of South Florida. (See Appendix A)

Sample Criteria

All patients with cancer related pain treated in the Palliative Care Clinic at H. Lee Moffitt Cancer Center from March through August 2003 who completed the data package were included in this study.

Instruments

Brief Pain Inventory (BPI)

The purpose of the (BPI) is to assess pain in cancer and non-cancer patients by using a self administered questionnaire that measures pain at its worst, its least, average, and current level. It also uses a checklist of adjectives to characterize the pain, and information is collected on the impact of treatment and the impact of pain on function (Daut, et al, 1983; McCormick et al., 1993). The majority of the instrument is scored on a 0-10 numeric rating scale for level of pain and interference with activities from no pain (0) and does not interfere (0) to pain as bad as you can imagine (10) and completely interferes (10). Pain is shaded on a body diagram in areas where the patient feels pain. One question on percent of pain relief with current regimen is included. The instrument is completed if there has been any pain from the current time through the last month. Pain has generally been interpreted on a 0-10 scale as follows: 0-3 (mild pain); 4-6 (moderate pain); and 7-10 (severe pain). The BPI has undergone validity testing through determining the relationship between pain medication use and overall pain ratings. The correlation between usual pain ratings and pain interference was also high (r = .624; p = .001). Test-retest reliability revealed higher reliability when the interval was short (r = .93 for the worst pain, r = .78 for usual pain, r = .59 for pain right now). (See Appendix I)

Toronto Alexithymia Scale (TAS)

The TAS (Kirkmayer & Robbins, 1993) is a self-report questionnaire that measures the ability to describe and identify feelings, the ability to distinguish between feelings and bodily

sensations, the tendency to daydream, and the tendency to exhibit externally oriented thinking. Subjects respond to TAS items (e.g., "I have feelings that I can't quite identify") on a 5-point scale, which ranges from "Strongly Disagree" to "Strongly Agree." The TAS exhibits test-retest stability (one week r = 0.82; five week r = 0.75; Taylor et al., 1985) and construct and criterion-related validity (Bagby, Taylor, & Atkinson, 1988; Kirkmayer & Robbins, 1993). The internal consistency of the TAS ranges from 0.68 (Kirkmayer & Robbins, 1993) to 0.75 (Bagby, Taylor, & Atkinson, 1988). (See Appendix F)

Toronto Alexithymia Scale (TAS) - sample question and scoring

Using the scale as a guide, indicate how much you agree or disagree with each of the following statements by checking the appropriate box. Give only one answer for each statement.

I am often confused about what emotion I am feeling.

1 = strongly disagree

2 = moderately disagree

3 = neither agree or disagree

4 = moderately agree

5 = strongly agree

Profile of Mood States (POMS)

The POMS (McNair et al, 1992) is a 65 five-point objective rating scale that evaluates six affective states: (1) Tension-Anxiety; (2) Depression-Dejection; (3) Anger-Hostility; (4) Vigor-Activity; (5) Fatigue-Inertia; and (6) Confusion-Bewilderment. Internal consistency among these subscales ranged from .87 to .95. Test-retest reliability ranged from .65 to .74. (See Appendix E)

Profile of Mood States (POMS) - sample question and scoring

Below is a list of words that describe feelings people have. Please read each one carefully. Then CIRCLE ONE number which best describes HOW YOU HAVE BEEN FEELING DURING THE PAST WEEK INCLUDING TODAY.

Tense, Fatigue, Energetic, Helpful, etc.

0 = not at all

1 = a little

2 = moderately

3 = quite a bit

4 = extremely

The Brief COPE Scale

The Brief COPE Scale (Carver et al, 1989) is a 60 item scale utilizing a 5-point Likert-type answer format that allows scoring of problem-based coping. It incorporates 15 conceptually distinct scales: Active Coping, Planning, Seeking Instrumental Social Support, Seeking Emotional Social Support, Suppression of Competing Activities, Religion, Positive Reinterpretation and Growth, Restraint Coping, Acceptance, Focus on and Venting of Emotions, Denial, Mental Disengagement, Behavioral Disengagement, Alcohol/Drug Abuse, and Humor. These scales come together into three component scales representing problem-based, emotion-based, and mixed coping strategies. There are two forms that may be used; situational and dispositional. The situational form was used in this study. The instrument has undergone psychometric evaluation and possesses acceptable test-retest reliability (.48-. 77) for the various subscales. Internal consistency assessed by Cronbach's alpha range from .45-92 for the various subscales. (See Appendix G)

Brief COPE Scale - sample question and scoring

We are interested in how people respond when they confront difficult or stressful events in their lives. This questionnaire asks you to indicate what you generally feel when you experience stressful events. Respond to each of the following items by circling one number for each, using the response choices listed. Please try to respond to each item separately in your mind from each other item.

I try to get advice or help from other people about what to do.

0 = I usually don't do this at all

1 = I usually do this a little bit

2 = I usually do this a medium amount

3 = I usually do this a lot

Apathy Evaluation Scale (AES)

Conceptually, apathy is defined as lack of motivation not attributable to diminished level of consciousness, cognitive impairment, or emotional distress. Operationally, the AES (Marin, Biedrzycki & Firinciogullari, 1991) treats apathy as a psychological dimension defined by simultaneous deficits in the overt behavioral, cognitive, and emotional concomitants of goal-directed behavior (Marin 1997). The AES is an 18-item instrument using a 4-point Likert-type scale ("1" = not at all; "4" = a lot). This instrument has been shown to have validity and interrater reliability. Test–retest reliability coefficients from 0.81 to 0.90 have been obtained. It is important to note that a high score on the apathy evaluation scale is interpreted as a lower level of apathy. (See Appendix H)

Apathy Evaluation Scale (AES) - sample question and scoring

Please read the items below that pertain to your interests and daily routines. Then, check the box that most closely agrees with how characteristics the statement is for you. Please check only one box per item. Ratings should be based on the past 4 weeks.

Getting things started on my own is important to me.

1 = not at all

2 = slightly

3 = somewhat

4 = a lot

Subjective Incompetence Scale (SIS)

The subjective incompetence scale is a 12-item scale developed by deFiguiredo (2000) to measure the hallmark of demoralization. Items include stress evaluations, performance inadequacy and indecisiveness. This instrument has face and content validity. (See Appendix D)

Subjective Incompetence Scale (SIS) - sample question and scoring

Below are several statements about how people feel when they experience a stressful situation. Please read each statement carefully and choose the numbered response that best describes how you felt when you were trying to deal with your diagnosis.

Were you able to plan and initiate concerted action as well as you thought you could?

0 = none of the time

1 = a little bit of the time

2 = a good bit of the time

3 = most of the time

4 = all of the time

Informed Consent

Since the study was a retrospective chart review and patient identification was not included in the collected information an exempt status was approved by the Institutional Review Board (IRB). (See Appendix A)

Data Collection

During the period from March through August 2003, all patients meeting the study's inclusion criteria of cancer pain who were treated in the Palliative Care Clinic at Moffitt Cancer Center were identified using palliative care service records. The researcher briefly reviewed the medical records of all potential study participants for obvious exclusion criteria. If no exclusion criteria were found, a retrospective chart review was performed.

Data Management

An Excel database that was password protected was used to track survey response, maximize efficiency and minimize the cost of data collection. Each chart was assigned a unique identifier. The researcher entered the data into the excel sheet and imported it into a SPSS spreadsheet for analysis.

Missing Data

Any missing item in a multiple item scale could significantly affect the data analysis. In order to maximize the usage of all collected data the following rules were used to deal with missing items.

1. In order to use any replacement score at least eighty percent of the items had to have been completed by the respondent
2. The mean of the subject's responses was used as a replacement score.

Data Analysis

The data were entered into SPSS (version 9.0 for Windows). Univariate statistics were used to describe the sample. Bivariate correlations with two-tailed test of significance were run on all of the scales. The resulting correlation matrix was examined for similarity and differences in the Pearson product moments.

Results

Descriptive statistics, including univariate frequency distributions, means and standard deviations were calculated to examine the characteristics of the sample. Of the charts reviewed, 112 met the inclusion criteria. The subjects' ages ranged from 20 to 81 years with a mean age of 52.46 (SD = 12.22). The sample was composed of 48% males and 52% females. The racial diversity of the sample reflected the population of patients treated at H. Lee Moffitt Cancer Center. Sixty-seven percent were White, 1.8% were Black and the remaining 4.5% were Hispanic and other minorities. Nearly 26% (25.9%) of the respondents chose not to answer the ethnicity question. The reliabilities of the scales were examined to determine the internal consistency at the time of administration of the questionnaires. Internal consistency assessed by Cronbach's alpha were as follows: SIS .92, POMS .89, TAS.81, Cope.75 and AES.83. The values of the reliability estimates ranged from .75 to .92 indicating sufficient reliability to continue with the analysis of the data. The scales were recoded according to instructions. Means were inserted for missing values at 80% in order to maximize the available data.

To assess convergent and divergent validity of the SIS, the Pearson correlation coefficients were examined between the subjective incompetence scale, the full scales and the subscales for direction and level of significance. The SIS was compared to the Brief Cope, TAS, AES, and the POMS. There was a weak but significant relationship with the Brief Cope r =.195 (p=.03). There was a weak and significant relationship with the TAS, r =.296 (p= .002) and a moderate negative and significant relationship with the AES, r = -.425 (p<.001). It is important to

note that higher scores on the AES indicate lower levels of apathy. There was a strong and significant correlation with the POMS r =.714 (p<.001). For the subscale of the Brief Cope that pertains to aviodant coping strategies a moderate and significant relationship was found r = .531(p<. 001). The Apathy Evaluation Scale is divided into subscales that reflect a deficit in the areas of behavioral (AESBEH), cognitive (AESCOG) and emotional (AESEMT) concomitants of goal-directed behavior. The findings for the AES subscales were AESBEH -.376 (p<.001), AESCOG r =-.396 (p<.001) and AESEMT r = -.216(p=.02). The POMS examines the mood states of Tension-Anxiety, Depression-Dejection, Anger-Hostility, Vigor-Activity, Fatigue-Inertia, and Confusion-Bewilderment. For the POMS subscales the findings were Tension-Anxiety r = .295 (p =.002), Depression-Dejection r =.720 (p<.001), Anger-Hostility r =.667 (p<. 001), Fatigue-Inertia r = .667 (p<.001), Vigor-Activity r = -.598 (p<. 001), Confusion-Bewilderment r = .243 (p = .01) (See Table 4).

Discussion

The twelve-item Subjective Incompetence Scale examined in this study demonstrated strong internal consistency (.92) and strong indices of being a reliable and valid measure of subjective incompetence. As expected there was a weak relationship in a positive direction with pain and confusion, a moderate and positive relationship with avoidant coping, and a strong and positive relationship depression, anger and fatigue. There was a moderate and negative correlation with apathy which was also in the direction expected. The relationship with depression (r =.720; p<.001) demonstrated that subjective incompetence and depression share 52% unique variance. The controversial concept of distinct but overlapping constructs was addressed with a review of literature in the area.

That constructs may be distinct but related has been discussed in the psychology literature. The concern that constructs with moderate to large correlations might not be distinct

Table 4
Pearson correlations between the Subjective Incompetence Scale (SIS) and related variables.

Variables	SIS	DEP	PAIN	COPE	AES	ANG	FAT	CON	AVOID
SIS	1.000								
DEP	.720 .000	1.000							
PAIN	.240 .011	.262 .005	1.000						
COPE	.195 .039	.106 .226	.138 .144	1.000					
AES	-.425 .000	-.483 .000	-.066 .487	.259 .006	1.000				
ANG	.667 .000	.737 .000	.137 .151	.165 .081	-.349 .000	1.000			
FAT	.691 .000	.861 .000	.294 .002	.113 .236	-.415 .000	.726 .000	1.000		
CON	.243 .010	.469 .000	.257 .006	.006 .950	-.159 .095	.259 .000	.524 .000	1.000	
AVOID	.531 .000	.525 .000	.253 .007	.450 .000	-.241 .010	.376 .000	.362 .000	.251 .008	1.000

Note: Table abbreviations are Subjective Incompetence Scale (SIS), Depression (DEP), Pain (PAIN), Brief COPE (COPE), Apathy Evaluation Scale (AES), Anger (ANG), Fatigue (FAT), and Confusion (CON).

was addressed during the development of the Toronto Alexithymia Scale (TAS) that was used in this study. Alexithymia measured with the TAS and depression operationalized with the Beck Depression Inventory showed a moderately high correlation (r =.60, n=81, p = .001) in an undergraduate student population. Investigations in abstinent alcoholics, substance abusers and medical students demonstrated similar correlations. A study using the statistical method of factor analysis yielded a four-factor solution with virtually no overlap of the factor loadings on the respective constructs (Parker, Bagby & Taylor, 1991). This method has since been used to clarify

the distinction between similar constructs of anxiety and depression (Endler, Macrodimitris, 2003) and depression and alexithymia (Hintikka, Honkalampi, Lehtonen, & Viinamaki, (2001). Further testing of the SIS was carried out in phase two of this study.

Phase Two

Once reliability and validity had been established for the Subjective Incompetence Scale the application for phase two of the study was sent to the Scientific Review Committee (SRC) of H. Lee Moffitt Cancer Center. Following the receipt of the letter of approval from the SRC an application for the study was sent to the Institutional Review Board of the University of South Florida. Once the study was approved by the IRB (Appendix B), data collection was started. The intent of the second study was to determine if level of demoralization could be used to predict the stage of change (SOC) according to the Transtheroretical Theory of Change (TCC). The study was guided by the logic model depicted in Figure 2.

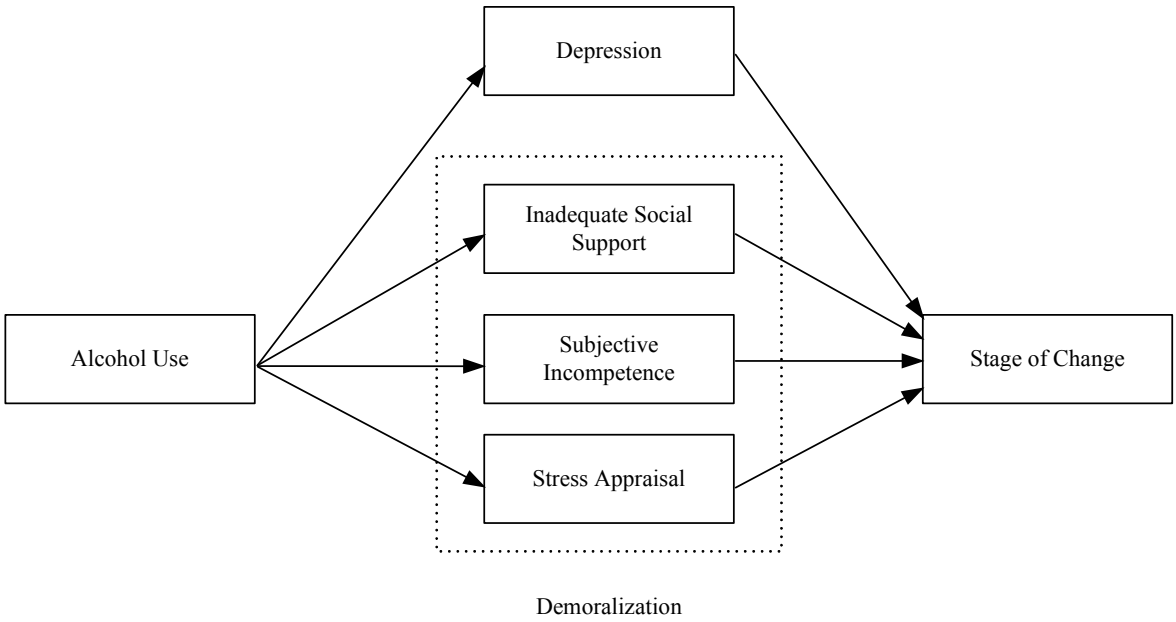

Figure 2 Logic Model for Predicting Stage of Change from Level of Demoralization

The logic model depicts the interactions between alcohol, the three components of demoralization, depression and stage of change. Demoralization is seen as a mediating variable between alcohol and stage of change. Depression was assessed as a moderate in the relationship.

Definitions

Alcohol Abuse

A maladaptive pattern of alcohol use leading to clinically significant impairment or distress as manifested by one or more of the following symptoms occurring within a twelve month period: recurrent alcohol use resulting in a failure to fulfill major role obligations at work, school or home, recurrent alcohol use in situations in which it is physically hazardous, recurrent alcohol related legal problems, continued alcohol use despite having persistent or recurrent social or interpersonal problems caused by or exacerbated by the effects of alcohol (DSM-IV, 2001). Alcohol abuse was operationalized using the patient's self-report and the Structured Clinical Interview for DSM-IV-TR (SCID) Alcohol Module.

Depression

Depression is defined using the criteria for a Major Depressive Episode. The patient experiences symptoms most of the day for more that two weeks at a time. One of two criteria symptoms is present, low mood or loss of interest or pleasure and four of the secondary symptoms: significant weight loss when not dieting, insomnia or hypersomnia, psychomotor agitation or retardation, loss of energy, feelings of worthlessness, diminished ability to think or concentrate, and recurrent thoughts of death (DSM-IV, 2001). Depression was operationalized in phase two of the study using the Center for Epidemiologic Studies Depression Scale (CES-D).

Inadequate Social Support

Social supports are the meaningful connections that link an individual to others in their social network. They are composed of shared symbols, common sentiments and values that are dominant in that group (de Figueiredo & Frank, 1982). Support is expressed in terms of physical and psychological comfort provided by friends and relatives in times of stress. The sense of social engagement provides a safe ground for the individual to reflect on their experiences. Social support functions to give a person broader focus on a problem and positive self-image. The adequacy of an individuals' support system is self perceived, whereas one individual with two close friends has adequate social support another may need the support of ten or more friends to feel supported. Inadequate social supports put an individual at risk for isolation, misinterpretation of experiences and damaging assessments of their personal competence.

Subjective Incompetence

Subjective incompetence is a state of self-perceived incapacity to act at some minimal level according to an internalized standard in a specific stressful situation (de Figueiredo & Frank, 1982).

Distress

Distress is an emotional response to a self-perceived threatening situation. It is manifested by symptoms, such as anxiety, sadness, discouragement, anger and resentment.

Demoralization

Demoralization occurs when a person experiences a disconfirming event or stressor in the presence of inadequate social bonds. The person's self-schema is challenged and without the buffering effect of social support a sense of subjective incompetence evolves and the individual becomes demoralized. (de Figueiredo, 1992).

Stage of Change (SOC)

Stage of Change is a six-stage theory of change developed by Prochaska, Norcross and Diclemente (1992) used to guide individuals through the process of behavioral change.

Precontemplation. Precontemplation is the first identified stage in the SOC. In this stage the individual is not aware that the target behavior is causing problems.

Contemplation. Contemplation is the second stage of the SOC in which the individual becomes aware of the target behavior and begins to think seriously about changing it. The transition from this stage to the next is marked by concentration on solutions to the problem behavior and on the concept of a future without the target behavior.

Preparation. During this stage the individual plans to change their behavior within the next six months. They make public their intention to change and prepare for action. Individuals in this stage may still be ambivalent about changing their behavior

Action. In this stage the person commits to change. They take the actions that surround the change process and confront their fears and ambivalence.

Maintenance. The work in this stage is the consolidation of the previous stages and requires a strong commitment to nurture and support the continued effort to sustain the new behavior.

Termination. The final stage of change is one in which the new behavior becomes the default behavior. Experts debate the stability of this stage. Some believe that once this stage is completed the individual is no longer at risk for relapse; others claim that this stage continues

throughout the individual's lifetime and that there is always a risk that stressors could trigger a relapse.

Purpose of the Study

Diagnosis, physical illness and invasive therapies all contribute to the burden of stress experienced by oncology patients. Ongoing addictive behaviors negatively impact chemotherapy, pain management, palliation, and end of life care. Although many patients intend to abstain from their substance of choice, acute stress in the newly abstinent patient may result in a regulation failure that initiates the patterns of behavior that reinforce negative affect and result in relapse. Demoralization plays a significant role in the patient's perceived inability to change addictive behaviors or in maintaining that change.

The ultimate goal of this study is to enhance the understanding of potential psychological processes that influence alcohol-abusing cancer patients' acknowledgement of and readiness to address their addiction. This area has been neglected in the oncology research literature. Studying the concept of demoralization in an alcohol using cancer population as one of those psychological mechanisms will significantly advance the field and provide important evidence that may lead to the development of empirically based interventions directed at improving quality of care. Interventions aimed at reducing appraised stress, increasing social support and challenging subjective incompetence may support patients' efforts to change addictive behaviors.

Hypothesis

Hypothesis 1

Depression and demoralization are distinct but related variables.

Hypothesis 2

Patients with higher levels of alcohol consumption will have higher levels of the three components of demoralization (i.e., subjective incompetence, inadequate social support, and perceived stress).

Hypothesis 3

Increased levels of demoralization will predict lower scores on Stage of Change (SOC).

Methodology

Research Design

Phase two was a correlational study using a survey research design, aimed at examining the relationship between alcohol use, level of demoralization and stage of change. Subjects were compared on measures of depression (CES-D), subjective incompetence (SIS), stress appraisal (IES), social support (ISELSF) and stage of change (SOC).

Methods

The researcher identified potential subjects by screening the Gastrointestinal Clinic schedule. When potential subjects registered they were approached in the waiting area and offered the opportunity to participate in the study. In order to assure that the clinic flow was not interrupted the subjects were taken to a consult room, the informed consent and HIPAA (Health Insurance Portability and Accountability Act, 1996) papers were signed and the Structured Clinical Interview for DSM-IV-TR (SCID) modules were completed. Permission for use of SCID Research Modules was sought (Appendix K). The subjects were then given the survey package, with a pencil enclosed, in a return-mailing envelope. Many subjects completed the survey while waiting for their appointments and returned them to the research member.

Sample Criteria

The sample for this dissertation research consisted of 62 subjects recruited from three gastrointestinal clinics at Moffitt Cancer Center. The sample included both men and women of a range of ethnic backgrounds that reflected the patient population at Moffitt Cancer Center, who met the following criteria:

1. Between 20 and 90 years of age
2. A diagnosis of colorectal or gastrointestinal cancer
3. Able to read and understand English

Individuals, who were near to end of life, as defined by hospice admission, were excluded.

Power Analysis

The number of subjects was determined using statistical power analysis. With an alpha of .05 assuming a medium effect size (r =. 25) and power of .80 the number of subjects required was a total of 120. When data had been gathered and analyzed on sixty-one subjects the regression model produced a change in R^2 = .273, F(3,53)= 3.049, p =.036 and the data collection was discontinued.

Instruments

Variables measured included: the individuals' demographic characteristics, level of alcohol consumption (SCID Alcohol Module and patient's self-report), level of depression (CES-D, SCID Mood Module), perceived stress (Impact of Events Scale, ECOG-PSR), social support (Interpersonal Social Evaluation List), and stage of change (Stage of Change Assessment for Alcohol). The six questionnaires and the demographics data form required approximately 30-45 minutes to complete.

The Structured Clinical Interview for DSM-IV-TR (SCID)

The Structured Clinical Interview for DSM-IV-TR (SCID) is a semi-structured diagnostic interview designed to assist clinicians, researchers, and trainees in making reliable DSM-IV psychiatric diagnoses. For the purpose of this study, the Mood and Alcohol modules were used in the initial interview of the subject. (See Appendices L and M)

Center for Epidemiologic Studies Depression Scale (CES-D)

The CES-D (Radloff, 1977) is a 20-item self-report screening measure developed by the National Institute of Mental Health (NIMH) for assessing the frequency of depressive mood and symptoms during the past week. The respondent selects one of four encoded choices: (less than 1 day = 0; 1 to 2 days = 1; 3 to 4 days = 2; and 5 to 7 days = 3). The scale includes four reverse scored items phrased in a non-depressive direction. A total score indicative of the level of depression symptoms is the sum of the 20 weighted responses (Radloff, 1977). In the general population, a cutpoint score of 16 or greater suggests a high level of depressive symptoms. The CES-D has well-established normative, reliability, and validity data [inter-item reliability estimates (.80s to .90s), test-retest reliability coefficients (.40s to .70s), and correlations to the BDI (> .80). (See Appendix J)

Center for Epidemiologic Studies Depression Scale (CES-D) - sample question and scoring

Fill in the number for each statement which best describes how often you felt or behaved this way – DURING THE PAST WEEK.

I was bothered by things that usually don't bother me.

0 = none of the time

1 = a little of the time

2 = occasionally

3 = all of the time

Impact of Events Scale (IES)

The IES (Horowitz, Wilner, & Alvarez, 1979) is a broadly applicable self-report measure designed to assess current subjective distress for any specific life event. It is a 15-item questionnaire evaluating experiences of avoidance and intrusion, which attempts to "reflect the intensity of the post-traumatic phenomena". Both the intrusion and avoidance scales have displayed acceptable reliability (alpha of .79 and .82, respectively). (See Appendix N)

Impact Events Scale (IES) - sample question and scoring

Below is a list of comments made by people about stressful events. For each item, fill in the circle that indicates how frequently the comments were true for you.

I had waves of strong feelings about it.

0 = not at all

1 = rarely

2 = sometimes

3 = often

Subjective Incompetence Scale (SIS)

The Subjective Incompetence Scale (de Figueiredo, 1982) is a twelve-item scale that was piloted in Phase One for use in this dissertation. It had face validity, reliability with a Cronbach's alpha of .92. (See Appendix D)

Subjective Incompetence Scale (SIS) - sample question and scoring

Below are several statements about how people feel when they experience a stressful situation. Please read each statement carefully and choose the numbered response that best describes how you felt when you were trying to deal with your diagnosis.

Were you able to plan and initiate concerted action as well as you thought you could?

0 = none of the time

1 = a little bit of the time

2 = a good bit of the time

3 = most of the time

4 = all of the time

Eastern Cooperative Oncology Group Performance Status Rating (ECOG)

The ECOG (Zubrod, et al. 1960) is one item using a 5-point Likert-type format that measures functional status from "0-fully ambulatory with no symptoms" to "4-spending 100% of time in bed." It is one of the most commonly used measures of functional status on the oncology literature. It has been shown to have acceptable validity and reliability. (See Appendix O)

Eastern Cooperative Oncology Group Performance Status Rating (ECOG) - sample question and scoring

Please fill in the circle next to the number that describes your current level of activity.

Capable of only limited self care, confined to bed or chair more than 50% of waking hours.

0 = fully active

1 = physically restricted but ambulatory

2 = ambulatory and capable of self care

3 = limited self care; confined to bed 50%

4 = completely disabled

Stages of Change Assessment for Alcohol (*SOC)*

The Stages of Change Assessment for Alcohol is a six-item questionnaire developed by Laforge et.al. (1998) to determine which stage of change an individual is currently in regarding alcohol related behaviors. (See Appendix Q)

Stage of Change (SOC) - sample question and scoring

Select the single item that best describes you. In the last month have you had 5 or more drinks in a row? (Females use 4 or more drinks in a row)

Yes, and I do not intend to stop drinking 5 or more drinks in a row.

1 = precontemplation

2 = contemplation

3 = preparation

4 = action

5 = maintenance

6 = termination

Marlowe-Crowne Social Desirability Scale (MC)

The Marlowe-Crowne Social Desirability Scale (M-C 20) (Crowne & Marlowe, 1960) is a 20-item true-false scale that is commonly used to measure defensiveness. It asks the respondent about common negative traits (e.g., jealousy) and positive characteristics of unusual levels of responsibility and general virtue. The items were chosen to be unrelated to psychopathology. The MC has good internal consistency (KR-20 = 0.88) and test-retest reliability (r = .89).

(See Appendix R)

Marlowe-Crowne Social Desirability Scale (M-C 20) - sample question and scoring

Listed below are a number of statements concerning personal attitudes and traits. Read each item and fill in T for true and F for false to indicate how each statement applies to you.

I'm always willing to admit it when I make a mistake.

0 = false

1 = true

ISELSF (Interpersonal Social Evaluation List-Short Form)

The 40-item ISEL (Cohen, Mermelstein, Kamarck & Hoberman, 1985) has four sub-scales, each intended to measure the availability of a different type of social support: tangible, concerning the provision of material aid; appraisal, the belief that one has people to turn to for advice on one's problems; self-esteem, the belief that one's status is equal to that of friends; and belonging, concerning access to people with whom one can engage in activities. Across several studies, alpha coefficients for the four subscales have ranged from .62 (self-esteem) to .82 (appraisal), and two-day test-retest reliability coefficients have ranged from .67 (belonging) to .84 (appraisal). (See Appendix P)

Interpersonal Social Evaluation List – Short Form (ISELSF) - sample question and scoring

This scale is made up of a list of statements, each of which may or may not be true about you. Please read each statement, then fill in the circle that best describes how true or false that statement is about you.

If I were sick, I would have trouble finding someone to help me with my daily chores.

1 = completely false

2 = somewhat false

3 = somewhat true

4 = completely true

Informed Consent

Prior to enrollment, the purpose of the study, voluntary participation, benefits and potential risks were verbally described to potential subjects by the researcher. They were also given a proper copy of the informed consent that contained contact information. (See Appendix S)

Research Authorization

Prior to enrollment in the study the Health Information Portability and Accountability Act document was explained to potential subjects. They were informed of the measures taken to protect their privacy and given a hard copy of the Research Authorization document / HIPAA document. (See Appendix T)

Data Collection

The study sample consisted of patients with a diagnosis of gastrointestinal (GI) or colorectal (CR) cancer from three gastrointestinal clinics at Moffitt Cancer Center. During the period from August 2003 through February 2004, all patients meeting the study's inclusion criteria were approached and invited to participate. A member of the study team reviewed the informed consent and HIPAA documents with them, interviewed them using the Mood and Alcohol SCID and gave them a self addressed envelope that contained the study surveys. The subject had the option of completing the surveys while in the clinic or returning them by mail.

Data Management

In order to ensure confidentiality a password protected Excel spreadsheet was used to track survey response, maximize efficiency and minimize the cost of data collection. Each subject was assigned a unique identifier. Data was collected on Teleform and entered into an Excel spreadsheet. It was then imported into an SPSS program and descriptive statistics were used to describe the characteristics of the sample. The data were examined for data entry accuracy, distribution and outliers.

Missing Data

Any missing data in a multiple item scale can have a significant effect on data analysis. The scoring of the CES-D, IES, ECOG, IES, ISEL and the SOC is the summation of the instruments items. Therefore, missing data were replaced with a mean of at least 80% of valid items For example the missing data of the ISEL could be replaced when at least twelve of fifteen items were answered.

Data Analysis

Hypothesis #1. Depression and demoralization are distinct but related variables. The relationship between depression and demoralization was assessed by examining the correlation between depression and the three components of demoralization (i.e., subjective incompetence, stress appraisal, inadequate social support). It was hypothesized that depression and demoralization are distinct but related variables. Univariate analysis involved computing correlations between scores on the CES-D, SIS, and the scores for the various measures of perceived stress and social support (IES and ISEL). The authors determined that presence of a moderate correlation ($r < 0.8$) would provide support for the hypothesis.

Hypothesis # 2. Patients with higher levels of alcohol consumption will have higher levels of the three components of demoralization (i.e., subjective incompetence, inadequate social support, and perceived stress). The extent of the relationship between alcohol use and the components of demoralization were determined by examining the correlations of alcohol use with scores on the three components of demoralization. It is also suggested that there would be a social desirability bias in self-report of alcohol use. To determine the extent of the relationship between alcohol use and the components of demoralization, Pearson product moment correlations were calculated using the alcohol use question, , SIS, IES, and ISELSF. To determine the impact of social desirability on self report of alcohol in this population, a Pearson product moment correlation was calculated using the alcohol use question (Drinkday) and the Marlowe-Crowne.

Hypothesis #3. Increased levels of demoralization will predict lower scores on Stage of Change (SOC). The relative importance of depression and the three components of demoralization as predictors of stage of change was assessed by regressing the stage of change scores on the four variables. The importance of depression and the construct of demoralization as predictors of stage of change were determined through a multiple hierarchical regression analysis. Pearson product moment correlations were performed on the demographic and medical variables with stage of change. Those demographic and medical variables that were found to be significantly correlated to stage of change or were integral parts of the model were entered into the first step of the hierarchical regression equation. The next regression equation consisted of the significant demographic and medical variables and depression (i.e., CES-D) that were forced into the first step. This determined the amount of variance in stage of change for which depression is responsible above and beyond that responsible by the demographic and medical variables. The three components of demoralization (i.e., subjective incompetence, stress appraisal, inadequate social support) were then allowed to enter in the third step of the regression equation in order to determine the amount of variance in stage of change for which demoralization was responsible.

The author determined that a $R^2 > 0.06$ would support the hypothesis that demoralization serves as an independent predictor of stage of change.

The results of the data analysis for the second phase of the study are presented in Chapter Four.

CHAPTER FOUR

Results

Descriptive Statistics

Descriptive statistics, including univariate frequency distributions, means and standard deviations were calculated to examine the characteristics of the study sample for phase two. A total of 91 subjects were approached to participate in the study. Of that number, 11 (12 %) subjects refused citing pain, or concern that their appointment with the physician might be delayed, 4 (5 %) withdrew from the study, 1 (1%) deceased, 9 (10 %) did not return their packages and 71 (78 %) packages were completed and returned. Of those that withdrew from the study the majority cited worsening illness as the reason. Twenty-seven (38%) of the potential participants were female and 62 (62%) were male. Their ages ranged from 28 to 85 with a mean age of 61years (SD=13.47). Racial diversity was not well represented in the sample. Of the potential participants 6 (7%) were Hispanic, 1 (1%) was Asian, 3 (3%) were Black and 80 (89%) were White. This was consistent with the population served by the cancer center.

The data collection was conducted from August 5, 2003 through February 12, 2004. Table 5 is a comparison of the demographics for those with alcohol abuse (+ETOH), those without alcohol abuse (-ETOH), those with depression (+Depression), those without depression (-Depression) and those who were approached and declined to participate in the study.

Univariate analysis

The reliability of the scales was examined to determine the internal consistency of the mean of the items on each scale at the time of administration of the questionnaire. Internal consistency coefficient assessed by Cronbach's alpha were as follows Subjective Incompetence Scale (SIS) .80, Impact of Events scale (IES) .91, Interpersonal Social Evaluation List Short Form (ISELSF) .81, Center for Epidemiologic Studies Depression Scale *(*CES-D) .77. The values of the reliability estimates ranged from .75 to .92 indicating sufficient reliability to continue with the analysis of

the data. The scales were recoded according to scoring instructions. Missing values were dealt with by inserting mean scores in scales where subjects had answered at least eighty percent of the questions in the scale in order to maximize the available data.

Table 5
Comparison of Respondents on Alcohol & Depression Screens to Subjects that Refused.

	+ETOH	-ETOH	+Depression	-Depression	Refused
Mean Age	59	63	62	62	59
Ethnicity					
White	91%	90%	100%	88%	80%
Black	0%	5%	0%	4%	0%
Hispanic	9%	5%	0%	8%	10%
Asian	0%	0%	0%	0%	10%
Gender					
Male	78%	55%	31%	69%	30%
Female	22%	45%	69%	31%	70%
Cancer					
Gastric	4.3%	10%	0%	8%	10%
Colon	39.1%	43%	56%	42%	20%
Rectal	47.8%	32%	31%	34%	60%
Pancreatic	4.3%	12%	13%	12%	10%
Liver	4.3%	3%	0%	4%	0%

Hypothesis Testing

Hypothesis #1

It was hypothesized that depression and demoralization are distinct but related variables. The Logic Model of Demoralization and Stage of Change (Figure 2) was used to guide the analysis and hypothesis testing. The relationship between depression and demoralization was assessed by examining the correlation between depression measured by Center for Epidemiologic Studies Depression Scale (CES-D) and the three components of demoralization Subjective incompetence Scale (SIS), Impact of Events (IES), and the Interpersonal Social Evaluation List (ISELSF). A total of 71 individuals had valid scores on the variables for depression and the three components of demoralization. IES (.188 p = .117) was slightly but not significantly correlated

with CES-D. The [(SIS), (.226 p = .058)] and the (ISELSF), (-.242, p = .042)] were slightly and significantly correlated with the (CES-D*)* It was noted that the correlation between the SIS and the CES-D were much lower than the correlation between the SIS and the depression/dejection sub-scale on the Profile of Mood States in phase one, despite the fact that both scales measure depression. This issue will be discussed in the interpretation section on p.59. This hypothesis was supported.

Hypothesis #2

It was hypothesized that those patients with higher levels of alcohol consumption would have higher levels of the three components of demoralization. The extent of the relationship between alcohol use and the components of demoralization was determined by examining the correlations of alcohol use with scores on demoralization. Current alcohol use (Drinkdays) was not correlated with subjective incompetence (SIS)(-.024 ,p=.842), social support (ISELSF) (-.117, p=.329) or perceived stress (IES)(.115,p=.341). When none of the correlations were significant, a secondary analysis of the means of the components of demoralization on the SCID Alcohol Module confirmed these results. This hypothesis was not supported.

The researcher suspected that the correlation between levels of alcohol use (Drinkdays) and the components of demoralization (SIS, IES, and ISELSF) was so low because subjects did not report their alcohol consumption accurately due to social desirability bias. To determine the impact of social desirability on self-report of alcohol use in this population, a Pearson product moment correlation was calculated using Alcohol (Drinkdays) and the Marlowe-Crowne (MC-20). Of 71 subjects only 63 subjects answered the alcohol use question. In order to maximize the data available the group mean was inserted for the subjects who did not respond to the alcohol use question. The report of alcohol use was slightly but significantly correlated with social desirability (-.275, p=.020). This indicates that there was a social desirability bias in the reporting of alcohol use. Further discussion of this result can be found in the interpretation section.

Hypothesis #3

It was hypothesized that increased levels of demoralization would predict lower scores on Stage of Change (SOC). The means of the components of demoralization were compared on Stage of Change (See Table 6).

Table 6:
Means of Components of Demoralization by Stage of Change.

SOC	IES	SIS	ISELSF
1	21.750	12.500	49.000
2	39.000	14.000	44.000
4	12.786	6.000	56.000
5	17.915	11.950	53.603
6	10.234	9.989	53.381

Note: Table abbreviations are Stage of Change (SOC), Impact of Events Scale (IES), Subjective Incompetence Scale (SIS), and Interpersonal Social Evaluation List-Short Form (ISELSF).

The Impact of Events Scale was used to operationalize perceived stress. As expected subjects in the precontemplation stage had lower levels of perceived stress than those in the contemplation stage. Subjects in precontemplation are oblivious to their addictive behavior and therefore it is not perceived as stressful. Higher stress levels were associated with stage two of the stage of contemplation. As subjects become aware of the impact of their addictions and begin considering change their perceived level of stress increases. There were no subjects in the preparation stage. Lower levels of perceived stress were associated with the action stage as the subject actively engaged in change. Increased levels of stress were associated with the maintenance stage which is supported in the literature. As patients come to grips with no longer using alcohol to cope and before alternate coping skills are stabilized they may experience higher

levels of perceived stress. The stage of termination had the lowest mean level of perceived stress as would be expected in subjects who had resolved their addictions. All of the means supported the literature on the stage of change. The fluctuations in scores on the SIS followed the same pattern as those on the IES. This supported the idea that levels of subjective incompetence would be high in the precontemplation stage when a subject was actively drinking.

Those scores would be expected to increase as the individual became aware of their addiction and began to consider change. When the patients are actively engaged in changing their addictive behavior they may feel more confident. As they try to stabilize their new behavior their subjective incompetence level increases slightly as their resolve to remain sober is tested. Finally as the patient's behavior pattern stabilizes and they no longer are engaged in change, their level of subjective incompetence is at its lowest.

These findings reflected the expected association between subjective incompetence and stage of change. Social support was operationalized with the Interpersonal Social Evaluation List (ISELSF). The means in the stage of precontemplation were higher than those in the second stage. This may mean that those subjects actively drinking felt the support of their drinking peers. Social support scores were lower in the contemplation stage which may be associated with a change in peer group. In the action stage (stage four) higher perceived levels of social support might be associated with a new support group. Stages five and six reflect very similar scores on the social support instrument.

This may indicate that their new social network has stabilized and they have adjusted to the lifestyle change. All of these means supported the expected patterns.

The Pearson correlations between components of demoralization and related medical variables were examined (See Table 7). There was a slight correlation between Interpersonal Social Evaluation List (ISELSF) and Stage of Change (SOC) in a positive direction, which indicated that those in earlier stages of change had lower levels of social support. There was a moderate and significant correlation in a negative direction between the Impact of Events Scale

(IES) and SOC. Increased stress was associated with lower scores on SOC. There was a slight correlation between the Subjective Incompetence Scale (SIS) and the SOC in a negative direction. Increased levels of subjective incompetence were slightly associated with lower scores on SOC. There were slight correlations between SOC and scores on depression and age.

Those who were in the earlier stages of change expressed more depressive features and older subjects tended to be in earlier stages of change. Years of education were slightly correlated with stage of change suggesting that education may facilitate movement through the stages.

Table 7
Pearson Correlations Between Components of Demoralization and Related Medical Variables.

Variables	ISELSF	IES	SIS	DEP	AGE	YRED	SOC	DRKDY
ISELSF	1.000							
IES	-.028 .415	1.000						
SIS	-.147 .129	.418 .000	1.000					
DEP	-.227 .039	.215 .048	.167 .099	1.000				
AGE	.023 .431	-.375 .001	-.448 .000	-.202 .060	1.000			
YRED	.205 .056	.048 .358	.124 .171	-.181 .082	-.055 .337	1.000		
SOC	.150 .124	-.302 .009	-.097 .229	.182 .081	.130 .159	.219 .045	1.000	
DRKDY	-.160 .109	.104 .214	-.046 .362	.068 .301	-.169 .096	-.086 .255	-.142 .137	1.000

Note: Table abbreviations are Interpersonal Social Evaluation List-Short Form (ISELSF),), Impact of Events Scale (IES), Subjective Incompetence Scale (SIS), Depression (DEP), Age (AGE), Years of Education (YRED), Stage of Change (SOC), and Drinks per Day (DRKDY).

Increased alcohol consumption was slightly correlated with stage of change in a negative direction. Those with ongoing alcohol consumption were in earlier stages of change. All of these correlations were in the directions predicted hence a multiple regression was run in order to further explain these relationships.

The relative importance of depression and the three components of demoralization as predictors of stage of change (SOC) were assessed by regressing the SOC scores on the four variables (CES-D, IES, SIS, and ISELSF). Sixty-nine subjects responded to the Stage of Change (SOC) question (1 = precontemplation, 2 = contemplation 3 = preparation, 4 = action, 5 = maintenance, 6 = termination) and the mean score of the group was 5.04 with a standard deviation of 1.24. Of the group, four were in the precontemplation stage; one was in contemplation; one was in preparation; two were in the action stage; 35 were in the maintenance stage and the remaining 26 considered themselves to be in the termination stage. The importance of depression and the construct of demoralization as predictors of stage of change were determined through a multiple hierarchical regression analysis.

A 2 step multiple regression was employed to determine if addition of information regarding social support (ISELSF), perceived stress (IES) and subjective incompetence (SIS) improved prediction of stage of change beyond that afforded by differences in depression (CES-D), age (AGE), years of education (EDU) and alcohol use (ETOH). Analysis was preformed using SPSS REGRESSION and SPSS FREQUENCIES for evaluations of assumptions. Multivariate outliers were sought using subject identification as part of an SPSS REGRESSION run in which the Mahalanobis distance of each case to the centriod was computed and the ten cases with the largest distance were printed. The critical value of chi-square (χ^2) at $\alpha = .001$ for 5 df was 20.52 and none of the cases exceeded that value. Subjects with incomplete data were eliminated and the result was sixty-one cases.

After step 1with depression (CES-D), age (AGE), years of education (EDU), alcohol use (ETOH) in the equation $R^2 = .15$, F (4,56)= 2.43, p =.058. After step 2, with social support

(ISELSF), perceived stress (IES) and subjective incompetence (SIS) added to prediction of stage of change, produced a change in R^2 = .273, F (3,53)= 3.049, p =.036. The addition of social support (ISELSF), perceived stress (IES) and subjective incompetence (SIS) resulted in a significant increment in R^2. The whole model produced R^2 =.284, F (7,53)= 2.847, p =.013 which explained a significant portion of the variance in stage of change. Table 8 displays the unstandardized regression coefficients (*B*), the standard error of B (SE B) and the standardized regression coefficient (β).

Table 8
Summary of Hierarchical Regression Analysis for Variables Predicting Stage of Change

Variables	*B*	SE *B*	β
Depression	.044	.016	.360*
Education	.087	.041	.266*
Age	.005	.010	.073
Alcohol Use	-.028	.051	-.069
Stress	-.030	.011	-.358*
Social Support	.025	.020	.156
Subjective Incompetence	.002	.026	.012

Note R^2 =.148 for step 1; Δ R^2 = .125 for step 2 *p<.05.

Summary

The data supported the hypotheses that that depression and demoralization are distinct but related variables and that increased levels of demoralization would predict lower scores on Stage of Change (SOC). The data did not support the hypothesis that patients with higher levels of alcohol

consumption would have higher levels of the three components of demoralization. The results and implications for practice and research are discussed in Chapter Five.

CHAPTER FIVE

Conclusion, Limitations and Implications for Practice and Future Research

Introduction

This chapter focuses on the interpretation, implications, limitations, discussion and conclusions related to the results obtained from this study. Limitations of the study are posited with possible solutions for alleviation.

Interpretation

In the case of hypothesis one, that depression and demoralization are distinct but related variables, the relationship between depression and demoralization was assessed by examining the correlation between depression and the three components of demoralization. Depression and two of the three components of demoralization were slightly and significantly correlated, Interpersonal Social Evaluation List Short Form (ISELSF) (-.242, p=.042) and Subjective Incompetence Scale (SIS) (.226, p=.058) in the direction predicted. The researcher concluded that depression and demoralization are distinct but related variables. It was noted that the correlation between the SIS and the CES-D was much lower than the correlation between the SIS and the depression/dejection subscale on the Profile of Mood States in phase one, despite the fact that both scales measure depression. This may reflect the differences between the scales. The POMS is not limited to depression but measures a varied of mood states and the sub-scale measures depression and dejection. The POMS is a simplistic word association scale that asks subjects to rate how much they experienced a mood state described by a single word. The CES-D asks the subject to rate their emotional experience using a sentence format (i.e., "I was bothered by things that usually don't bother me"). The higher correlation with the POMS may have reflected the difference in the two subject samples. Patients in the Pain and Palliative Care Clinic may be sensitized to their feelings of depression since they are assessed for depression at each visit

whereas those in the Gastrointestinal clinic are referred to an out-patient psychiatrist if they report depression. Since all three components of demoralization were assessed in phase two, it would have been appropriate to use the same measurement for depression in both phases. The consistent use of the POMS would have allowed for a comparison of the correlations among the three components of demoralization in different populations. On the other hand, assuming the trends found on the CES-D were to continue in the direction indicated, statistical significance might be obtained by including additional participants.

With regards to hypothesis two, it was hypothesized that those patients with higher levels of alcohol consumption would have higher levels of the three components of demoralization. The correlations did not support this hypothesis and the trends did not indicate that an increase in the number of participants would likely render a significant difference in the outcome. A second analysis supported these results. The correlation of the numbers of drinks per day (Drinkday) and the Marlowe-Crowne was significant (-.275, p=.020). This indicates that there was a social desirability bias in reporting of alcohol use (those that drank more tended to report less accurately and in a more socially desirable way). The existence of a social desirability bias was supported by the fact that only sixty-three subjects answered the drinks per day question as compared to seventy-one responses to the majority of other questions. Furthermore, there was a discrepancy found when examining the responses on the SCID Alcohol module. Twenty-three (28% **)** subjects screened positive for alcohol abuse on the SCID Alcohol questionnaire, while forty-six subjects (65%) acknowledged current alcohol use. This may have been a factor of the face to face interview. The difference might also be attributed to survey format. The question about how many alcoholic beverages are consumed a day was worded in two tenses" did you or do you" in order to illicit information from those who have stopped drinking alcoholic beverages. The resulting ambiguity may have accounted for some response bias. However, even taking into account possible bias the data did not support this hypothesis. A number of explanations were possible. The sample contained few subjects in the precontemplation (4) or contemplation stages

(1). This may have been a factor of having been in treatment for their medical diagnosis. Some physicians educate patients regarding the impact of alcohol use on their medical conditions. Patients may also change their lifestyle when they are diagnosed with a life threatening illness in order to improve their chance of recovery. Many of these patients were being treated with chemotherapy and radiation and the associated nausea and vomiting could have discouraged alcohol intake. On the other hand patients who are actively drinking may not feel demoralized. Since alcohol is often consumed to alter mood state those patients actively drinking may feel more confident and less demoralized.

Hypothesis three involved assessing the relative importance of depression and the three components of demoralization as predictors of stage of change by regressing the stage of change scores on the four variables. The findings, were statistically significant R^2 =.284, $F(7, 53)$ = 2.847, p =.013 and indicated that levels of demoralization can be used to predict Stage of Change. These findings will be discussed further in the section on Limitations and Implications for Practice.

Limitations

There were several limitations to this study. Between Aug 2003 and February 2004 there was a change in the physicians in the Gastrointestinal (GI) Clinic. This had implications for the study. The director of the GI clinic, a physician who had been a member of the research team, moved out of the area. His support had lent weight to the study activities. When a new physician arrived to take his place he was introduced to the study team. There was a period of time before the new physician developed confidence that the study team would not interrupt the workflow of his clinic. Despite verbal expressions of support of the study some of the physicians would not allow their patient to be approached prior to their visit. Patients approached as they left the clinic were reluctant to stay long enough to have the study explained to them. Several attempts were made to rectify the situation, without improvement. In the future it would be an advantage to have

the clinic director support the study. To increase accrual it was suggested that a letter be sent from the primary investigator notifying the potential participants of the study and its risks and benefits. Although this might have increased enrollment it would not have decreased the resistance within the clinic itself.

A second limitation was the lack of a call back schedule during the initial stage of the study. This was due in part to the investigator's inexperience and reluctance to pressure participants to return survey packages. Later in the study the participants were informed at the time of contact that if their package had not been returned within two weeks the interviewer would contact them to determine if they needed a second package or if they wished to withdraw. This approach met with a positive response and the return rate improved.

In the development of the study the researcher had to weigh the amount of information required against the subject burden. Initially it appeared that the package would take thirty to forty-five minutes to complete. After several subjects were enrolled the researchers found that the time to complete the package was fifteen to twenty minutes. The respondent burden in this medically compromised population had been one of the factors that determined the number of instruments included in the study. As a result of the concern that too many instruments would negatively impact the accrual rate and quality of the returned data, fewer instruments were included in the package. Only a single measure for each item was collected in phase one. A second measure for depression, apathy, and alexithymia would have enhanced the assessment of convergent and divergent validity by allowing for the use of the multi-trait-multi-method assessment of convergent and divergent validity.

The instrument used to measure Stage of Change (SOC) was developed by Laforge, Maddock, & Rossi (1998) and was tested in a college age population. It was chosen since it was the only available instrument to measure stage of change in alcohol use. In retrospect the instrument could have been adjusted to reflect the current definition of excessive alcohol use in an adult population as described by the American Medical Association. The question should have

asked about three drinks a day for men and one drink a day for women. Framing the question in this manner might have given a more accurate assessment of stage of change in this population.

Although the General Background Information (GBI) which was used to collect demographic information was helpful, the ambiguity in the question's wording made data collection and entry less than optimal. For example the question on alcohol use intended to determine past or present use was worded "how many alcoholic beverages do/did you typically consume each day?" There was no way to determine if the number of drinks entered in response to the question was in the present or past tense.

The use of Teleform to enter data was not as effective as the researchers expected it to be. Many entries required correction and the export process became time consuming.

It became apparent during the interviews that the amount of social support in the cancer population was for the most part substantial. In time of a medical crisis families may come together to support the cancer patient. This phenomenon of increased social support may have impacted outcomes on the ISELSF.

Implications for Practice

This study demonstrated that many of the patients in the gastrointestinal (GI) clinic had underlying problems with alcohol. When the study was initially discussed with the oncologist in the GI clinic they were aware of the literature on the relationship between alcohol and gastrointestinal cancers. They expressed the opinion that there was likely a relationship between past alcohol use and colorectal and gastrointestinal cancers. What they were not aware of and what became apparent during the study, was that many of the patients in the GI clinic continued to use alcohol or had only recently discontinued the use of alcohol. The implication of these findings is that patients in the GI clinic would benefit from screening for alcohol abuse when they are initially seen in the clinic. Once patients' pattern of alcohol use was established they could be offered information on the impact of ongoing use of alcohol on chemotherapy, pain treatment and

palliative care. Patients identified as having alcohol abuse or dependency should be offered treatment resources.

The literature review revealed that patients with ongoing alcohol abuse and dependency are at greater risk for developing alcohol withdrawal and delirium following surgery. Those patients identified with ongoing alcohol problems should be detoxified prior to admission for surgery. Benzodiazepines are frequently used for detoxification and some surgeons have expressed concern regarding their use during the postoperative period. The suggested alternative is the use of an alcohol drip during the pre and postoperative period. This intervention is an effective means of preventing alcohol withdrawal and delirium while the patient is in hospital. The underlying assumption is that patients with ongoing alcohol problems will resume their alcohol consumption following discharge. However, a patient debilitated by surgery and house bound may not have access to sufficient supplies of alcohol at home to prevent withdrawal. Patients in this situation are at risk for untreated alcohol withdrawal, delirium, seizure and death.

From a clinical perspective this study emphasizes the need for alcohol assessment of all patients admitted to hospital. Education and support should be offered for any patient identified with alcohol abuse or dependency. Demoralized patients should be offered treatment that effectively addresses each of the components of their problem. By definition subjective incompetence occurs when one's self-concept is challenged by a disconfirming event. This disconfirmation engenders feelings of confusion, helplessness, anxiety, uncertainty and social estrangement. As a result of inadequate social bonds the individual has insufficient resources and opportunities to challenge this self perceived failure. When challenged by a new stressor, the individual loses the capacity to act at some minimal level according to some internalized standard. Since subjective incompetence appears to be a cognitive distortion it might best be addressed with cognitive behavioral therapy that challenges the patient’s misperception of self-capacity. Offering that type of therapy in a group setting might increase the patient's social support and buffer them against further stressors.

Future Research

The operationalization of demoralization was achieved by using three separate instruments, the Subjective Incompetence Scale, the Impact of Events Scale and the Interpersonal Social Evaluation List-Short Form. When the three instruments were combined they included a total of forty-two items which made the instrument cumbersome. The researcher proposes that future research include a principle component analysis aimed at reducing the number of items to only those that most effectively measured the concept.

Secondly a factor analysis should be done with a measure of depression and demoralization to support the idea that the constructs are distinct but related.

Since the study findings were hampered by the limited number of precontemplators a sample of subjects more likely to be in the precontemplation phase should be done. The researcher suggests a sample from a general medical practice would be appropriate.

This study documents the initial attempt at developing an instrument to measure demoralization. The results of phase one suggest that demoralization is distinct but related to depression. This may support Rickleman's (2002) theory that demoralization is a precursor of depression and can be conceptualized on a continuum of mood disorders. Phase two of the study supports the idea that a patient's level of demoralization is indicative of his or her stage of change. The concept of demoralization appears to be an effective means to frame the experience that impacts individuals attempting to change addictive behaviors. As the patient advances through change, he or she becomes less demoralized. This predictive relationship indicates that interventions aimed at reducing levels of demoralization may help a patient change addictive behavior.

These studies document the initial attempt at developing an instrument to measure demoralization. The concept appears to be an effective means to frame the experience that impacts individuals attempting to change addictive behaviors. Further exploration of the concept is warranted.

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APPENDICES

Appendix A

University of South Florida
USF

EXEMPTION CERTIFICATION

MEMO: Michael Weitzner, M.D.
Palliative Care
MDC 44 MOD 1 Pain
Attn: Christine Marsella

FROM: Institutional Review Board BBB/ds

SUBJECT: Exemption Certification for Protocol No. IRB# 101291

DATE: April 8, 2003

On March 27, 2003, it was determined that your project entitled, **Demoralization and Negative Affect in Patients with Chronic Cancer Pain - MCC 13337 - CHART REVIEW**, meets federal criteria to qualify as an exempt study.

Because the study has been certified as exempt, you will not be required to complete continuation or final review reports. However, it is your responsibility to notify the IRB prior to making any changes to the study. Please note that changes made to an exempt protocol may disqualify it from exempt status and may require an expedited or full review.

If you have any questions, please contact the Division of Research Compliance at (813) 974-5638

cc: MCC

Office of Research, Division of Research Compliance
Institutional Review Boards, FWA No. 00001669
University of South Florida • 12901 Bruce B. Downs Blvd., MDC035 • Tampa, Florida 33612-4799
(813) 974-5638 • FAX (813) 974-5618

Appendix B

H. LEE MOFFITT Cancer Center & Research Institute

The End Of Cancer Begins Here.

A National Cancer Institute Comprehensive Cancer Center
At the University of South Florida

June 12, 2003

Michael Weitzner, M.D.
Dept of Interdisciplinary Oncology
University of South Florida

Dear Dr. Weitzner:

Your project entitled, **"Level of Demoralization as a Predictor of Stage of Change in Patients with Gastrointestinal and Colorectal Cancer"** (MCC-13410/MCC----) has met all scientific, ethical, financial and operational requirements and is eligible for activation at the H. Lee Moffitt Cancer Center & Research Institute.

For all accruing studies, patients must be entered into the Research Administration Data System (RADS) at the time of informed consent is signed. Please contact my office at 615-4202 or our web site at http://inside.moffitt.usf.edu/Research/Admin/cto/index.htm#how for details and to make arrangements for patient entry.

Please process and submit via RADS any changes pertaining to this project such as adverse events, amendments/changes, continuing reviews, suspensions and closures. All notices which apply to the aforementioned changes or closure of protocols should be forwarded to the Clinical Trials Office with the appropriate updated materials or documentation.

The Protocol Monitoring Committee (PMC) reviews all clinical projects on an annual basis for scientific progress, including accrual and adverse events. Therefore, all enrolled patients and adverse events must be entered into RADS. Adverse events on investigator-initiated trials are reviewed by the PMC within one month of reporting. The Committee also audits all clinical protocols on an annual basis.

The Research Administration Data System (RADS) is the Cancer Center's mechanism for required submission and review of materials requiring Institutional Review Board review as well as items requiring review by the Protocol Monitoring and Scientific Review Committees. If you are not currently reporting the necessary research activities, such as patient accrual, changes in procedure, adverse events and continuing reviews in RADS, please contact my office or our web site as above for direction.

Sincerely,

Amy Roberts, Regulatory Supervisor
Clinical Trials Office

cc: MCC#13410
Debbie Magley
Ashley Helms
Melissa Cochran, MSPH
Cheryl Cockram, MSN, ARNP

NCI CCC
A Comprehensive Cancer Center Designated by the National Cancer Institute

12902 Magnolia Drive
Tampa, Florida 33612-9497
Phone (813) 972-4673
Fax (813) 972-8495
www.MoffittCancerCenter.org

Appendix C

9074

ID#_____ Date:_____

GENERAL BACKGROUND INFORMATION

1. Today's Date: _____/_____/_____

2. Age: ☐☐

1 ○○
2 ○○
3 ○○
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8 ○○
9 ○○
0 ○○

3. Race and Ethnicity group (Please fill in **one** item in each column)

A	B
○ A. Hispanic or Latino	○ A. American Indian or Alaskan Native
○ B. Not Hispanic or Latino	○ B. Asian
	○ C. Black or African American
	○ D. Native American or Other Pacific Islander
	○ E. White

4. Marital Status (Please fill in one item)

○ A. Never married ○ B. Currently married ○ C. Separated ○ D. Divorced ○ E. Widowed

5. Current living arrangement (Please fill in one item)

○ A. Live alone
○ B. Live with spouse/partner
○ C. Live with spouse/partner and children
○ D. Live with children (no spouse/partner)
○ E. Live with roommate who is no partner
○ F. Live with parents
○ G. Other (specify_____)

List the ages of all your children living at home:_____

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1 ○○○○
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4 ○○○○
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8 ○○○○
9 ○○○○
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Appendix C continued

9074

6. How long in current living arrangement (Please fill in one number):

- O A. Less than 1 month
- O B. One to 6 months
- O C. Seven months to 2 years
- O D. Two to 5 years
- O E. More than 5 years

7. Level of school completed (Please fill in one item):

- O A. Less than 7th grade
- O B. Junior High School (7th, 8th, & 9th grade)
- O C. Partial High School (10th or 11th grade)
- O D. High School graduate
- O E. Partial college or specialized training
- O F. College or university graduate
- O G. Graduate professional training (graduate degree)

8. Total number of years of education: ☐☐

9. Current employment situation (Please fill in all items that apply in both column A and B):

A	B
O WORKING	O A. Full time at job O B. Part time at job
O ON LEAVE	O C. On leave with pay O D. Disabled
O NOT EMPLOYED	O E. Seeking Work O F. Retired O G. Homemaker O H. Student

Office Use Only

☐☐☐☐

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6 O O O O
7 O O O O
8 O O O O
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Appendix C continued

9074

10. Which category best describes **your** usual occupation? If you are not currently employed, which category best describes your **LAST** job? (Please fill in one number)

- O A. Professional (e.g., teachers/professors, nurses, lawyers, physicians, & engineers)
- O B. Manager/Administrator (e.g., sales managers)
- O C. Clerical (e.g., secretaries, clerks or mail carriers)
- O D. Sales (e.g., sales persons, agents & brokers)
- O E. Service (e.g., police, cooks, waitress, or hairdressers)
- O F. Skilled Crafts, Repairer (e.g., carpenters)
- O G. Equipment or Vehicle Operator (e.g., truck drivers)
- O H. Laborer (e.g., maintenance factory workers)
- O I. Farmer (e.g., owners, managers, operators or tenants)
- O J. Member of the military
- O K. Homemaker (with no job outside the home)
- O L. Other (please describe)_____

11. Which category best describes your **spouse's** usual occupation? If your spouse is not currently employed, which category best describes his/her **LAST** job? (Please fill in the number)

- O A. Professional (e.g., teachers/professors, nurses, lawyers, physicians, & engineers)
- O B. Manager/Administrator (e.g., sales managers)
- O C. Clerical (e.g., secretaries, clerks or mail carriers)
- O D. Sales (e.g., sales persons, agents & brokers)
- O E. Service (e.g., police, cooks, waitress, or hairdressers)
- O F. Skilled Crafts, Repairer (e.g., carpenters)
- O G. Equipment or Vehicle Operator (e.g., truck drivers)
- O H. Laborer (e.g., maintenance factory workers)
- O I. Farmer (e.g., owners, managers, operators or tenants)
- O J. Member of the military
- O K. Homemaker (with no job outside the home)
- O L. Other (please describe)_____

Office Use Only

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4	O	O	O	O
5	O	O	O	O
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8	O	O	O	O
9	O	O	O	O
0	O	O	O	O

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Appendix C continued

9074

12. What is **your** approximate annual gross income? (Please fill in one item)
**Please remember all information you provide will remain completely confidential.*

- O A. Less than $10,000
- O B. $10,000-$19,999
- O C. $20,000-$39,999
- O D. $40,000-$59,999
- O E. $60,000-$100,000
- O F. Greater than $100,000

13. Approximate annual gross income for your **household**? (Please fill in one item)
**Please remember all information you provide will remain completely confidential.*

- O A. Less than $10,000
- O B. $10,000-$19,999
- O C. $20,000-$39,999
- O D. $40,000-$59,999
- O E. $60,000-$100,000
- O F. Greater than $100,000

14. In general, how is your health compared to other people your age? (Please fill in one item)

O A. EXCELLENT O B. VERY GOOD O C. GOOD O D. FAIR O E. POOR

15. During your lifetime, have you smoked at least 100 cigarettes (=5 packs)? O No O Yes

IF YES:

a) How many cigarettes do/did you typically smoke each day? ☐☐ (# of cigarettes)

b) Have you smoked in the past month?

Yes, approximately ☐☐ cigarettes per day

No, I quit about ☐☐ O Months O Years ago.

c) How many years in total have you smoked, or if you have quit, how many years did you smoke?

☐☐ (Number of years)

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☐☐☐☐

1	O	O	O	O
2	O	O	O	O
3	O	O	O	O
4	O	O	O	O
5	O	O	O	O
6	O	O	O	O
7	O	O	O	O
8	O	O	O	O
9	O	O	O	O
0	O	O	O	O

Appendix C continued

9074

16. During your lifetime, have you ever consumed alcoholic beverages? O No O Yes

IF YES:

a) Age of first drink? ☐☐

b) How many alcoholic beveraged do/did you typically consume each day? ☐☐

c) Have you consumed alcoholic beverages in the past month?

Yes, approximately ☐☐ drinks per day

No, I quit about ☐☐ O Months O Years ago.

d) How many years in totaly have you consumed alcohol, or if you have quit, how many years did you drink?

☐☐ (Number of years)

**Note: One beverage equals: one 12 oz. can of beer, one 6 oz. glass of wine, one 1 oz. shot of hard liquor.)*

17. Have you consumed (illicit) non-prescription drugs (marijuana, cocaine) in the past month? O No O Yes

IF YES:

a) What type of drug did you consume? _____

b) How often did you use the drug in the past month (Fill in one)?

O A. 1-3 times a month
O B. 1-3 times a week
O C. 4-6 times a week
O D. 1 time a day
O E. 2 times a day
O F. 3 or more times a day

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☐☐☐☐

1 O O O O
2 O O O O
3 O O O O
4 O O O O
5 O O O O
6 O O O O
7 O O O O
8 O O O O
9 O O O O
0 O O O O

Appendix D

9289

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1 2 3 4 5 6 7 8 9 0

SIS

Below are several statements about how people may feel when they experience a stressful situation. *Please read each statement carefully and choose the numbered response that best describes how you felt when you were trying to deal with your diagnosis or the diagnosis of your partner. For example if you experienced the feelings described none of the time, you would indicate so by choosing zero. If you experienced the feelings described all of the time, you would indicate so by choosing five.*

	None of the time	A little bit of the time	A good bit of the time	Most of the time	All of the time
1. Were you able to plan and initiate concerted action as well as you thought you could?	O 0	O 1	O 2	O 3	O 4
2. Were you puzzled, indecisive, and uncertain as to what actions, if any you should take?	O 0	O 1	O 2	O 3	O 4
3. Did you feel you were facing a quandary, a dilemma, or a predicament?	O 0	O 1	O 2	O 3	O 4
4. Did you reach a point where you felt you could no longer plan, strategize, and initiate appropriate action?	O 0	O 1	O 2	O 3	O 4
5. Did you feel that you were running out of ideas to handle the situation?	O 0	O 1	O 2	O 3	O 4
6. Did you reach a point where you became convinced that the situation was out of your hands?	O 0	O 1	O 2	O 3	O 4
7. Did you reach a point where you became convinced that someone else would be able to handle the situation better than you would?	O 0	O 1	O 2	O 3	O 4
8. Did you change your mind about your ability to deal with similar situations?	O 0	O 1	O 2	O 3	O 4
9. Did the situation convince you that your assumptions about other people, such as their eagerness to help you, were no longer certain?	O 0	O 1	O 2	O 3	O 4
10. When you were experiencing this situation, did you feel that you could not carry out your usual activities, (such as, your doing your housework, concnetrating, or visiting people)?	O 0	O 1	O 2	O 3	O 4
11. While you were dealing with the situation, did the situation shake your confidence in your ability to deal with future problems you may encounter in your life?	O 0	O 1	O 2	O 3	O 4

Now think about the time right after the stressful situation was over and answer the following question.

12. After the situation was over, did the situation leave you with any new doubts about your ability to deal with any future problems you may encounter in your life?	O 0	O 1	O 2	O 3	O 4

Appendix E

POMS

Below is a list of words that describe feelings people have. Please read each one carefully. Then CIRCLE number which best describes **HOW YOU HAVE BEEN FEELING DURING THE PAST WEEK INCLUDING TODAY.**

	Not at all	*A little*	*Moderately*	*Quite a bit*	*Extremely*
1. Friendly	☐	☐	☐	☐	☐
2. Tense	☐	☐	☐	☐	☐
3. Angry	☐	☐	☐	☐	☐
4. Worn out	☐	☐	☐	☐	☐
5. Unhappy	☐	☐	☐	☐	☐
6. Clear-headed	☐	☐	☐	☐	☐
7. Lively	☐	☐	☐	☐	☐
8. Confused	☐	☐	☐	☐	☐
9. Sorry for things done	☐	☐	☐	☐	☐
10. Shaky	☐	☐	☐	☐	☐
11. Listless	☐	☐	☐	☐	☐
12. Peeved	☐	☐	☐	☐	☐
13. Considerate	☐	☐	☐	☐	☐
14. Sad	☐	☐	☐	☐	☐
15. Active	☐	☐	☐	☐	☐
16. On edge	☐	☐	☐	☐	☐
17. Grouchy	☐	☐	☐	☐	☐

Appendix E continued

	Not at all	*A little*	*Moderately*	*Quite a bit*	*Extremely*
18. Blue	☐	☐	☐	☐	☐
19. Energetic	☐	☐	☐	☐	☐
20. Panicky	☐	☐	☐	☐	☐
21. Hopeless	☐	☐	☐	☐	☐
22. Relaxed	☐	☐	☐	☐	☐
23. Unworthy	☐	☐	☐	☐	☐
24. Spiteful	☐	☐	☐	☐	☐
25. Sympathetic	☐	☐	☐	☐	☐
26. Uneasy	☐	☐	☐	☐	☐
27. Restless	☐	☐	☐	☐	☐
28. Unable to concentrate	☐	☐	☐	☐	☐
29. Fatigued	☐	☐	☐	☐	☐
30. Helpful	☐	☐	☐	☐	☐
31. Annoyed	☐	☐	☐	☐	☐
32.		☐	☐	☐	☐
33. Resentful	☐	☐	☐	☐	☐
34. Nervous	☐	☐	☐	☐	☐
35. Lonely	☐	☐	☐	☐	☐
36. Miserable	☐	☐	☐	☐	☐
37. Muddled	☐	☐	☐	☐	☐

Appendix E continued

	Not at all	*A little*	*Moderately*	*Quite a bit*	*Extremely*
38. Cheerful	☐	☐	☐	☐	☐
39. Bitter	☐	☐	☐	☐	☐
40. Exhausted	☐	☐	☐	☐	☐
41. Anxious	☐	☐	☐	☐	☐
42. Ready to fight	☐	☐	☐	☐	☐
43. Good natured	☐	☐	☐	☐	☐
44 Gloomy	☐	☐	☐	☐	☐
45. Desperate	☐	☐	☐	☐	☐
46. Sluggish	☐	☐	☐	☐	☐
47. Rebellious	☐	☐	☐	☐	☐
48. Helpless	☐	☐	☐	☐	☐
49. Weary	☐	☐	☐	☐	☐
50. Bewildered	☐	☐	☐	☐	☐
51. Alert	☐	☐	☐	☐	☐
52. Deceived	☐	☐	☐	☐	☐
53. Furious	☐	☐	☐	☐	☐
54. Efficient	☐	☐	☐	☐	☐
55. Trusting	☐	☐	☐	☐	☐
56. Full of pep	☐	☐	☐	☐	☐
57. Bad-tempered	☐	☐	☐	☐	☐
58. Worthless	☐	☐	☐	☐	☐

Appendix E continued

	Not at all	A little	Moderately	Quite a bit	Extremely
59. Forgetful	☐	☐	☐	☐	☐
60. Carefree	☐	☐	☐	☐	☐
61. Terrified	☐	☐	☐	☐	☐
62. Guilty	☐	☐	☐	☐	☐
63. Vigorous	☐	☐	☐	☐	☐
64. Uncertain about things	☐	☐	☐	☐	☐
65. Bushed	☐	☐	☐	☐	☐

Appendix F

TAS

Name: _____ Date: ____/____/_____

Rater: _____

Using the scale provided as a guide, indicate how much you agree or disagree with each of the following statements by checking the appropriate box. Give only one answer for each statement: Strongly Disagree, Moderately Disagree, Neither Disagree Nor Agree, Moderately Agree, Strongly Agree.

		Strongly Disagree	Moderately Disagree	Neither Disagree Nor Agree	Moderately Agree	Strongly
1.	When I cry I always know why.	☐	☐	☐	☐	☐
2.	Daydreaming is a waste of time.	☐	☐	☐	☐	☐
3.	I wish I were not so shy.	☐	☐	☐	☐	☐
4.	I am often confused about what emotion I am feeling.	☐	☐	☐	☐	☐
5.	I often daydream about the future.	☐	☐	☐	☐	☐
6.	I seem to make friends as easily as others do.	☐	☐	☐	☐	☐
7.	Knowing the answers to problems is more important than knowing the reasons for the answers.	☐	☐	☐	☐	☐
8.	It is difficult for me to find the right words for my feelings.	☐	☐	☐	☐	☐
9.	I like to let people know where I stand on things.	☐	☐	☐	☐	☐

Appendix F continued

		Strongly Disagree	Moderately Disagree	Neither Disagree Nor Agree	Moderately Agree	Strongly Agree
10.	I have physical sensations that even doctors don't understand.	☐	☐	☐	☐	☐
11.	It's not enough for me that something gets the job done; I need to know why and how it works.	☐	☐	☐	☐	☐
12.	I'm able to describe My feelings easily.	☐	☐	☐	☐	☐
13.	I prefer to analyze problems rather than just describe them.	☐	☐	☐	☐	☐
14.	When I am upset, I don't know if I am sad, frightened, or angry.	☐	☐	☐	☐	☐
15.	I use my imagination a great deal.	☐	☐	☐	☐	☐
	I spend much time daydreaming whenever I have nothing else to do.	☐	☐	☐	☐	☐
16.	I am often puzzled by sensations in my body.	☐	☐	☐	☐	☐
17.	I daydream rarely.	☐	☐	☐	☐	☐
18.	I prefer to just let things happen rather than to understand why they turned out that way.	☐	☐	☐	☐	☐
19.	I have feelings that I can't quite identify.	☐	☐	☐	☐	☐

Appendix F continued

		Strongly Disagree	Moderately Disagree	Neither Disagree Nor Agree	Moderately Agree	Strongly Agree
20.	Being in touch with emotions is essential	☐	☐	☐	☐	☐
21.	I find it hard to describe how I feel about people.	☐	☐	☐	☐	☐
22.	People tell me to describe my feelings more.	☐	☐	☐	☐	☐
23.	One should look for deeper explanations.	☐	☐	☐	☐	☐
24.	I don't know what's going on inside me.	☐	☐	☐	☐	☐
25.	I often don't know why I am angry.	☐	☐	☐	☐	☐

Appendix G

The Brief COPE

We are interested in how people respond when they confront difficult or stressful events in their lives. There are lots of ways to try to deal with stress. This questionnaire asks you to indicate what you generally do and feel when you experience stressful events. Obviously, different events bring out somewhat different responses, but think about what you *usually* do when you are under a lot of stress.

Then respond to each of the following items by circling one number for each, using the response choices listed. Please try to respond to each item *separately in your mind from each other item*. Choose your answers thoughtfully, and make your answers as true FOR YOU as you can. Please answer *every* item. There are no "right" or "wrong" answers, so choose the most accurate answer for YOU--not what you think "most people" would say or do. Indicate what YOU usually do when YOU experience a stressful event.

	I usually don't do this at all	*I usually do this a little bit*	*I usually do this a medium amount*	*I usually do this a lot*
1. I turn to work or other activities to take my mind off things.	☐0	☐1	☐2	☐3
2. I concentrate my efforts on doing something about the situation I'm in.	☐0	☐1	☐2	☐3
3. I say to myself "this isn't real".	☐0	☐1	☐2	☐3
4. I use alcohol or other drugs to make myself feel better.	☐0	☐1	☐2	☐3
5. I get emotional support from others.	☐0	☐1	☐2	☐3
6. I give up trying to deal with it.	☐0	☐1	☐2	☐3
7. I take action to try to make the situation better.	☐0	☐1	☐2	☐3
8. I refuse to believe that it has happened.	☐0	☐1	☐2	☐3
9. I say things to let my unpleasant feelings escape.	☐0	☐1	☐2	☐3
10. I try to get advice or help from other people about what to do.	☐0	☐1	☐2	☐3
11. I use alcohol or other drugs to help me get through it.	☐0	☐1	☐2	☐3

Appendix G continued

12. I try to see it in a different light to make it seem more positive	☐0	☐1	☐2	☐3
13. I criticize myself.	☐0	☐1	☐2	☐3
14. I try to come up with a strategy about what to do.	☐0	☐1	☐2	☐3

	I usually don't do this at all	*I usually do this a little bit*	*I usually do this a medium amount*	*I usually do this a lot*
15. I get comfort and understanding from someone.	☐0	☐1	☐2	☐3
16. I give up the attempt to cope.	☐0	☐1	☐2	☐3
17. I look for something good in what is happening.	☐0	☐1	☐2	☐3
18. I make jokes about it.	☐0	☐1	☐2	☐3
19. I do something to think about it less, such as going to movies, watching TV, reading, daydreaming, sleeping, or shopping.	☐0	☐1	☐2	☐3
20. I accept the reality of the fact that it has happened.	☐0	☐1	☐2	☐3
21. I express my negative feelings	☐0	☐1	☐2	☐3
22. I try to find comfort in my religion or spiritual beliefs.	☐0	☐1	☐2	☐3
23. I've been getting help and advice from other people.	☐0	☐1	☐2	☐3
24. I learn to live with it	☐0	☐1	☐2	☐3
25. I think hard about what steps to take	☐0	☐1	☐2	☐3
26. I blame myself for things that happened.	☐0	☐1	☐2	☐3
27. I pray or meditate	☐0	☐1	☐2	☐3
28. I make fun of the situation.	☐0	☐1	☐2	☐3

Appendix H

Apathy Evaluation Scale (Clinician Version)

Name: _____ Date: ____/____/_____

Rater: _____

Rate each item based on an interview of the subject. The interview should begin with a description of the subject's interests, activities, and daily routine. Base your ratings on both verbal and non-verbal information.
Ratings should be based on the past 4 weeks. For each item, rating should be judged:

	Not at All Characteristic 1	Slightly Characteristic 2	Somewhat Characteristic 3	A Lot Characteristic 4	
1. S/he is interested in things.....	☐	☐	☐	☐	+ C Q*
2. S/he gets things done during the day.....	☐	☐	☐	☐	+ B Q
3. Getting things started on his/her own is important to him/her.	☐	☐	☐	☐	+ C SE
4. S/he is interested in having new experiences.....	☐	☐	☐	☐	+ C Q
5. S/he is interesting learning new things.	☐	☐	☐	☐	+ C Q
6. S/he puts little effort into anything.	☐	☐	☐	☐	- B
7. S/he approaches life with intensity.	☐	☐	☐	☐	+ E
8. Seeing a job through to the end is important to her/him.	☐	☐	☐	☐	+ C SE
9. S/he spends time doing things that interest her/him.	☐	☐	☐	☐	+ B
10. Someone has to tell her/him what to do each day....	☐	☐	☐	☐	- B
11. S/he is less concerned about her/is problems than s/he should be.	☐	☐	☐	☐	- C
12. S/he has friends.....	☐	☐	☐	☐	+ B Q
13. Getting together with friends is important to him/her.	☐	☐	☐	☐	+ C SE
14. When something good happens, s/he gets excited...	☐	☐	☐	☐	+ E
15. S/he has an accurate understanding of her/his problems.	☐	☐	☐	☐	+ O
16. Getting things some during the day is important to her/him.	☐	☐	☐	☐	+ C SE
17. S/he has initiative.	☐	☐	☐	☐	+ O
18. S/he has motivation.	☐	☐	☐	☐	+ O

The Apathy Evaluatioin Scale was developed by Robert S. Marin, M.D. Development, validation studies, and administration guidelines are described in Marin RS, Biedzycki RC, Firinciogullari S. Reliability and validity of the Apathy Evaluation Scale. *Psychiatry Res.* 1991; 38:143-162. Table reprinted with permission. Supplementary administration guidelines are available from the author.
Note: Items that have positive versus negative syntax are identified by +/-. Type of item: C = cognitive; B = behavioral; E = emotional; O = other. The definitions of self-evaluation (SE) items and quantifiable items (Q) are discussed in the administration guidelines.

Appendix I

H. Lee Moffitt Cancer Center & Research Center
Moffitt Interdisciplinary Pain Program (MIPP)
Patient Pain Assessment Guide

Initials:_____ Today's date:_____

Where is your pain located? (please list each site if more than one)

_____

_____

How long have you had this pain?

_____

Circle the words that describe your pain:

Aching	Sharp	Penetrating
Throbbing	Tender	Nagging
Shooting	Burning	Numb
Stabbing	Exhausting	Miserable
Gnawing	Tiring	Unbearable
Tingling	Electric-like	Dull

Is your pain (circle one): continuous occasional (comes and goes)

If your pain is occasional (comes and goes), how long does the pain last?_____

How many times per day do you experience this pain?_____

What time of day is your pain the worst? (circle one)
morning afternoon evening nighttime

Rate your pain by circling the number that best describes your pain *RIGHT NOW*:
No pain 0 1 2 3 4 5 6 7 8 9 10 Worst imaginable pain

Rate your pain by circling the number that best describes your pain *AT ITS WORST*:
No pain 0 1 2 3 4 5 6 7 8 9 10 Worst imaginable pain

Rate your pain by circling the number that best describes your pain *AT ITS LEAST*:
No pain 0 1 2 3 4 5 6 7 8 9 10 Worst imaginable pain

Rate your pain by circling the number that best describes your pain *ON AVERAGE*:

Appendix I continued

Does Not Interfere 0 1 2 3 4 5 6 7 8 9 10 Completely Interferes

e. Relationships with Other People
Does Not Interfere 0 1 2 3 4 5 6 7 8 9 10 Completely Interferes

f. Sleep
Does Not Interfere 0 1 2 3 4 5 6 7 8 9 10 Completely Interferes

g. Enjoyment of Life
Does Not Interfere 0 1 2 3 4 5 6 7 8 9 10 Completely Interferes

Caregiver Information.

Who is the person that provides the most care for you at home? (excluding home healthcare staff, hospice staff, or private healthcare staff)_____

How many work days does your caregiver miss per month due to your pain?_____

How much physical strain by the caregiver is involved in your care?
No strain 0 1 2 3 4 5 6 7 8 9 10 Very much physical strain

How much emotional strain on the caregiver is involved in your care?
No strain 0 1 2 3 4 5 6 7 8 9 10 Very much emotional strain

How much financial hardship on the caregiver is involved in your care?
No hardship 0 1 2 3 4 5 6 7 8 9 10 Very much hardship

Appendix J

45448

CES-D SCALE

Fill in the number for each statement which best describes how often you felt or behaved this way -- DURING THE PAST WEEK.

	Rarely or None of the Time (Less than 1 Day)	Some or a Little of the Time (1-2 Days)	Occasionally (3-4 Days)	Most or All of the Time (5-7 Days)
1. I was bothered by things that usually don't bother me.	o	o	o	o
2. I did not feel like eating; my appetite was poor.	o	o	o	o
3. I felt that I could not shake off the blues even with help from family and friends.	o	o	o	o
4. I felt that I was just as good as other people.	o	o	o	o
5. I had trouble keeping my mind on what I was doing.	o	o	o	o
6. I felt depressed.	o	o	o	o
7. I felt that everything I did was an effort.	o	o	o	o
8. I felt hopeful about the future.	o	o	o	o
9. I thought my life had been a failure.	o	o	o	o
10. I felt fearful.	o	o	o	o
11. My sleep was restless.	o	o	o	o
12. I was happy.	o	o	o	o
13. I talked less than usual.	o	o	o	o
14. I felt lonely.	o	o	o	o
15. People were unfriendly.	o	o	o	o
16. I enjoyed life.	o	o	o	o
17. I had crying spells.	o	o	o	o
18. I felt sad.	o	o	o	o
19. I felt that other people disliked me.	-	-	-	-
20. I could not get "going".	o	o	o	o

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1 2 3 4 5 6 7 8 9 0

Appendix K

Permission to Make Copies of Research Version

SCID Central
Biometrics Research Department
New York State Psychiatric Institute
1051 Riverside Drive - Unit 60
New York, NY 10032

Telephone: 212-543-5524
FAX: 212-543-5525
e-mail: mbf2@columbia.edu

Michael B. First, MD (Editor, SCID Web page)
Miriam Gibbon, MSW (Co-editor, SCID Web page)
Robert L. Spitzer, MD (Director, Biometrics Research)
Janet B. W. Williams, DSW (Deputy Director, Biometrics Research)

Phone: 212-543-5524
EMAll..: mbf2@columbia.edu FAX: 212-543-5525

Memorandum

DATE: July 3, 2003

TO: Users of Research Version of SCill-I

FROM: Biometrics Research Department of New York State Psychiatric RE: Permission to

make photocopies of the SCID.

> The Research Version of the SCID is distributed as a single-sided master copy. The Biometrics Research Department of New York State Psychiatric Institute, the developer of the SCID, hereby grants permission to any investigator doing research funded by non-for-profit institutions (e.g., NIMH, NARSAD, Veteran's Administration) to make as many photocopies as they need-of the entire document or of any modules.
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http://cumc.columbia.edu/dept/scid/permform.htm
2/27/2004

Appendix L

A - 1

SCID

CURRENT MAJOR DEPRESSIVE EPISODE	MDE CRITERIA		
Now I am going to ask you some questions about your mood.	A. Five (or more) of the following symptoms have been present during the same two-week period and represent a change from previous functioning; at least one of the symptoms is either (1) depressed mood, or (2) loss of interest or pleasure.		
In the last month… …has there been a period of time when you were feeling depressed or down most of the day nearly every day? (What was that like?) IF YES: How long did it last? (as long as two weeks?)	depressed mood most of the day, nearly every day, as indicated either by subjective report (e.g., feels sad or empty) or observation made by others (e.g., appears tearful). Note: in children and adolescents can be irritable mood.	1 I i	3 III iii
…what about losing interest or pleasure in things you usually enjoyed? IF YES: Was it nearly every day? How long did it last? (As long as two weeks?)	(2) markedly diminished interest or pleasure in all, or almost all, activities most of the day, nearly every day (as indicated either by subjective account or observation made by others).	1 I i	3 III iii

FOR DSM-IV CRITERIA:
1=ABSENT OR FALSE
3=THRESHOLD OR TRUE

FOR HIGH THRESHOLD (SOMATIC R/O MED):
I=ABSENT OR FALSE
III=THRESHOLD OR TRUE

FOR SUBSTITUTIVE ITEMS:
i =ABSENT OR FALSE
iii=THRESHOLD OR TRUE

Appendix L continued

A - 2

FOR THE FOLLOWING QUESTIONS, FOCUS ON THE WORST TWO WEEKS IN THE PAST MONTH (OR ELSE THE PAST TWO WEEKS IF EQUALLY DEPRESSED FOR ENTIRE MONTH) During this (TWO WEEK PERIOD)…			
…did you lose or gain any weight? (How much?) (Were you trying to lose weight?) *IF NO*: How was your appetite? (What about compared to your usual appetite?) (Did you have to force yourself to eat?) (Eat [less/more] than usual?) (Was that nearly every day?)	(3) significant weight loss when not dieting, or weight gain (e.g., a change of more than 5% of body weight in a month) or decrease or increase in appetite nearly every day. Note: in children, consider failure to make expected weight gains. Check if: _____ weight loss _____ decreased appetite _____ weight gain _____ increased appetite	**1** **I**	**3** **III**
…how were you sleeping? (Trouble falling asleep, waking frequently, trouble staying asleep, waking too early, OR sleeping too much? How many hours a night compared to usual? Was that nearly every night?)	(4) insomnia or hypersomnia nearly every day Check if: _____ insomnia _____ hypersomnia	**1** **I**	**3** **III**
…were you so fidgety or restless that you were unable to sit still? (Was it so bad that other people noticed it? What did they notice? Was that nearly every day?) *IF NO*: What about the opposite—talking or moving more slowly than is normal for you? (Was it so bad that other people noticed it? What did they notice? Was that nearly every day?)	(5) psychomotor agitation or retardation nearly every day (observable by others, not merely subjective feelings of restlessness or being slowed down) Note: Also consider behavior during the interview Check if: _____ psychomotor retardation _____ psychomotor agitation	1 I i	3 III iii

FOR DSM-IV CRITERIA:
1=ABSENT OR FALSE
3=THRESHOLD OR TRUE

FOR HIGH THRESHOLD (SOMATIC R/O MED):
I=ABSENT OR FALSE
III=THRESHOLD OR TRUE

FOR SUBSTITUTIVE ITEMS:
i =ABSENT OR FALSE
iii=THRESHOLD OR TRUE

Appendix L continued

A - 3

During this time…

…what was your energy like? (Tired all the time? Nearly every day?)	(6) fatigue or loss of energy nearly every day	**1** **I**	**3** **III**
…how did you feel about yourself? (Worthless?) (Nearly every day?) *IF NO*: What about feeling guilty about things you had done or not done? (Nearly every day?)	(7) feelings of worthlessness or excessive or inappropriate guilt (which may be delusional) nearly every day (not merely self-reproach or guilt about being sick) Note: Code "1" or "2" if only low self-esteem Check if: _____ worthlessness _____ inappropriate guilt	1 I i	3 III iii
…did you have trouble thinking or concentrating? (What kinds of things did it interfere with?) (Nearly every day?) *IF NO*: Was it hard to make decisions about everyday things? (Nearly every day?)	(8) diminished ability to think or concentrate, or indecisiveness, nearly every day (either by subjective account or as observed by others) Check if: _____ diminished ability to think _____ indecisiveness	**1** **I**	**3** **III**
…did you worry a lot? (How much did you worry?) (What kinds of things were you worrying about?) (How much of your time was spent in this?) (Nearly every day?) (Were you able to get your mind off it?)	(9) worrying, brooding, painful preoccupation and inability to get mind off unpleasant thoughts (may or may not be accompanied by depressive mood)	i	iii

FOR DSM-IV CRITERIA:
1=ABSENT OR FALSE
3=THRESHOLD OR TRUE

FOR HIGH THRESHOLD (SOMATIC R/O MED):
I=ABSENT OR FALSE
III=THRESHOLD OR TRUE

FOR SUBSTITUTIVE ITEMS:
i =ABSENT OR FALSE
iii=THRESHOLD OR TRUE

Appendix L continued

		A - 4	
During this (TWO WEEK PERIOD)…			
…did you feel anxious, frightened, fearful, scared, or apprehensive? (How often did you feel this way?) (Nearly every day?) (How bad did it get?)	(10) psychic anxiety. Subjective feelings of anxiety, fearfulness, or apprehension, excluding anxiety attacks, whether or not accompanied by physical symptoms of anxiety, or whether focused on specific concerns or not.	i	iii
…did you lose interest in being around others or in engaging in conversation? (Nearly every day?) (What did you do when others would visit?) (Did you find it difficult to interact with them?)	(11) social withdrawal or decreased talkativeness. Pervasiveness of loss of interest in being around others, in engaging in conversation	i	iii
…were people unable to say things to cheer you up? (Did you find things less humorous than before?) (Did things that you found funny before now seem less humorous?) (Did TV programs, radio shows, or things you read that you found funny before seem less humorous now?) (Was this true nearly every day during this time period?)	(12) sense of humor. Patient cannot be cheered up, does not smile, no response to good news or funny situations	i	iii
…were you discouraged, pessimistic, or hopeless? (Nearly every day?) (Did you see yourself or your situation getting any better?) [(What kind of future do you see for yourself?) (How do you think things will work out?)]	(13) discouragement, pessimism, hopelessness	i	iii

FOR DSM-IV CRITERIA:
1=ABSENT OR FALSE
3=THRESHOLD OR TRUE

FOR HIGH THRESHOLD (SOMATIC R/O MED):
1=ABSENT OR FALSE
III=THRESHOLD OR TRUE

FOR SUBSTITUTIVE ITEMS:
i =ABSENT OR FALSE
iii=THRESHOLD OR TRUE

Appendix L continued

A - 5

…were things so bad that you were thinking a lot about death or that you would be better off dead? What about thinking of hurting yourself? IF YES: Did you do anything to hurt yourself?	(14) recurrent thoughts of death (not just fear of dying), recurrent suicidal ideation without a specific plan for committing suicide Note: code "1" for self-mutilation w/o suicidal intent Check if: _____ thoughts of own death _____ suicidal ideation _____ specific plan _____ suicide attempt	1 I i	3 III iii

Please code as follows:

0 No information
1 Not at all
2 Slight, e.g., occasional thoughts, "I would be better off dead"
3 Mild, e.g., frequent thoughts; no plan
4 Moderate, e.g., often thinks of suicide or has a specific plan
5 Severe, e.g., often thinks of suicide; has mentally rehearsed a plan, or verbal gesture
6 Extreme, e.g., has prepared for a serious suicide attempt
7 Very extreme, e.g., suicidal attempt with definite intent to die

CONTINUE IF AT LEAST FIVE OF THESE ITEMS ARE CODED "3" AND AT LEAST ONE OF THESE ITEMS IS ITEM (1) OR (2)	1 **&** **GO TO *PAST MAJOR DEPRES-SIVE EPI-SODE,* A. 7**	3

FOR DSM-IV CRITERIA:
1=ABSENT OR FALSE
3=THRESHOLD OR TRUE

FOR HIGH THRESHOLD (SOMATIC R/O MED):
I=ABSENT OR FALSE
III=THRESHOLD OR TRUE

FOR SUBSTITUTIVE ITEMS:
i =ABSENT OR FALSE
iii=THRESHOLD OR TRUE

Appendix L continued

A - 6

IF UNCLEAR: Has (DEPRESSIVE EPISODE/OWN WORDS) made it hard for you to do your work, take care of things at home, or get along with other people?	B. The symptoms cause clinically significant distress or impairment in social, occupational, or other important areas of functioning.	1 **&** **GO TO *PAST MAJOR DEPRES-SIVE EPI-SODE,* A. 7**	3
Just before this began, were you drinking or using any street drugs?	C. Not due to the direct physiological effects of a substance. IF SUBSTANCE MAY BE ETIOLOGICALLY ASSOCIATED WITH DEPRESSION, GO TO ***SUBSTANCE,* A. 38** AND RETURN HERE TO MAKE RATING OF "1" OR "3."	1 **&** DUE TO SUBSTANCE USE. GO TO ***PAST MAJOR DEPRESSIVE EPISODE,*A. 7**	3
(Did this begin soon after someone close to you died?)	D. Not better accounted for by Bereavement, i.e., after the loss of a loved one, the symptoms persist for longer than 2 months or are characterized by marked functional impairment, morbid preoccupation with worthlessness, suicidal ideation, psychotic symptoms, or psychomotor retardation.	1 **&** *SIMPLE BEREAVE-MENT* **GO TO *PAST MAJOR DEPRES-SIVE EPI-SODE,* A. 7**	3 **&** NOT SIMPLE BE-REAVE-MENT *CURRENT MAJOR DEPRES-SIVE EPISODE*
How many separate times in your life have you been (depressed/OWN WORDS) nearly every day for at least two weeks and had several of the symptoms that you described like (SXS OF WORST EPISODE)?	Total number of Major Depressive Episodes, including current (CODE 99 IF TOO NUMEROUS OR INDISTINCT TO COUNT)	____ ____ **&** **GO TO *CURRENT MANIC EPISODE,* A. 17**	

FOR DSM-IV CRITERIA:
1=ABSENT OR FALSE
3=THRESHOLD OR TRUE

FOR HIGH THRESHOLD (SOMATIC R/O MED):
I=ABSENT OR FALSE
III=THRESHOLD OR TRUE

FOR SUBSTITUTIVE ITEMS:
i =ABSENT OR FALSE
iii=THRESHOLD OR TRUE

Appendix L continued

A - 7

PAST MAJOR DEPRESSIVE EPISODE

- IF NOT CURRENTLY DEPRESSED: Have you ever had a period when you were feeling depressed or down most of the day nearly every day? (What was that like?)
- IF CURRENTLY DEPRESSED BUT FULL CRITERIA ARE NOT MET, SCREEN FOR PAST MDE: Has there ever been another time when you were depressed or down most of the day nearly every day? (What was that like?)
  IF YES: When was that? How long did it last? (As long as two weeks?)
- IF PAST DEPRESSED MOOD: During that time, did you lose interest or pleasure in things you usually enjoyed? (What was that like?)
- IF NO PAST DEPRESSED MOOD: What about a time when you lost interest or pleasure in things you usually enjoyed? (What was that like?) _____.
  IF YES: When was that? Was it nearly every day? How long did it last? (As long as two weeks?)

Have you had more than one time like that? (Which time was the worst?)
IF UNCLEAR: Have you had any times like that in the past year?

MDE CRITERIA

A. Five or more of the following symptoms have been present during the same two-week period and represent a change from previous functioning; at least one of the symptoms was either
(1) depressed mood or
(2) loss of interest or pleasure.

(1) depressed mood most of the day, nearly every day, as indicated by either subjective report (e.g., feels sad or empty) or observation made by others (e.g., appears tearful). Note: in children and adolescents, can be irritable mood.	1 I i	3 III iii
(2) Markedly diminished interest or pleasure in all, or almost all, activities most of the day, nearly every day (as indicated either by subjective account or observation made by others)	1 I i	3 III iii

&

IF NEITHER ITEM (1) OR (2) IS CODED "3 (III/iii)," GO TO *CURRENT MANIC EPISODE* A. 17

NOTE: IF MORE THAN ONE PAST EPIDSODE IS LIKELY, SELECT THE "WORST" ONE FOR YOUR INQUIRY ABOUT A PAST MAJOR DEPRESSIVE EPIDOSE. HOWEVER, IF THERE WAS AN EPISODE IN THE PAST YEAR, ASK ABOUT THAT EPISODE EVEN IF IT WAS NOT THE WORST.

FOR DSM-IV CRITERIA:
1=ABSENT OR FALSE
3=THRESHOLD OR TRUE

FOR HIGH THRESHOLD (SOMATIC R/O MED):
I=ABSENT OR FALSE
III=THRESHOLD OR TRUE

FOR SUBSTITUTIVE ITEMS:
i =ABSENT OR FALSE
iii=THRESHOLD OR TRUE

Appendix L continued

A - 8

FOR THE FOLLOWING QUESTIONS, FOCUS ON THE WORST TWO WEEKS IN THE PAST MONTH (OR ELSE THE PAST TWO WEEKS IF EQUALLY DEPRESSED FOR ENTIRE MONTH)			
During this (TWO WEEK PERIOD)…			
…did you lose or gain any weight? (How much?) (Were you trying to lose weight?) *IF NO*: How was your appetite? (What about compared to your usual appetite?) (Did you have to force yourself to eat?) (Eat [less/more] than usual?) (Was that nearly every day?)	(3) significant weight loss when not dieting, or weight gain (e.g., a change of more than 5% of body weight in a month) or decrease or increase in appetite nearly every day. Note: in children, consider failure to make expected weight gains. Check if: _____ weight loss _____ decreased appetite _____ weight gain _____ increased appetite	**1** **I**	**3** **III**
…how were you sleeping? (Trouble falling asleep, waking frequently, trouble staying asleep, waking too early, OR sleeping too much? How many hours a night compared to usual? Was that nearly every night?)	(4) insomnia or hypersomnia nearly every day Check if: _____ insomnia _____ hypersomnia	**1** **I**	**3** **III**
…were you so fidgety or restless that you were unable to sit still? (Was it so bad that other people noticed it? What did they notice? Was that nearly every day?) *IF NO*: What about the opposite—talking or moving more slowly than is normal for you? (Was it so bad that other people noticed it? What did they notice? Was that nearly every day?)	(5) psychomotor agitation or retardation nearly every day (observable by others, not merely subjective feelings of restlessness or being slowed down) Note: Also consider behavior during the interview Check if: _____ psychomotor retardation _____ psychomotor agitation	1 I i	3 III iii

FOR DSM-IV CRITERIA:
1=ABSENT OR FALSE
3=THRESHOLD OR TRUE

FOR HIGH THRESHOLD (SOMATIC R/O MED):
I=ABSENT OR FALSE
III=THRESHOLD OR TRUE

FOR SUBSTITUTIVE ITEMS:
i =ABSENT OR FALSE
iii=THRESHOLD OR TRUE

Appendix L continued

A - 9

During this time…

…what was your energy like? (Tired all the time? Nearly every day?)	(6) fatigue or loss of energy nearly every day	**1** **I**	**3** **III**
…how did you feel about yourself? (Worthless?) (Nearly every day?) *IF NO*: What about feeling guilty about things you had done or not done? (Nearly every day?)	(7) feelings of worthlessness or excessive or inappropriate guilt (which may be delusional) nearly every day (not merely self-reproach or guilt about being sick) Note: Code "1" or "2" if only low self-esteem Check if: _____ worthlessness _____ inappropriate guilt	1 I i	3 III iii
…did you have trouble thinking or concentrating? (What kinds of things did it interfere with?) (Nearly every day?) *IF NO*: Was it hard to make decisions about everyday things? (Nearly every day?)	(8) diminished ability to think or concentrate, or indecisiveness, nearly every day (either by subjective account or as observed by others) Check if: _____ diminished ability to think _____ indecisiveness	**1** **I**	**3** **III**
…did you worry a lot? (How much did you worry?) (What kinds of things were you worrying about?) (How much of your time was spent in this?) (Nearly every day?) (Were you able to get your mind off it?)	(9) worrying, brooding, painful preoccupation and inability to get mind off unpleasant thoughts (may or may not be accompanied by depressive mood)	i	iii

FOR DSM-IV CRITERIA:
1=ABSENT OR FALSE
3=THRESHOLD OR TRUE

FOR HIGH THRESHOLD (SOMATIC R/O MED):
I=ABSENT OR FALSE
III=THRESHOLD OR TRUE

FOR SUBSTITUTIVE ITEMS:
i =ABSENT OR FALSE
iii=THRESHOLD OR TRUE

Appendix L continued

A - 10

During this (TWO WEEK PERIOD)…			
…did you feel anxious, frightened, fearful, scared, or apprehensive? (How often did you feel this way?) (Nearly every day?) (How bad did it get?)	(10) psychic anxiety. Subjective feelings of anxiety, fearfulness, or apprehension, excluding anxiety attacks, whether or not accompanied by physical symptoms of anxiety, or whether focused on specific concerns or not.	i	iii
…did you lose interest in being around others or in engaging in conversation? (Nearly every day?) (What did you do when others would visit?) (Did you find it difficult to interact with them?)	(11) social withdrawal or decreased talkativeness. Pervasiveness of loss of interest in being around others, in engaging in conversation	i	iii
…were people unable to say things to cheer you up? (Did you find things less humorous than before?) (Did things that you found funny before now seem less humorous?) (Did TV programs, radio shows, or things you read that you found funny before seem less humorous now?) (Was this true nearly every day during this time period?)	(12) sensc of humor. Patient cannot be cheered up, does not smile, no response to good news or funny situations	i	iii
…were you discouraged, pessimistic, or hopeless? (Nearly every day?) (Did you see yourself or your situation getting any better?) [(What kind of future do you see for yourself?) (How do you think things will work out?)]	(13) discouragement pessimism, hopelessness	i	iii

FOR DSM-IV CRITERIA:
1=ABSENT OR FALSE
3=THRESHOLD OR TRUE

FOR HIGH THRESHOLD (SOMATIC R/O MED):
I=ABSENT OR FALSE
III=THRESHOLD OR TRUE

FOR SUBSTITUTIVE ITEMS
i =ABSENT OR FALSE
iii=THRESHOLD OR TRUE

Appendix L continued

A - 11

…were things so bad that you were thinking a lot about death or that you would be better off dead? What about thinking of hurting yourself?

IF YES: Did you do anything to hurt yourself?

(14) recurrent thoughts of death (not just fear of dying), recurrent suicidal ideation without a specific plan for committing suicide

Note: code "1" for self-mutilation w/o suicidal intent

Check if:
_____ thoughts of own death
_____ suicidal ideation
_____ specific plan
_____ suicide attempt

1	3
I	III
i	iii

Please code as follows:
0 No information
1 Not at all
2 Slight, e.g., occasional thoughts, "I would be better off dead"
3 Mild, e.g., frequent thoughts; no plan
4 Moderate, e.g., often thinks of suicide or has a specific plan
5 Severe, e.g., often thinks of suicide; has mentally rehearsed a plan, or verbal gesture
6 Extreme, e.g., has prepared for a serious suicide attempt
7 Very extreme, e.g., suicidal attempt with definite intent to die

CONTINUE IF AT LEAST FIVE OF THESE ITEMS ARE CODED "3" AND AT LEAST ONE OF THESE ITEMS IS ITEM (1) OR (2)

1 & → GO TO NEXT PAGE, A. 12

3 & → GO TO PAGE A. 13

FOR DSM-IV CRITERIA:
1=ABSENT OR FALSE
3=THRESHOLD OR TRUE

FOR HIGH THRESHOLD (SOMATIC R/O MED):
I=ABSENT OR FALSE
III=THRESHOLD OR TRUE

FOR SUBSTITUTIVE ITEMS
i =ABSENT OR FALSE
iii=THRESHOLD OR TRUE

Appendix L continued

IF NOT ALREADY ASKED: Has there been any other time when you were (depressed/OWN WORDS) and had even more of the symptoms than I just asked you about?

IF YES: RETURN TO ***PAST MAJOR DEPRESSIVE EPISODE,*** A. 7, AND CHECK WHETHER THERE HAVE BEEN ANY OTHER MAJOR DEPRESSIVE EPISODES THAT WERE MORE SEVERE AND/OR CAUSED MORE SYMPTOMS. IF SO, ASK ABOUT THAT EPISODE.

IF NO: GO TO ***CURRENT MANIC EPISODE,* A. 17**

FOR DSM-IV CRITERIA:
1=ABSENT OR FALSE
3=THRESHOLD OR TRUE

FOR HIGH THRESHOLD (SOMATIC R/O MED):
I=ABSENT OR FALSE
III=THRESHOLD OR TRUE

FOR SUBSTITUTIVE ITEMS:
i =ABSENT OR FALSE
iii=THRESHOLD OR TRUE

Appendix M

SCID-I Version 2.0 (for DSM-IV) Alcohol Use Disorders (FEB 1996 FINAL) E. 1

E. SUBSTANCE USE DISORDERS

ALCOHOL USE DISORDERS (LIFETIME)

IF SCREENING QUESTION #1 ANSWERED "NO," CHECK HERE ____ AND SKIP TO ***NON-ALCOHOL SUBSTANCE USE DISORDERS,*** E. 10

SCREEN Q#1: YES | NO

IF NO: GO TO ***NON-ALCOHOL USE DISORDERS*** E. 10

IF SCREENER NOT USED OR IF QUESTION #1 IS ANSWERED "YES," CONTINUE:

What are your drinking habits like? (How much do you drink?) (Has there ever been a time in your life when you had five or more drinks on one occasion?)

When in your life were you drinking the most? (How long did that period last?)

RECORD DATE OF HEAVIEST USE AND DESCRIBE PATTERN:

_____

_____

During that time...

how often were you drinking?

what were you drinking? how much?

During that time...

did your drinking cause problems for you?

did anyone object to your drinking?

IF ALCOHOL DEPENDENCE SEEMS LIKELY, CHECK HERE ___ AND SKIP TO ***ALCOHOL DEPENDENCE,*** E. 4.

E1

IF ANY INCIDENTS OF EXCESSIVE DRINKING OR ANY EVIDENCE OF ALCOHOL-RELATED PROBLEMS, CONTINUE WITH ***ALCOHOL ABUSE,*** ON NEXT PAGE.

IF NEVER HAD ANY INCIDENTS OF EXCESSIVE DRINKING AND THERE IS NO EVIDENCE OF ANY ALCOHOL-RELATED PROBLEMS, SKIP TO ***NON-ALCOHOL SUBSTNCE USE DISORDERS,*** E. 10

?=inadequate information 1=absent or false 2=subthreshold 3=threshold or true

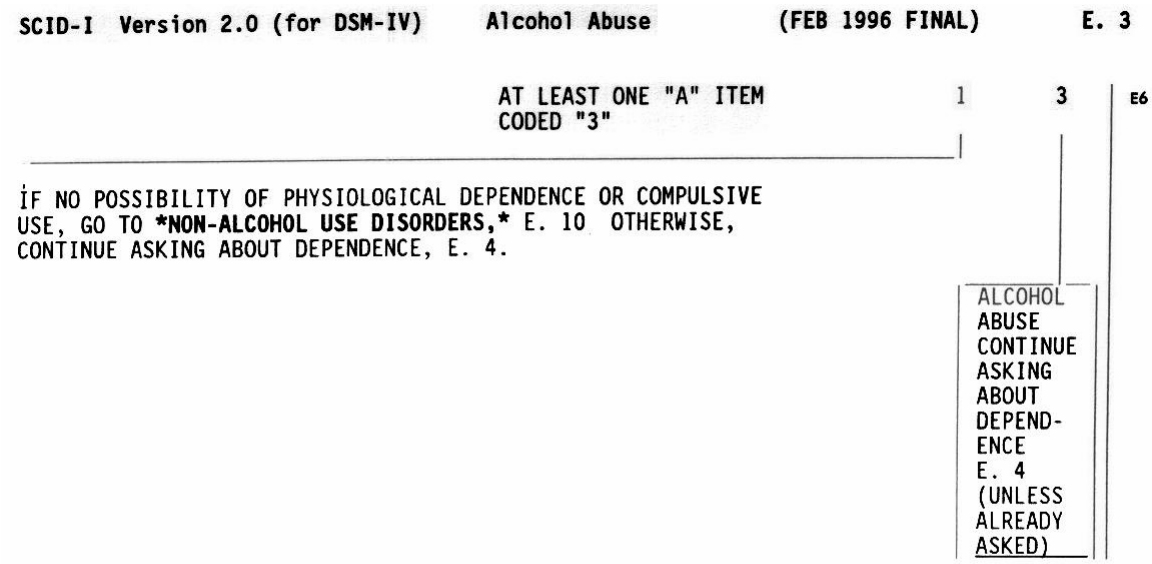
Appendix M continued

SCID-I Version 2.0 (for DSM-IV)	Alcohol Abuse	(FEB 1996 FINAL)	E. 2

LIFETIME ALCOHOL ABUSE	ALCOHOL ABUSE CRITERIA		
Let me ask you a few more questions about your drinking habits.	A. A maladaptive pattern of substance use leading to clinically significant impairment or distress, as manifested by one (or more) of the following occurring within a twelve month period:		
Have you ever missed work or school because you were intoxicated, high, or very hung over? (How often? What about doing a bad job at work or failing courses at school because of your drinking?) IF NO: What about not keeping your house clean or not taking proper care of your children because of your drinking? (How often?) IF YES TO EITHER OF ABOVE: How often? (Over what period of time?)	(1) recurrent alcohol use resulting in a failure to fulfill major role obligations at work, school, or home (e.g., repeated absences or poor work performance related to alcohol use; alcohol-related absences, suspensions, or expulsions from school; neglect of children or household)	? 1 2 3	E2
Did you ever drink in a situation in which it might have been dangerous to drink at all? (Did you ever drive while you were really too drunk to drive?) IF YES AND UNKNOWN: How often? (Over what period of time?)	(2) recurrent alcohol use in situations in which it is physically hazardous (e.g., driving an automobile or operating a machine when impaired by alcohol use)	? 1 2 **3**	E3
Has your drinking gotten you into trouble with the law? IF YES AND UNKNOWN: How often? (Over what period of time?)	(3) recurrent alcohol-related legal problems (e.g., arrests for alcohol-related disorderly conduct)	? 1 2 3	E4
IF NOT ALREADY KNOWN: Has your drinking caused problems with other people, such as with family members, friends, or people at work? (Have you ever gotten into physical fights or had bad arguments about your drinking?) IF YES: Did you keep on drinking anyway? (Over what period of time?)	(4) continued alcohol use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of alcohol (e.g., arguments with spouse about consequences of intoxication, physical fights)	? 1 2 3	E5

?=inadequate information 1=absent or false 2=subthreshold 3=threshold or true

Appendix M continued



Appendix M continued

SCID-I Version 2.0 (for DSM-IV) Alcohol Abuse (FEB 1996 FINAL) E. 4

ALCOHOL DEPENDENCE	ALCOHOL DEPENDENCE CRITERIA					
I'd now like to ask you some more questions about your drinking habits.	A maladaptive pattern of alcohol use, leading to clinically significant impairment or distress, as manifested by three (or more) of the following occurring at any time in the same twelve month period: NOTE: CRITERIA FOR ALCOHOL DEPENDENCE ARE NOT IN DSM-IV ORDER					
Have you often found that when you started drinking you ended up drinking much more than you were planning to? IF NO: What about drinking for a much longer period of time than you were planning to?	(3) alcohol is often taken in larger amounts OR over a longer period than was intended	?	1	2	3	E7
Have you tried to cut down or stop drinking alcohol? IF YES: Did you ever actually stop drinking altogether? (How many times did you try to cut down or stop altogether?) IF NO: Did you want to stop or cut down? (Is this something you kept worrying about?)	(4) there is a persistent desire OR unsuccessful efforts to cut down or control substance use	?	1	2	3	E8
Have you spent a lot of time drinking, being high, or hung over?	(5) a great deal of time is spent in activities necessary to obtain alcohol, use alcohol, or recover from its effects	?	1	2	3	E9
Have you had times when you would drink so often that you started to drink instead of working or spending time at hobbies or with your family or friends?	(6) important social, occupational, or recreational activities given up or reduced because of alcohol use	?	1	2	3	E10

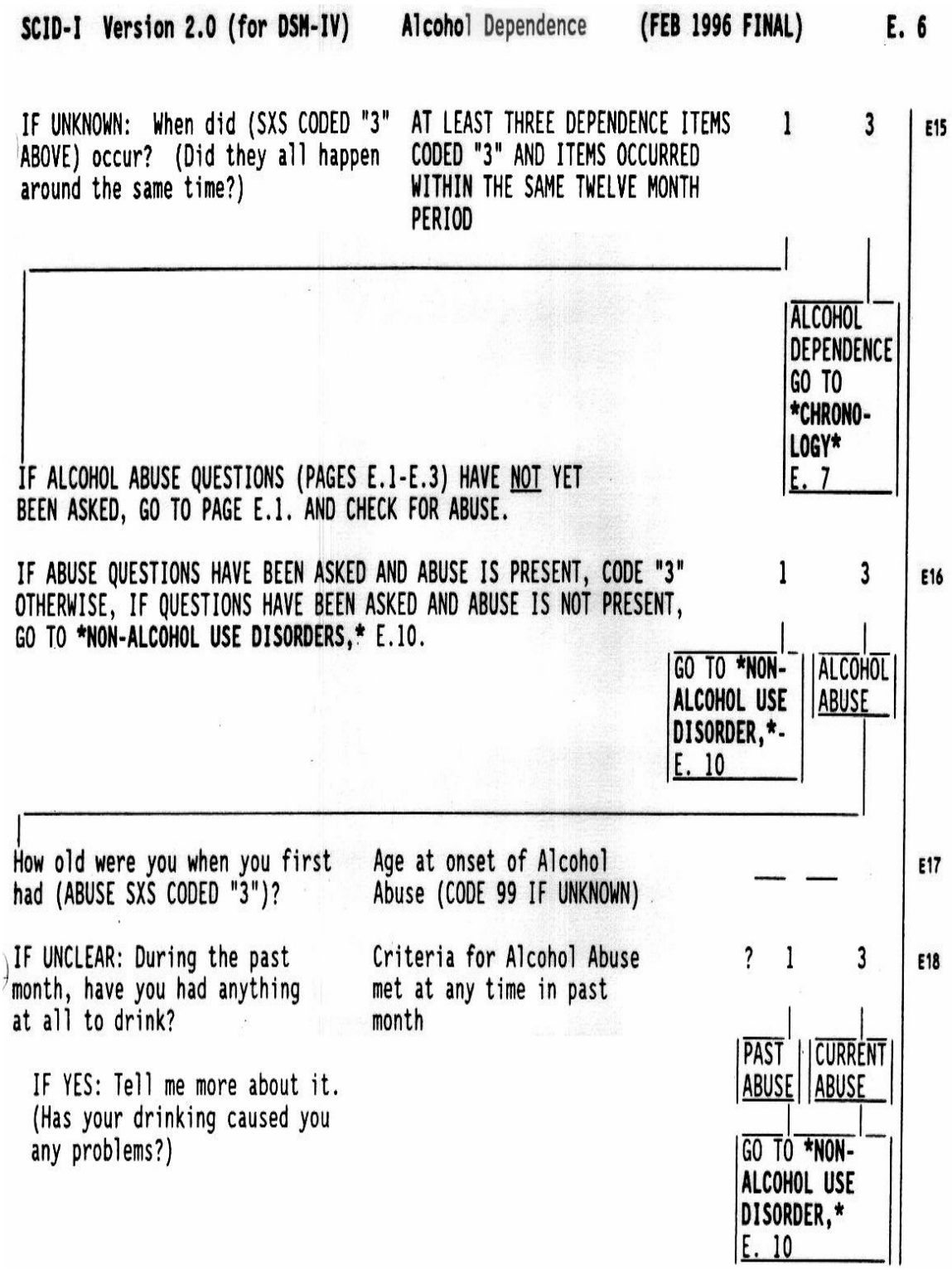
?=inadequate information 1=absent or false 2=subthreshold 3=threshold or true

Appendix M continued

SCID-I Version 2.0 (for DSM-IV)	Alcohol Dependence (FEB 1996 FINAL)					E. 5
IF NOT ALREADY KNOWN: Has your drinking ever caused any psychological problems like making you depressed or anxious, making it difficult to sleep, or causing "blackouts?" IF NOT ALREADY KNOWN: Has your drinking ever caused significant physical problems or made a physical problem worse? IF YES TO EITHER OF ABOVE: Did you keep on drinking anyway?	(7) alcohol use is continued despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by alcohol (e.g., continued drinking despite recognition that an ulcer was made worse by alcohol consumption)	?	1	2	3	E11
Have you found that you needed to drink a lot more in order to get the feeling you wanted than you did when you first started drinking? IF YES: How much more? IF NO: What about finding that when you drank the same amount, it had much less effect than before?	(1) tolerance, as defined by either of the following: (a) a need for markedly increased amounts of alcohol to achieve intoxication or desired effect (b) markedly diminished effect with continued use of the same amount of alcohol	?	1	2	3	E12
Have you ever had any withdrawal symptoms when you cut down or stopped drinking like... ...sweating or racing heart? ...hand shakes? ...trouble sleeping? ...feeling nauseated or vomiting? ...feeling agitated? ...or feeling anxious? (How about having a seizure or seeing, feeling, or hearing things that weren't really there?)	(2) withdrawal, as manifested by either (a) or (b): (a) at least TWO of the following: -- autonomic hyperactivity (e.g., sweating or pulse rate greater than 100) -- increased hand tremor -- insomnia -- nausea or vomiting -- psychomotor agitation -- anxiety -- grand mal seizures -- transient visual, tactile, or auditory hallucinations or illusions	?	1	2	3	E13
IF NO: Have you ever started the day with a drink, or did you often drink to keep yourself from getting the shakes or becoming sick?	(b) alcohol (or a substance from the sedative/hypnotic/anxiolytic class) taken to relieve or avoid withdrawal symptoms					E14

?=inadequate information 1=absent or false 2=subthreshold 3=threshold or true

Appendix M continued



SCID-I Version 2.0 (for DSM-IV) Alcohol Dependence (FEB 1996 FINAL) E. 6

IF UNKNOWN: When did (SXS CODED "3" ABOVE) occur? (Did they all happen around the same time?)	AT LEAST THREE DEPENDENCE ITEMS CODED "3" AND ITEMS OCCURRED WITHIN THE SAME TWELVE MONTH PERIOD	1	3	E15

→ 3: ALCOHOL DEPENDENCE GO TO *CHRONOLOGY* E. 7

IF ALCOHOL ABUSE QUESTIONS (PAGES E.1-E.3) HAVE NOT YET BEEN ASKED, GO TO PAGE E.1. AND CHECK FOR ABUSE.

IF ABUSE QUESTIONS HAVE BEEN ASKED AND ABUSE IS PRESENT, CODE "3" OTHERWISE, IF QUESTIONS HAVE BEEN ASKED AND ABUSE IS NOT PRESENT, GO TO *NON-ALCOHOL USE DISORDERS,* E.10.		1	3	E16

→ 1: GO TO *NON-ALCOHOL USE DISORDER,* E. 10

→ 3: ALCOHOL ABUSE

How old were you when you first had (ABUSE SXS CODED "3")?	Age at onset of Alcohol Abuse (CODE 99 IF UNKNOWN)	__ __		E17
IF UNCLEAR: During the past month, have you had anything at all to drink? IF YES: Tell me more about it. (Has your drinking caused you any problems?)	Criteria for Alcohol Abuse met at any time in past month	?	1 3	E18

→ 1: PAST ABUSE

→ 3: CURRENT ABUSE

→ GO TO *NON-ALCOHOL USE DISORDER,* E. 10

Appendix M continued

SCID-I Version 2.0 (for DSM-IV) Alcohol Dependence (FEB 1996 FINAL) E. 7

CHRONOLOGY FOR DEPENDENCE

How old were you when you first had (LIST OF ALCOHOL DEPENDENCE OR ABUSE SXS CODED "3")?	Age at onset of Alcohol Dependence or Abuse (CODE 99 IF UNKNOWN)	___ ___	E19
IF UNCLEAR: During the past month, have you had anything at all to drink? IF YES: Tell me more about it. (Has your drinking caused you any problems?)	Full criteria for Alcohol Dependence met at any time in past month (or never had a month without symptoms of Dependence or Abuse since onset of Dependence)	? 1 3 GO TO *REMISSION SPECIFIERS* E.8 CURRENT DEPEND-ENCE	E20

Indicate if: E21

1 - **With Physiological Dependence** (current evidence of tolerance or withdrawal)

2 - **Without Physiological Dependence** (no current evidence of tolerance or withdrawal)

NOTE SEVERITY OF DEPENDENCE FOR WORST WEEK OF PAST MONTH (Additional questions about the effect of alcohol on social and occupational functioning may be necessary.) E22

1 Mild: Few, if any, symptoms in excess of those required to make the diagnosis, and the symptoms result in no more than mild impairment in occupational functioning or in usual social activities or relationships with others (or criteria met for Dependence in the past and some current problems).

2 Moderate: Symptoms or functional impairment between "mild" and "severe."

3 Severe: Many symptoms in excess of those required to make the diagnosis, and the symptoms markedly interfere with occupational functioning or with usual social activities or relationships with others.

GO TO NON-ALCOHOL USE DISORDERS, E.10

Appendix M continued

SCID-I Version 2.0 (for DSM-IV) Alcohol Dependence (FEB 1996 FINAL) E.8

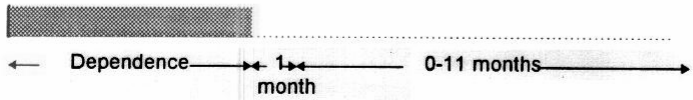
REMISSION SPECIFIERS FOR DEPENDENCE

THE FOLLOWING REMISSION SPECIFIERS CAN BE APPLIED ONLY AFTER NO CRITERIA FOR DEPENDENCE OR ABUSE HAVE BEEN MET FOR AT LEAST ONE MONTH IN THE PAST.

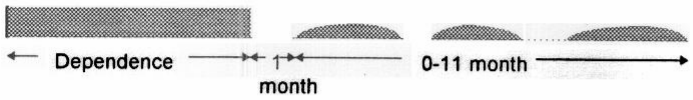
Note: These specifiers do not apply if the individual is **On Agonist Therapy** or **In a Controlled Environment** (next page).

Number of months prior to interview when last had some problems with Alcohol. ___ ___ ___ E23

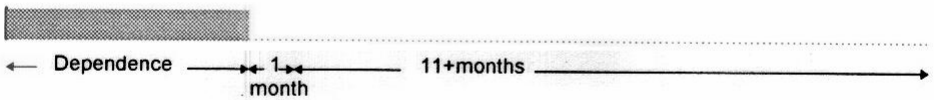
1 **Early Full Remission**: For at least one month, but less than twelve months, no criteria for Dependence or Abuse have been met. E24



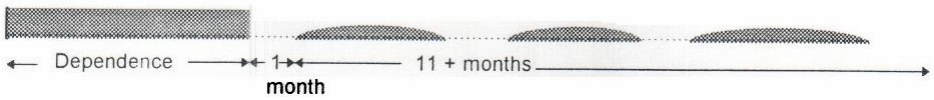
2 **Early Partial Remission:** For at least one month, but less than twelve months, one or more criteria for Dependence or Abuse have been met (but the full criteria for Dependence have not been met).



3 **Sustained Full Remission**: None of the criteria for Dependence or Abuse have been met at any time during a period of twelve months or longer.



4 **Sustained Partial Remission**: Full criteria for Dependence have not been met for a period of twelve months or longer; however, one or more criteria for Dependence or Abuse have been met.



Appendix M continued

SCID-I Version 2.0 (for DSM-IV) Alcohol Dependence (FEB 1996 FINAL) E. 9

Check ____ if **On Agonist Therapy:** The individual is on a prescribed agonist medication (e.g., valium) and no criteria for Dependence or Abuse have been met for that class of medication for at least the past month (except tolerance to, or withdrawal from, the agonist). This category also applies to those being treated for Dependence using a partial agonist or a mixed agonist/antagonist. E25

Check ____ if **In A Controlled Environment:** The individual is in an environment where access to alcohol and controlled substances is restricted and no criteria for Dependence or Abuse have been met for at least the past month. Examples are closely-supervised and substance-free jails, therapeutic communities, and locked hospital units. E26

?=inadequate information 1=absent or false 2=subthreshold 3=threshold or true

Appendix N

9207

IES

Below is a list of comments made by people about stressful events. For each item, fill in the circle that indicates how frequently the comments were true for you DURING THE PAST WEEK INCLUDING TODAY ABOUT YOUR CANCER AND ITS TREATMENT. If they did not occur during that time, please fill in the "not at all" bubble.

	Not at all	*Rarely*	*Sometimes*	*Often*
1. Thought about it when I didn't mean to.	O	O	O	O
2. I avoided letting myself get upset when I thought about it or was reminded of it.	O	O	O	O
3. I tried to remove it from memory.	O	O	O	O
4. I had trouble falling asleep or staying asleep, because of pictures or thoughts about it that came into my mind.	O	O	O	O
5. I had waves of strong feelings about it.	O	O	O	O
6. I had dreams about it.	O	O	O	O
7. I stayed away from reminders of it.	O	O	O	O
8. I felt as if it was not real.	O	O	O	O
9. I tried not to talk about it.	O	O	O	O
10. Pictures about it popped into my mind.	O	O	O	O
11. Other things kept making me think about it.	O	O	O	O
12. I was aware that I had a lot of feelings about it, but I didn't deal with them.	O	O	O	O
13. I tried not to think about it.	O	O	O	O
14. Any reminder brought back feelings about it.	O	O	O	O
15. My feelings about it were kind of numb.	O	O	O	O

Office Use Only

1 2 3 4 5 6 7 8 9 0

Appendix O

9136

ID#_____ Date_____

ECOG

Directions: Please fill in the circle next to the number that describes your current level of activity.

O 0	Fully active, able to carry on all pre-disease performance without restriction.
O 1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work.
O 2	Ambulatory and capable of all self care but unable to carry out any work activities. Up and about more than 50% of waking hours.
O 3	Capable of only limited self care, confined to bed or chair more than 50% of waking hours.
O 4	Completely disabled. Cannot carry on any self care. Totally confined to bed or chair.

Office Use Only

1 O O O O
2 O O O O
3 O O O O
4 O O O O
5 O O O O
6 O O O O
7 O O O O
8 O O O O
9 O O O O
0 O O O O

Appendix P

9245

ISEL-SF

This scale is made up of a list of statements, each of which may or may not be true about you. Please read each statement, then fill in the circle that best describes **how true or false that statement is about you**. Remember to darken only one circle for each statement.

	Completely False	*Somewhat False*	*Somewhat True*	*Completely True*
1. If I had to go out of town for a few weeks, someone I know would look after my home, such as watering the plants or taking care of the pets.	O	O	O	O
2. If I were sick and needed someone to drive me to the doctor, I would have trouble finding someone.	O	O	O	O
3. If I were sick, I would have trouble finding someone to help me with my daily chores.	O	O	O	O
4. If I needed help moving, I would be able to find someone to help me.	O	O	O	O
5. If I needed a place to stay for a week because of an emergency, such as the water or electricity being out in my home, I could easily find someone who would put me up.	O	O	O	O
6. There is at least one person I know whose advice I really trust.	O	O	O	O
7. There is no one I know who will tell me honestly how I am handling my problems.	O	O	O	O

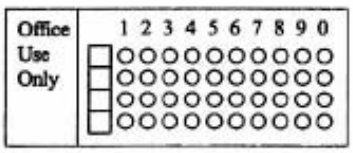
Office Use Only

1 2 3 4 5 6 7 8 9 0

Appendix P continued

9245

	Completely False	*Somewhat False*	*Somewhat True*	*Completely True*
8. When I need suggestions about how to deal with a personal problem, I know there is someone I can turn to.	o	o	o	o
9. There isn't anyone I feel comfortable talking to about intimate personal problems.	o	o	o	o
10. There is no one I trust to give me good advice about money matters.	o	o	o	o
11. I am usually invited to do things with others.	o	o	o	o
12. When I feel lonely, there are several people I could talk to.	o	o	o	o
13. I regularly meet or talk with friends or members of my family.	o	o	o	o
14. I often feel left out by my circle of friends.	o	o	o	o
15. There are several different I enjoy spending time with.	o	o	o	o



Appendix Q

23050

SOC

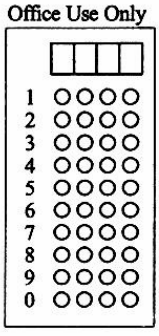
Select the single item that best describes you.

Males (females use 4 or more in a row)

In the last month have you had 5 or more drinks in a row?

1. Yes, and I do not intend to stop drinking 5 or more drinks in a row.	O
2. Yes, but I intend to stop drinking 5 or more drinks in a row during the next 6 months.	O
3. Yes, but I intend to stop drinking 5 or more drinks in a row during the next 30 days.	O
4. No, but I have had 5 or more drinks in a row in the past 6 months.	O
5. No, and I have not had 5 or more drinks in a row in the past 6 months.	O
6. No, I have never had 5 or more drinks in a row.	O

Office Use Only



Appendix R

M-C 20

Listed below are a number of statements concerning personal attitudes and traits. Read each item and circle T for true or F for false to indicate how each statement applies to you.

T F 1. I'm always willing to admit it when I make a mistake.

T F 2. I always try to practice what I preach.

T F 3. I never resent being asked to return a favor.

T F 4. I have never been irked when people expressed ideas very different from my own.

T F 5. I have never deliberately said something that hurt someone's feelings.

T F 6. I like to gossip at times.

T F 7. There have been occasions when I took advantage of someone.

T F 8. I sometimes try to get even rather than forgive and forget.

T F 9. At times I have really insisted on having things my own way.

T F 10. There have been occasions when I felt like smashing things.

T F 11. I never hesitate to go out of my way to help someone in trouble.

T F 12 .I have never intensely disliked anyone.

T F 13. When I don't know something I don't at all mind admitting it.

T F 14. I am always courteous, even to people who are disagreeable.

T F 15. I would never think of letting someone else be punished for my wrong doings.

T F 16. I sometimes feel resentful when I don't get my way.

T F 17. There have been times when I felt like rebelling against people in authority even though I knew they were right.

T F 18. I can remember "playing sick" to get out of something.

T F 19. There have been times when I was quite jealous of the good fortune of others.

T F 20. I am sometimes irritated by people who ask favors of me.

Appendix S

IRB Approval
FWA 00001669
IRB Number: 101403
From 9.20.03
Thru 6.3.04

Informed Consent for an Adult

University of South Florida

Information for people who are being asked to take part in a research study

IRB Study # 101403

Researchers at the University of South Florida (USF) study diseases and other health problems. We try to find better ways to treat these health problems. To do this, we need the help of people who agree to take part in a research study.

Title of research study: Level of Demoralization as a Predictor of Stage of Change in Patients with Gastrointestinal and Colorectal Cancer

Doctor in charge of study: Michael A. Weitzner, MD

Other doctors or staff: Cheryl Cockram, RN, ARNP, Jennifer Strickland, Pharm.D, and Vimbai Mudimu

Where the study will be done: H. Lee Moffitt Cancer Center

Who is paying for it: There is no sponsor for this study

Should you take part in this study?

This form tells you about this research study. You can decide if you want to take part in it. You do not have to take part. Reading this form can help you decide.

Before you decide:

- Read this form.
- Talk about this study with the study doctor or the person explaining the study. You can have someone with you when you talk about the study.
- Find out what the study is about.

You can ask questions:

- You may have questions this form does not answer. If you do, ask the study doctor or study staff as you go along.
- You don't have to guess at things you don't understand. Ask the people doing the study to explain things in a way you can understand.

Appendix S continued

IRB #: 101403
Approved From 9.20.03
Approved Thru 6.3.04

After you read this form, you can:

- Take your time to think about it.
- Have a friend or family member read it.
- Talk it over with your regular doctor.

It's up to you. If you choose to be in the study, then you can sign the form. If you do not want to take part in this study, do not sign the form.

Why is this research being done?

The purpose of this research study is to learn more about the health-related behaviors and emotions of patients with gastrointestinal or colorectal cancer. One of the research assistants will ask you questions from two brief questionnaires designed to assess your mood and health related behaviors. Then you will be given a package of self-report questionnaires designed to gather further information about how your mood has been and how you have been coping with the stress of your diagnosis and daily life. You will be asked to complete the questionnaires and return them in their package to the researcher

Why are you being asked to take part?

You are being asked to take part in this study because you are the identified patient with gastrointestinal or colorectal cancer and we are interested in understanding how patients with gastrointestinal or colorectal cancer cope with stress.

How long will you be asked to stay in the study?

The questionnaires should take approximately 45-60 minutes to complete and if you have time they can be done while you are at the clinic. If not you may take the questionnaires home with you and return them by mail.

How often will you need to come for study visits?

This study will not involve any follow-up visits only that you complete and return the questionnaires

How many other people will take part?

About 120 people will take part in this study at USF.

Appendix S continued

Will the treatment you get change if you take part in this study?

The treatment you now get from your regular doctor will not change if you take part in this study.

You will keep seeing your regular doctor. Your regular doctor will give you the same kind of treatment you would get anyway.

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

If you decide not to take part in this study, that is okay.

How do you get started?

If you decide to take part in this study, you will need to sign this consent form.

Will you be paid for taking part in this study?

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

What will it cost you to take part in this study?

It will not cost you anything to take part in the study.

What are the potential benefits if you take part in this study?

We cannot tell whether you will benefit from taking part in this intervention study. On the other hand, by taking part in this research study, you may increase our overall knowledge of the health-related behaviors and emotions that patients with colorectal or gastrointestinal cancer experience.

What are the risks if you take part in this study?

It is unlikely that participation in this study will cause any risks to you. Although many of the questions asked in the questionnaires are of a personal nature, all responses will be kept strictly confidential. Should you experience any distress regarding your participation in the study, Dr. Weitzner is available to speak to you about that at (813) 972-8483. In addition, should your participation in the study cause you significant distress that warrants further psychological assessment and/or treatment, Dr. Weitzner can make arrangements for you to see one of the mental health clinicians at Moffitt Cancer Center.

Appendix S continued

What if you get sick or hurt while you are in the study?

If you are harmed because you are take part in the study:

- We will pay your medical costs if you were harmed because our staff did something they should not have done.
- Florida law limits how much USF is able to pay. USF cannot pay for lost wages, disability, or discomfort. Read Florida Statute 768.28 to find out how much USF is able to pay. You can get a copy of the law by calling USF Research Compliance at (813) 974-5638.
- Call the USF Self Insurance Programs (SIP) at (813) 974-8008 and ask them to look into what happened.

What will we do to keep your study records from being seen by others?

Federal law requires us to keep your study records private.

Your research records will be kept locked in a file cabinet to protect your privacy to the full extent of the law.

However, certain people may need to see your study records. By law, anyone who looks at your records must keep them confidential. The only people who will be allowed to see these records are:

- The study staff and the medical staff who are taking care of you.
- People who make sure that we are doing the study in the right way. They also make sure that we protect your rights and safety:
  - The USF Institutional Review Board (IRB)
  - Department of Health and Human Services (DHHS)
  - United Stated Food and Drug Administration (FDA)
  - Other individuals listed on the research authorization form

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

What happens if you decide not to take part in this study?

You should only take part in this study if you want to take part.

Appendix S continued

If you decide not to take part:

- You won't be in trouble or lose any rights you normally have.
- You will still have the same health care benefits.
- You can still get your regular treatments from your regular doctor.

What if you join the study and then later decide you want to stop?

If you decide you want to stop taking part in the study, tell the study staff as soon as you can.

- If you decide to stop, you can go on getting care from your regular doctor.

You can get the answers to your questions.

If you have any questions about this research study, contact Michael Weitzner, MD at (813) 972-8483

If you have questions about your rights as a person who is taking part in a study, call USF Research Compliance at (813) 974-5638.

Signatures for Consent to Take Part in this Research Study

It's up to you. You can decide if you want to take part in this study.

I freely give my consent to take part in this study. I understand that this is research. I have received a copy of this consent form.

_____ _____

Signature of Person Taking Part in Study Date

_____

Printed Name of Person Taking Part in Study

_____ _____

[Optional] Signature of Witness Date

_____

[Optional] Printed Name of Witness

IRB #: 101403
Approved From 9.20.03
Approved Thru 6.3.04

Appendix S continued

Statement of Person Obtaining Informed Consent

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

The person who is giving consent to take part in this study

- Understands the language that is used.
- Reads well enough to understand this form. Or is able to hear and understand when the form is read to him or her.
- Does not have any problems that could make it hard to understand what it means to take part in this study.
- Is not taking drugs that make it hard to understand what is being explained.

To the best of my knowledge, when this person signs this form, he or she understands:

- What the study is about.
- What needs to be done.
- What the potential benefits might be.
- What the known risks might be.
- That taking part in the study is voluntary.

_____ _____

Signature of person obtaining consent Date

_____

Printed name of person obtaining consent

_____ _____

[Optional] Signature of Witness Date

_____

[Optional] Printed Name of Witness

IRB #: 101403
Approved From 9.20.03
Approved Thru 6.3.04

Page 6 of 6

IRB Form ICAdult-M

Appendix T

APPROVED
Approval #: 03-70965
Date: 04/30/2003
HLMCC – Privacy Office

Level of Demoralization as a Predictor of Stage of Change in patients with Gastrointestinal and Colorectal Cancer

Patient Name: _____

Study Subject Medical Record No.: _____

MCC No: *13410*

IRB No: *_Pending*

H. Lee Moffitt Cancer Center and Research Institute
at the University of South Florida

RESEARCH AUTHORIZATION

We understand that information about you and your health is personal, and we are committed to protecting the privacy of that information. Because of this commitment, we must obtain your written authorization before we may use or disclose your protected health information for the research purposes described below. This form provides that authorization and helps us make sure that you are properly informed of how this information will be used or disclosed.

Research undertaken at the H. Lee Moffitt Cancer Center and Research Institute, Inc. or at any of its subsidiaries is undertaken jointly with the University of South Florida or other persons or entities under an organized health care arrangement. All persons or entities participating in such an organized healthcare arrangement are collectively referred to as the "Moffitt Cancer Center" in this form.

By signing this document you are permitting the Moffitt Cancer Center to use personal health information collected about you for research purposes internally within its organized health care arrangements. You are also allowing the Moffitt Cancer Center to disclose that personal health information to outside organizations or individuals that participate in this research study. Please read the information below carefully before signing this form.

USE AND DISCLOSURE COVERED BY THIS AUTHORIZATION

A representative of the Moffitt Cancer Center must answer these questions completely before providing this authorization form to you. DO NOT SIGN A BLANK FORM. You or your personal representative should read the descriptions below before signing this form.

Patient Label

Appendix T continued

APPROVED
Approval #: 03-70965
Date: 04/30/2003
HLMCC – Privacy Office

Level of Demoralization as a Predictor of Stage of Change in patients with Gastrointestinal and Colorectal Cancer

Patient Name: _____

Study Subject Medical Record No.: _____

MCC No: *13410* _____

IRB No: *_Pending* _____

Who will disclose, receive, and/or use the information? The workforce of the Moffitt Cancer Center is permitted by law to use and disclose your health information for treatment, payment and health care operations purposes. By signing below, you authorize the Moffitt Cancer Center to receive and obtain tests, results and your other personal health and related information arising from services or treatment provided to you by other health care providers in connection with this study. In addition to any uses or disclosures made for treatment, payment and health care operations purposes, the following person(s), class(es) of persons, and/or organization(s) will be allowed to disclose, use, and receive the information for the research purposes set forth in this form, but they may only use and disclose the information to the other parties on this list, to you or your personal representative, or as permitted by law.

1. Every research site for this study, including the Moffitt Cancer Center, and including each site's research staff and medical staff
2. Every health care provider and other member of the Moffitt Cancer Center workforce who provides services to you in connection with this study
3. Any laboratories and other individuals and organizations that use your health information in connection with this study in accordance with the study's protocol
4. Any sponsor of the study, including the following research sponsors: This study is not sponsored
5. The United States Food and Drug Administration, Department of Health and Human Services (DHHS) and any other federal, state or local governmental agency that regulates the research study
6. The designated research Protocol Review and Monitoring Committees and related staff of the Moffitt Cancer Center

Patient Label

Appendix T continued

APPROVED
Approval #: 03-70965
Date: 04/30/2003
HLMCC – Privacy Office

***Level of Demoralization as a Predictor of Stage of Change in** patients with Gastrointestinal and Colorectal Cancer*

Patient Name: _____

Study Subject Medical Record No.: _____

MCC No: *13410*

IRB No: *_Pending*

7. The National Cancer Institute in evaluating the ongoing research of the Moffitt Cancer Center as a Comprehensive Cancer Center

8. The members and staff of any Institutional Review Board that has oversight responsibility for this study

9. The members and staff of the Moffitt Cancer Center's affiliated Privacy Board

10. Members of the study team, including the Principal Investigator , co-investigators sub-investigators and others listed on your research study Informed Consent

11. Study Coordinators, Research Nurses and Data Managers involved in the research

12. Members of the Moffitt Cancer Center's Clinical Trials Office/Clinical Research Operations

13. Contract Research Organization

14. Data Safety Monitoring Board and Staff

Additionally, the following person(s), classes of person(s), and/or organization(s) (as described below):

_____

_____

The entities and persons listed above may employ or pay various consultants and companies to help them understand, analyze and conduct this study. All of these people may not be known now, but if you would like to have more specific information about this at any time during the study, you may ask the Principal Investigator and your questions will be answered.

The Moffitt Cancer Center cannot guarantee the privacy of your information, or block further use or distribution, after the information has left the Moffitt Cancer Center. The sponsor of this

Patient Label

Appendix T continued

APPROVED
Approval #: 03-70965
Date: 04/30/2003
HLMCC – Privacy Office

Level of Demoralization as a Predictor of Stage of Change in patients with Gastrointestinal and Colorectal Cancer

Patient Name: _____

Study Subject Medical Record No.: _____

MCC No: *13410*_____

IRB No: *_Pending*_____

study may further disclose your information. If disclosed by the sponsor or any other person or entity, the information may no longer be covered by the federal privacy regulations.

What information will be used or disclosed? By signing below, you authorize the use and disclosure of your entire research record and any medical or other records held by the Moffitt Cancer Center, including, but not limited to, HIV/AIDS, mental health, substance abuse or genetic information, except for information that you expressly exclude below. The purpose for the uses and disclosures you are authorizing is to conduct the research project explained to you during the informed consent process and to ensure that the information relating to that research is available to all parties who may need it for research purposes.

❑ Exclude the information expressly listed below (if blank, then no information excluded):

_____

_____

_____

SPECIFIC UNDERSTANDINGS

By signing this research authorization form, you authorize the use and/or disclosure of your protected health information described above. Your information may also be used as necessary for your research-related treatment, to collect payment for your research-related treatment (when applicable), and to run the business operations of the Moffitt Cancer Center.

This information may be redisclosed if the recipient(s) described on this form is not required by law to protect the privacy of the information.

You have a right to refuse to sign this authorization. While your health care outside the study, the payment for your health care, and your health care benefits will not be affected if you do not sign this form, you will not be able to participate in the research described in this authorization and will not receive treatment as a study participant if you do not sign this form.

Patient Label

Appendix T continued

APPROVED
Approval #: 03-70965
Date: 04/30/2003
HLMCC – Privacy Office

Level of Demoralization as a Predictor of Stage of Change in patients with Gastrointestinal and Colorectal Cancer

Patient Name: _____

Study Subject Medical Record No.: _____

MCC No: *13410* _____

IRB No: *_Pending* _____

If you sign this authorization, you will have the right to revoke it at any time, except to the extent that the Moffitt Cancer Center has already taken action based upon your authorization or needs the information to complete analysis and reports of data for this research. Your revocation will apply prospectively only. All data collected prior to your decision to withdraw your authorization to use the data for research purposes - including documentation of your decision to withdraw - may still be used by the Principal Investigator and cannot be revoked. If medically necessary, the Principal Investigator or study staff may follow-up with you. If you have decided to withdraw your authorization to use the data for research purposes this follow-up information cannot be used or disclosed for research unless required by law.

This authorization will never expire unless and until you expressly revoke it in writing. To revoke this authorization, please write to Dr. Michael Weitzner at the Moffitt Cancer Center, 12902 Magnolia Dr., Tampa, FL 33612.

By signing below, you acknowledge your receipt of a copy of this form.

SIGNATURE

I have read this form and all of my questions about this form have been answered. By signing below, I acknowledge that I have read and accept all of the above.

_____
Signature of Subject or Personal Representative

_____
Print Name of Subject or Personal Representative

Patient Label

Appendix T continued

APPROVED
Approval #: 03-70965
Date: 04/30/2003
HLMCC – Privacy Office

Level of Demoralization as a Predictor of Stage of Change in patients with Gastrointestinal and Colorectal Cancer

Patient Name: _____

Study Subject Medical Record No.: _____

MCC No: *13410*_____

IRB No: *_Pending*_____

_____
Date

_____
Description of Personal Representative's Authority

CONTACT INFORMATION

The contact information of the subject or personal representative who signed this form should be filled in below.

Address:

_____
_____
_____
_____

Telephone:

_____ (daytime)
_____ (evening)

Email Address (optional):

_____

THE SUBJECT OR HIS OR HER PERSONAL REPRESENTATIVE MUST BE PROVIDED WITH A COPY OF THIS FORM AFTER IT HAS BEEN SIGNED.

Patient Label

About the Author

Cheryl Cockram is an ARNP. working in a consultation liaison position in the Psychosocial and Palliative Care service at Moffitt Cancer Center. She earned her AA degree in nursing at Loyalist College in Belleville, Ontario, Canada. She immigrated to Tampa Florida in 1990 to continue her education and completed a Bachelor's Degree in Psychology at St.Leo's University. She went on to complete a Masters Degree in Adult Psychiatric and Mental Health at the University of South Florida. Her area of interest is in psychiatry and substance abuse.