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TESTING THE ROLE OF BODY VIGILANCE AS A PRECIPITATING FACTOR IN THE COGNITIVE BEHAVIORAL MODEL OF MEDICALLY UNEXPLAINED

ILLNESS

by

Aron M. Katz

A Dissertation

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Abstract

Katz, Aron Matthew Ph.D. The University of Memphis. August 2014. Testing body vigilance as a precipitating factor in the cognitive behavioral model of medically unexplained illness. Major Professor: Douglas Strohmer

Chronic illness affects nearly one in two Americans affected (CDC, 2009), often leading to psychological distress (Bohlmeijer, Prenger, Taal, & Cuijpers, 2010), including a rate of depression approximately 50% higher than the rate in peers without medical illness (Patten, 2001). Likewise, quality of life for those with chronic illnesses is lower than quality of life among healthy peers, measured by greater persistence of psychological distress, higher functional impairment, and medical services utilization (Aiarzaguena, Grandes, Salazar, Gaminde, & Sánchez, 2008; Feder et al., 2001). Despite continued medical advances, a significant portion of illness, pain and discomfort remains medically unexplained (Nettleton, Watt, O'Malley, & Duffey, 2005), creating challenges not only for those who experience illness distress, but for health care providers as well (Kroenke, 2000; Raine et al., 2002). Medically unexplained symptoms (MUS), defined as sets of symptoms that physical pathology does not adequately explain (Swanson, Hamilton, & Feldman, 2010), are both commonplace and problematic to health care providers (Kroenke, 2000; Swanson et al., 2010). Deary, Chalder, and Sharpe's (2007) cognitive behavioral model of medically unexplained symptoms describes the process by which correlates of illness-related distress prime, trigger and perpetuate the experience of aversive symptoms even in the absence of direct physiological causes. Although, in recent years, the cognitive behavioral model of MUS has garnered increasing empirical support for predisposing and perpetuating variables, no published articles to date have

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investigated the role of precipitating factors in the context of this model, leaving a critical component of the theory unexamined.

This study used a sample population of adults with Inflammatory Bowel Disease to test the role of body vigilance as a precipitating factor in the CBT model of MUS. Results indicated that the inclusion of body vigilance significantly improved explained variance. Although patterns of correlation between personality variables, illness cognitions, and health related quality of life were similar among persons with IBD and other diseases used to test the model, among adults with IBD, no personality variables explained significant variance in health-related quality of life. The implications of how these results may impact further research in MUS and chronic illness are provided.

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Chapter 1

Introduction

Over the past century, improvements in preventive care and treatment of medical illness have led to the emergence of growing population living with chronic illness (Cohen, McChargue, & Collins, 2003; Fennell, 2003). The Center for Disease Control estimates that nearly one in two Americans or approximately 133 million people have a chronic health condition (CDC, 2009), and the numbers are rising. The U.S. Department of Health and Human Services projects that, by the year 2020, approximately 157 million Americans will be living with some sort of chronic disease (Wu & Green, 2000).

Patients with chronic somatic diseases experience psychological distress at higher rates than their healthy peers (Bohlmeijer et al., 2010) including a rate of depression approximately 50% higher than peers without medical illness (Patten, 2001). Likewise, quality of life for those with chronic illnesses is lower than healthy peers, measured by greater persistence of psychological distress, higher functional impairment, and medical services utilization (Aiarzaguena et al., 2008; Feder et al., 2001).

Despite medical advances, a significant portion of illness, pain, and discomfort remains medically unexplained (Nettleton et al., 2005). Medically unexplained symptoms (MUS), defined as sets of symptoms that physical pathology does not adequately explain (Swanson et al., 2010), are both commonplace and problematic to health care providers (Kroenke, 2000; Swanson et al., 2010). In the U.K., over half of all primary care mental health consultations are for medically unexplained symptoms (Hague, 2005). In the U.S. between 15% (Aiarzaguena et al., 2008) and 20% (Hartz et

al., 2000) of patients presenting to general practitioners have somatic symptoms with no clear physiological basis.

MUS are particularly challenging to treat for health care providers (Kroenke, 2000; Raine et al., 2002). Patients with MUS use more health care services and often receive more tests and treatments at greater cost than may be necessary (Aiarzaguena et al., 2008). They also experience significant psychological distress and poorer quality of life (Koch et al., 2007). The impact of MUS extends beyond patient and provider, as it accounts for a significant proportion of disability in the workforce (Kroenke et al., 1994; Reid, Wessely, Crayford, & Hotopf, 2001).

Given the high instance rate, the impact on subjective quality of life and the challenges in effective management, there is a clear need for a theoretical framework from which to build empirically validated treatments for individuals with MUS (Deary et al., 2007). Cognitive-behavioral therapy (CBT) is the therapeutic approach with the most empirical support in the treatment of somatic symptoms including MUS (Burton, 2003; Nezu, Nezu, & Lombardo, 2001; Sumathipala, 2007). In addition, there is considerable support for a cognitive behavioral conceptual model for understanding the development and maintenance of symptoms in the absence of direct physiological pathology (Deary et al., 2007; Mai, 2004; Neimark, Caroff, & Stinnett, 2005). The cognitive behavioral model of MUS (Figure 1) outlines the relationships between sets of factors believed to be relevant in the development and maintenance of MUS. These factors are separated into three categories of variables: predisposing factors influence likelihood of the symptom, and perpetuating factors which are both effects and secondary causes of the symptom.

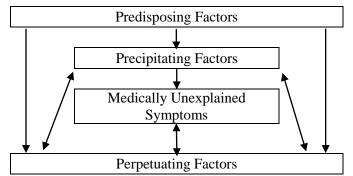


Figure 1. Relationship between categories of variables in the cognitive behavioral model of medically unexplained symptoms. Adapted from "The cognitive behavioural model of medically unexplained symptoms: a theoretical and empirical review," by Deary, V., Chalder, T., & Sharpe, M. (2007). *Clinical Psychology Review*, *27*, p. 9. Copyright 2007 by Elsevier Ltd.

The model helps illustrate the dynamic relationship between correlates of illnessrelated distress that prime, trigger and perpetuate the experience of aversive symptoms even in the absence of direct physiological causes. Although in recent years, the cognitive behavioral model of MUS has garnered increasing empirical support for predisposing and perpetuating variables, no published articles to date have examined the role of precipitating factors in the context of this model, leaving a critical component of the theory unexamined. Thus the purpose of the proposed research is to test the role of body vigilance as a precipitating factor in the cognitive behavioral model of MUS.

Cognitive Behavioral Model of MUS

The most comprehensive application of cognitive behavioral therapy to the class of disorders labeled MUS is found in Deary et al.'s (2007) cognitive behavioral model of medically unexplained symptoms. The "CBT model of MUS" helps explain the selfperpetuating elements of MUS that make them particularly difficult to treat. Based on Beck's cognitive therapy (Beck, 1976), the cognitive behavioral theory of MUS distinguishes between predisposing, perpetuating and precipitating factors in the development and maintenance of physical and emotional distress. The following section will provide a brief review of the theoretical rationale and current support for the CBT model of MUS.

Predisposing Factors. The CBT model of MUS defines predisposing factors as variables which influence a person's likelihood to experience illness-related distress. Included among the predisposing factors are one's genetics and personality traits which may prime a person to experience medically unexplained symptoms.

Deary et al. note that although a genetic component to MUS is possible, and has been demonstrated in select cases such as chronic fatigue and somatization (Farmer, Scourfield, Martin, Cardno, & McGuffin, 1999; Hickie, Kirk, & Martin, 1999; Kendler, Gardner, & Prescott, 2003), little is known about direct genetic links to MUS in general. However, gender, a social construct analogous to genetically determined sex, has a demonstrated association with MUS, with women reporting more frequent and more severe somatic distress than men (De Gucht, Fischler, & Heiser, 2004; Feder et al., 2001; Neimark et al., 2005; Wool & Barsky, 1994). The source of gender differences in frequency and severity of MUS is unclear. It is plausible, for instance, that similar internal experiences among males and females are differentially reported due to differences in perceived social acceptability of reporting physical complaints. In addition to gender, personality type, specifically trait neuroticism and alexithymia, is believed to predispose people to MUS.

Neuroticism, defined as the tendency to experience negative, distressing emotions and to possess associated behavioral and cognitive traits (Costa & McRae, 1987), is

linked to heightened reactivity, and an increase in perception of negative life events (Magnus, Diener, Fujita, & Pavot, 1993). Neuroticism is also associated with several components of the cognitive-behavioral model that may contribute to symptom detection and perpetuation of distress (Deary et al., 2007). Neuroticism is linked to autonomic arousal and neurologically based sensitivity to punishment signals (Matthews & Gilliland, 1999), thus changing the threshold for precipitation of distress. Watson and Pennebaker (1989) suggested it be seen not just as a psychological trait but as a more general predisposition to experience "somatopsychic distress." In this sense, a direct relationship between neuroticism and illness distress is possible. Higher neuroticism is associated with increased levels of depression and poorer prognosis in a variety of MUS (Deary et al., 2007). and is also associated with lower health-related quality of life in MUS (Deary et al., 1997). It is correlated highly with harm-avoidance (Cloninger, 1987), conditioning to noxious stimuli, and increased generalization of conditioned response (Van den Bergh, Winters, Devriese, & Van Diest, 2002).

Another dimension of personality that has been hypothesized to play a role in the development and persistence of MUS is alexithymia (De Gucht et al., 2004; Deary et al., 1997). Literally meaning "no words for feelings," alexithymia has three facets: difficulty identifying and describing feelings, difficulty in distinguishing between feelings and bodily sensations of emotional arousal, and the tendency to focus on the concrete details of external events (Lesser, 1981; Nemia, Freyberger, & Sifnos, 1976; Taylor 1984). Higher levels of alexithymia are associated with greater somatic distress, both among patients receiving medical care and in nonclinical populations (Bailey & Henry, 2007; Deary et al., 1997).

The CBT model of MUS predicts that these predisposing factors lower the initial threshold and raise the likelihood of the experience of distress. For instance, a person who has a neurotic disposition and experiences high levels of negative affect might be more apt to notice and to focus on painful or unpleasant sensations than a person whose affect is neutral or predominantly positive. Similarly, difficulty identifying, describing and distinguishing emotions and sensations could be anxiety provoking and unpleasant in its own right (Dorrian, Dempster, & Adair, 2009). Leventhal, Nerenz, and Purse (1984) theorized that ill individuals seek to label their condition, and may prematurely attribute ambiguous sensations as related to their conditions, lowering their assessments of functional independence. Both neuroticism and alexithymia fit in Deary's conceptualization of predisposing factors, which are intrinsic traits that influence the likelihood of distress before any symptoms are perceived. In contrast, perpetuating factors exert influence only after the symptoms surface. The following section will describe the role of perpetuating factors in the CBT model of MUS.

Perpetuating Factors. The CBT model of MUS defines perpetuating factors as variables which both result from and are a secondary cause of unexplained symptoms, and function to prolong illness-related distress. Included in Deary et al.'s (2007) conceptualization of perpetuating factors are beliefs, attitudes and responses to MUS, which in this study will be collectively referred to as cognitive representations. In the CBT model of MUS, cognitive representations resulting from chronic and unexplained somatic symptoms can prolong the symptoms, and affect sensitivity to future MUS, this perpetuating the cycle. This interaction perpetuates the cycle of MUS and illness-related distress. In the present study, illness representations include beliefs about illness identity

(the degree to which symptoms can be attributed to a specific diagnostic label), chronicity (the belief that the illness will be long lasting rather than acute and passing), cyclical nature (the belief that symptoms may alternate between periods of exacerbation and remission), consequences (the belief in the severity of the condition), personal control (the belief in one's ability to control symptoms when they emerge), treatment control (the belief that effective treatment can help to manage symptoms), illness coherence (the belief in a coherent understanding of one's condition), and emotional representation (specific emotional responses to illness states.) A number of studies support illness representations as a predictor of quality of life across a range of conditions, including rheumatoid arthritis, COPD and psoriasis (Scharloo et al., 1998), asthma (Leventhal, Diefenbach, & Leventhal, 1992), chronic fatigue syndrome (Heijmans & de Ridder, 1998), irritable bowel syndrome (Rutter & Rutter, 2002), and inflammatory bowel disease (Dorrian et al., 2009).

Specific cognitive illness representations can be both indicators of and contributors to somatic symptoms. For instance, a person who has lived with an intrusive MUS for an extended period of time may, as a result of direct experience, hold beliefs that his or her condition is disabling, unresponsive to medical treatment, poorly understood and uncontrollable. These thoughts, resulting from experience would be indicators of somatic distress. Additionally, they could contribute to distress and prime the individual to perceive distress more readily than a person with different cognitive representations. The cognitive behavioral model of MUS predicts that these cognitive representations perpetuate MUS by influencing the sensitivity and thus lowering the

threshold for symptom detection and precipitation of illness distress. The following section will describe the role of precipitating factors in the CBT model of MUS.

Precipitating Factors. The final set of factors in the cognitive behavioral model of MUS involves the triggering of the MUS, what Deary et al. (2007) call precipitating factors. In the model, precipitants to MUS encompass any stressors that trigger MUS and the start of the self-perpetuating cycle. A crucial component of the CBT model of MUS is the idea that the threshold for triggering MUS can change through sensitization.

Sensitization refers to the tendency for prior experience of a stimulus to induce a heightened reactivity to future stimuli (Deary et al., 2007). Rygh et al. (2005) have shown that long term potentiation in humans can be induced in pain pathways by prior experience of pain or noxious stimulation, which lowers the threshold for future stimulation. Rygh et al. (2005) suggested that mechanisms such as vigilance and attention, or the effects of anxiety, depression or stress, may dampen inhibition of these pathways, lowering the threshold further in line with Melzak's Gate Control Theory (1968). This could lead to normally benign sensations being experienced as pain, leading in turn to further sensitization and vigilance.

Such a relationship has been shown in patients with irritable bowel syndrome (IBS), in which aversive IBS symptoms produced a fear response, leading to discomfort intolerance, increased vigilance, perception, anxiety and again to IBS symptoms (Keough, Timpano, Zawilinski, & Schmidt, 2011). Body vigilance was found to correlate with symptom severity (r = .13; p < .01) (Keough et al., 2011). Although this finding is compelling, the association was studied without other elements of the CBT model of MUS. Without variables representing the complete model, it is impossible to

determine whether the relationship between vigilance and distress is unique or if the results may be due to overlapping constructs. To date, no study has examined body vigilance in the context of the CBT model of MUS.

Self Maintaining Nature of CBT Model of MUS

The CBT model of MUS proposes a self-reinforcing process wherein known correlates to illness-related distress also influence detection through sensitization, thus leading to and maintaining MUS. Deary et al. (2007) describe this process as "autopoeisis," borrowing the concept from systems theory and cell biology in which the components of the model, through their interaction, generate recursively the same network of processes which produced them.

In this model, predisposing factors including genetic predisposition and personality prime a person to heightened sensitivity, lower distress tolerance, and thus a heightened experience of symptoms and related distress. In turn, distress has unique bidirectional relationships with perpetuating factors such as illness-related cognitions, differential attention, and coping thoughts and behaviors, each of which could directly or indirectly, through heightened sensitization, lead to greater distress in a positive feedback loop. Chronic experience of somatic distress is believed to lead to increased attention and sensitization, and thus to greater perception of somatic distress, a process that Barsky and Wyshak called somatosensory amplification (Barsky & Wyshak, 1990). For example, a person who has experienced persistent, chronic pain may anticipate future pain, and increase attention paid to bodily sensations, effectively lowering the threshold to future detection. Brown expanded on this idea by proposing a multi-component model for MUS, which suggests that "rogue representations" in the cognitive system create memory traces functionally similar to those generated during symptom experience, and reinforce selective attention to physical sensations, disease-confirming beliefs and negative affect (Brown, 2004). In Deary's (2007) cognitive behavioral model of MUS, sensitization to medically unexplained symptoms over time may influence the reactivity of an individual to distress. This relationship is illustrated in Figure 2.

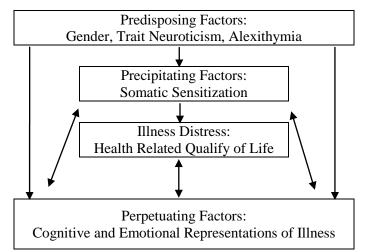


Figure 2. Application of the cognitive behavioral model of medically unexplained symptoms. Adapted from "The cognitive behavioural model of medically unexplained symptoms: a theoretical and empirical review," by Deary, V., Chalder, T., & Sharpe, M. (2007). *Clinical Psychology Review*, *27*, p. 9. Copyright 2007 by Elsevier Ltd.

Although research has supported many individual components of the cognitive model of MUS including the impact of personality (De Gucht, Fontaine, & Fischler, 2004; Deary, Scott, & Wilson, 1997), gender (Wool & Barsky, 1994), illness perception (Dorrian et al., 2009) and body vigilance (Keough, Timpano, Zawilinski, & Schmidt, 2011) with the subjective experience of illness, this body of literature is incomplete. Despite ample theoretical support, the current body of empirical research has failed to include the critical role of somatic sensitization in the context of other components of the CBT model of MUS. The purpose of the proposed research is to test the unique role of body vigilance as a contributor to MUS, as predicted in the CBT model of MUS, and in the process to create a more complete and accurate test of the model.

Applying the CBT model of MUS presents several practical challenges. By definition, MUS describes a broad category of conditions, and due to the limited scope of the present study it is not feasible to include all conditions for which symptom-related distress exceeds physiological explanation. Further, since the relationship between body vigilance to well-being has not been examined in the context of MUS, the relative strength of associations is unknown. Before this relationship can be applied to the broader class of MUS, it must be demonstrated in a model population of MUS. The present study uses a single type of illness to demonstrate the impact of body vigilance in development and maintenance of MUS. In the following section, the rationale used to select Inflammatory Bowel Disease as a prototypical example of MUS will be discussed.

MUS Case in Point: Inflammatory Bowel Disease

Inflammatory Bowel Disease (IBD), including both Crohn's Disease (CD) and Ulcerative Colitis (UC) is a chronic, relapsing and remitting, autoimmune disease

affecting approximately 1.4 million people in the United States (Kiebles, Doerfler, & Keefer, 2010). Both Crohn's disease and ulcerative colitis are organic, physiologically based diseases characterized by intermittent "flares" of the immune system, in which an excessive immune response to intestinal conditions results in inflammation and ulceration in the intestinal lining. Common symptoms include pain, nausea, and weight loss, as well as frequent painful, urgent and sometimes bloody bowel movements (Kalibjian, 2003; Sklar & Sklar, 2007). There is no consensus in the medical community regarding the cause of the disease; however it is generally accepted that both genetics and environment are influential (CCFA, 2009; Sklar & Sklar, 2007).

Like its functional analog, irritable bowel syndrome (IBS), IBD often involves illness-related distress in the absence of disease activity. Unlike IBS, a diagnosis of Crohn's disease and ulcerative colitis requires confirmation of physical pathology and involves substantial blood tests and imaging including CT scans and MRIs, colonoscopy and endoscopy with biopsies (Kalibjian, 2003; Sklar & Sklar, 2007) and can therefore be distinguished from somatization disorder. This distinction is important given the history in the medical community of dismissing unexplained or under-explained conditions as psychogenic, or symptoms of conversion disorder or malingering. By using a condition with a clearly evident physiological component, these labels may be avoided. IBD represents a particularly good fit for the CBT model of MUS previously discussed in this chapter. As is the case with other forms of MUS, people with diagnoses of IBD are at particular risk for psychological distress (Schwarz & Blanchard, 1990; Searle & Bennett, 2001) and have lower average quality of life than healthy peers (Cohen et al., 2003; Dorrian et al., 2009). Of the variables noted in the CBT model of MUS, people with IBD

typically score higher on measures of trait neuroticism as well as alexithymia as compared to controls (Moreno-Jiménez, López Blanco, Rodríguez-Muñoz, & Garrosa Hernández, 2007), and female gender appears to be associated with greater reported distress (Casellas et al., 2005; Casellas, Lopez-Vivancos, Casado, & Malagelada, 2002). IBD patients with clinical depression show elevated disease activity evidenced by increases in several biomarkers for inflammation (Miller, Rohleder, Stetler, & Kirschbaum, 2005). Higher levels of anxiety and lower health-related quality of life are associated with greater medical relapse and increased disease activity (Mittermaier et al., 2004), indicating a possible autopoietic feedback relationship consistent with the CBT model of MUS.

The course of the disease is unpredictable, and painful symptoms may appear with little warning, creating ideal conditions for somatosensory amplification (Barsky & Wyshak, 1990). Treating co-occurring psychological disturbances then may help not only the subjective experience of the patient, but may reduce the severity of the physical illness.

Given the complex nature of symptom experience, the impact of symptoms on quality of life, and the risk for somatosensory amplification, IBD presents an ideal opportunity to study the influence of body vigilance in the development and maintenance of medically unexplained symptoms. The present study addresses this potential feedback system by testing body vigilance as a predictor of health-related quality of life and thus as a potential sensitizing and precipitating factor in the CBT Model of MUS.

Relevance to the Field of Counseling Psychology

The likelihood of psychologists encountering a client with a medically unexplained symptom is high, particularly for those working in primary care settings or in collaboration with medical doctors in behavioral health and preventive medicine settings. As the instance rate of chronic conditions increases and the number of patients whose distress exceeds medical explanation continues to grow, the importance of psychologists in treatment will likewise increase.

Further, pressure by managed care organizations to employ empirically supported treatments, and psychologists' ethical duty to provide the best possible care makes evident the need for research in this area. Cognitive behavioral therapy has produced the most empirically validated treatments for the population with MUS, and the CBT model of MUS is the predominant guiding theory for treatment. Evidence that increased body vigilance is associated with greater MUS severity will give valuable insight to psychological interventions that could reduce subjective distress.

Research Hypothesis

Although there is support for several individual components of the CBT model of MUS including predisposing and perpetuating factors, less is known about what precipitates the experience of medically unexplained and under-explained symptoms. Research has shown that stable personality traits, such as neuroticism and alexithymia, contribute to and possibly predispose a person to heightened illness-related distress in patients with IBD. Additionally, it has been demonstrated that illness perceptions predict distress and health related quality of life. Although the CBT model of MUS predicts the role of feedback, support for the role of body vigilance in illness-related distress is

limited and has not been investigated in the context of MUS. The purpose of this study is to include body vigilance in the cognitive behavioral model to determine if body vigilance predicts unique variance in illness-related distress in IBD, over the variance accounted for by known predictors of illness-related distress. Specifically, the hypothesis in the proposed study is that, after controlling for the variance in health-related quality of life explained by predisposing factors (gender, neuroticism and alexithymia,) and perpetuating factors (chronicity, cyclical timeline, consequences, personal control, treatment control, illness coherence and emotional representation), the precipitating factor body vigilance will account for significant additional variance in health-related quality of life.

Chapter 2

Literature Review

Introduction

Improvements in biomedical knowledge and the efficacy of treatment in many common illnesses have changed the landscape of medical illness. While Western medicine has traditionally conceptualized illness as primarily acute conditions having discrete causes, predictable courses, and common symptoms and treatments, medical illness is increasingly becoming conceptualized as a chronic state (Fennell, 2003). Due in part to improvement in diagnosis and treatment of medical conditions, enough patients are now living long enough with illness to make chronic conditions a common occurrence (Fennell, 2003; Nettleton et al., 2005). Chronic illnesses are often difficult to treat and do not have single causes or predictable courses (Fennell, 2003). Despite advances, a significant amount of illness, pain and discomfort remains medically unexplained and poorly understood (Nettleton et al., 2005).

Defining Medically Unexplained Symptoms

Medically unexplained symptoms (MUS) have been defined in a variety of ways, and a single useful definition has been elusive (Deary et al., 2007). Alternatively labeled medically unexplained physical symptoms (Kleinstäuber, Witthöft, & Hiller, 2010) or unexplained complaints (Koch et al., 2007), definitions most often fall into three groups (Deary et al., 2007). The broadest definitions refer to MUS as the occurrence of symptoms in the absence of obvious pathology (Fink, Sorensen, Engberg, Holm, & Munk-Jorgensen, 1999). A more specific definition identifies MUS as specific individual clinical syndromes including chronic fatigue syndrome (CFS), fibromyalgia (FM), and irritable bowel syndrome (IBS) amongst others. A third category of definition uses MUS euphemistically to refer to a subset of DSM-IV somatoform disorders (De Waal, Arnold, Eekhof, & Van Hemert, 2004). This type of definition is the least helpful since even when physicians in primary care believe that patients meet criteria for somatoform disorders, they are reluctant to attach such labels to patients, leading to a gross underestimate of patients with MUS (Swanson et al., 2010). The prevalence rate of MUS varies according to the stringency of the definition, from over 60% of primary care consultations using the broadest definition (Fink et al., 1999) to 11% using the most restrictive definition (Ring, Dowrick, Humphris, & Salmon, 2004). Kirmayer et al. described MUS as a predicament, not a specific disorder (Kirmayer, Groleau, Looper, & Dominicé, 2004), and most theory-driven research on MUS has favored a simpler and less restrictive definition (Aiarzaguena et al., 2008; Deary et al., 2007; Escobar et al., 2010; Kroenke, 2000; Nettleton et al., 2005; Swanson et al., 2010). For the purposes of the proposed study, MUS will be defined as patient-reported physical symptoms that are not adequately explained by underlying physical pathology.

Implications of medically unexplained symptoms. Medically unexplained symptoms (MUS) are both commonplace and problematic to health care providers, making up nearly half of all consultations in primary care and hospital outpatient clinics (Price, 2008). General practitioners often feel frustration in balancing diagnostic skepticism with their duty to diagnose and relieve patients' suffering (Aiarzaguena et al., 2008) and sometimes feel pressure directly from the patient for aggressive treatment (Ring et al., 2004). As a result, patients with MUS typically use health care services at high rates and receive expensive and sometimes unnecessary tests and treatments

(Aiarzaguena et al., 2008; Ring et al., 2004). Patients may fall into a "chronic treatment trap" described by Peck and Love (1986) in which failed treatment frustrates medical providers, who label the unexplained distress as psychogenic in nature and refer to mental health providers for assistance. Patients then try to prove that distress is "real" and may become resistant or begin treatment-shopping for other providers whom they believe may be able to help them. As both patient and provider become frustrated, positive treatment outcomes become less likely. Patients with medically unexplained symptoms have approximately twice the outpatient and inpatient medical care utilization and twice the annual medical care costs of non-somatizing patients (Barsky, Orav, & Bates, 2005).

A particular challenge in treating patients MUS is "somatically focused" health beliefs that lead to an exaggerated perception of the importance of "true diagnoses" and "correct medical treatment," which in turn fuels dependence and overutilization of medical services (Kleinstäuber et al., 2010). In light of this overemphasis, psychosocial factors may initially be neglected and only addressed when first attempts have failed (Van Eijk et al., 1983). The shift in focus is often associated with a deterioration of the physician-patient relationship, as patients think that the physician has lost interest in them or views them as annoying (Kirmayer, 1994). Effective treatment of MUS involves collaboration between patient and health care provider in determining treatment goals including behavior modification, physical activity and increasing active coping (Kleinstäuber et al., 2010; Richardson & Engel, Jr., 2004).

The chronic nature of MUS leads to decreases in activity levels, working capacity and role functioning (De Waal et al., 2004). Patients with chronic somatic symptoms experience psychological distress at higher rates than their healthy peers (Bohlmeijer et

al., 2010) including a rate of depression approximately 50% higher than peers without medical illness (Patten, 2001). This is true regardless of medical explanation of one's condition (Escobar et al., 2010). In a study by Barsky et al. (Barsky et al., 2005) 31% of the participants with somatic symptoms fulfilled criteria of a major depressive disorder and 19% had a panic disorder. Likewise, patients with MUS experience significant psychological distress, high levels of medication use (Katon, 2003) and lower overall quality of life (Aiarzaguena et al., 2008; Feder et al., 2001; Kleinstäuber et al., 2010).

Medically unexplained symptoms are associated with distress and disability that is at least as severe as medically explained symptoms (Price, 2008). In fact, medical explanation is less important in predicting mood disorders such as depression and anxiety than the number of somatic complaints endorsed (Escobar et al., 2010). Regardless of full and accurate medical explanation of one's illness, somatic experiences appear to be a driving force in illness-related distress. Consequently, measures of health-related quality of life (HRQOL) that describe patients' subjective experience are appropriate and useful in treating chronic disease (Fitzpatrick, Davey, Buxton, & Jones, 1998) since they provide a more accurate representation of the experience of illness than specific clinical indicators (Han et al., 2005).

Although data pertaining to a patient's physiological state may be useful to a healthcare provider, it does not necessarily translate to functional capacity or well-being of the patient. Patients with similar clinical data may have vastly different levels of functional impairment or psychological distress (Guyatt, Feeny, & Patrick, 1993). Common measures of disease-specific health related quality of life typically include dimensions capturing specific and systemic symptoms, and social and emotional

functioning (Cohen, 2002). Health-related quality of life is a composite measure that is commonly used to assess the multidimensional impact of chronic disease (Guyatt et al., 1993).

Psychological conceptualization of medically unexplained symptoms. There is considerable support for cognitive behavioral therapy (CBT) both as a model for (Deary et al., 2007; Mai, 2004; Neimark et al., 2005), and as an effective treatment of MUS. The cognitive behavioral model of medically unexplained symptoms (CBT Model of MUS) (Deary et al., 2007) helps explain the dynamic relationship between correlates of illnessrelated distress that both prime and perpetuate the experience of aversive symptoms even in the absence of direct physiological causes. Based on Beck's cognitive theory, the cognitive behavioral model of MUS separates correlates of MUS into predisposing, precipitating, and perpetuating factors in the development and maintenance of emotional distress. People experiencing MUS are believed to have certain vulnerabilities and characteristics, for example, genetics and personality traits that increase both the instance rate and the severity of unexplained distress. Perpetuating factors are those elements that serve to maintain the symptoms such as cognitive processes, physiological arousal, behaviors and social factors. Precipitating factors are those which influence or trigger distress such as one's distress tolerance (Deary et al., 2007). The CBT model of MUS model differs from traditional bio-psycho-social conceptualizations in the inclusion of mutual and reciprocal feedback which self-maintains in the absence of physical pathology, a process Deary et al. describe as "autopoietic" (Deary et al., 2007). A description of the general model CBT Model of MUS can be found in chapter 1.

Applying the CBT model of MUS presents several practical challenges. MUS is by definition a broad category of conditions, and due to the limited scope of this study it is not feasible to include all conditions for which symptom-related distress exceeds physiological explanation. Before this relationship can be applied to the broader class of MUS, it must be demonstrated in a model population of MUS. This study uses a single type of illness to test whether body vigilance predicts unique variance in health-related quality of life and thereby shed light on the potential impact of body vigilance in development and maintenance of MUS. The following section will explain the rationale used to select Inflammatory Bowel Disease as a prototypical example of MUS.

MUS Case in Point: Inflammatory Bowel Disease

Inflammatory Bowel Disease (IBD), including both Crohn's disease and ulcerative colitis, is a chronic, relapsing and remitting, autoimmune disease affecting approximately 1.4 million people in the United States (Kiebles et al., 2010). Both Crohn's disease and ulcerative colitis are organic, physiologically-based diseases characterized by intermittent "flares" of the immune system, in which an excessive response to normal intestinal bacteria results in inflammation and ulceration in the intestinal lining. Common symptoms include pain, nausea, weight loss, frequent, painful, urgent and sometimes bloody bowel movements (Kalibjian, 2003; Sklar & Sklar, 2007). If untreated, flares cause ulcerations accompanied by pain, obstructions and the danger of perforation which may be fatal (Kalibjian, 2003; Sklar & Sklar, 2007). While Crohn's disease can occur at any point in the gastrointestinal tract, ulcerative colitis is by definition limited to the colon. There is no consensus in the medical community

regarding the cause of the disease; however it is generally accepted that genetics and environment are influential (CCFA, 2009).

Like its functional analog, irritable bowel syndrome (IBS), IBD can be considered a medically underexplained condition since illness-related distress may occur in the absence of disease activity. Unlike IBS, a diagnosis of IBD requires confirmation of physical pathology and involves substantial blood tests, imaging including CT scans and MRIs, colonoscopy and endoscopy with biopsies (Kalibjian, 2003; Sklar & Sklar, 2007) and can therefore be distinguished from somatization disorder.

Patients with IBD are at particular risk for psychological distress (Schwarz & Blanchard, 1991; Searle & Bennett, 2001), score higher on measures of alexithymia (Moreno-Jiménez et al., 2007) and have lower average quality of life than healthy peers (Cohen, 2002; Dorrian et al., 2009). IBD patients with clinical depression show elevated disease activity evidenced by increases in several biomarkers for inflammation (Miller et al., 2005), highlighting the dynamic and recursive nature of psychological and physical symptoms. Higher levels of anxiety and lower health-related quality of life are associated with greater medical relapse and increased disease activity (Mittermaier et al., 2004), indicating a possible autopoietic feedback relationship consistent with the CBT model of MUS. The course of the disease in unpredictable, and painful symptoms may appear with little warning, creating ideal conditions for somatosensory amplification (Barsky & Wyshak, 1990). Treating co-occuring psychological disturbances then may help not only the subjective experience of the patient, but may reduce the severity of the physical illness.

Because there are currently no prospects for a cure in patients with IBD, treatment focuses on prevention of complications, induction and maintenance of remission, and improvement and preservation of quality of life. The onset of IBD occurs most frequently in young adulthood, with a modal age in the early 20s, and results in no change to average lifespan (Kalibjian, 2003; Sklar & Sklar, 2007). No two cases of IBD are alike (Sklar & Sklar, 2007) and, adding to the complexity, subjective distress does not always correlate to disease activity, even in cases of medical urgency (Dorrian et al., 2009; Han et al., 2005; Kim et al., 1999). Patients with IBD will likely live with the condition for many years, adding to the potential impact of improving subjective wellbeing.

Measures of health-related quality of life are accepted as appropriate outcome indicators in chronic disease (Fitzpatrick et al., 1998) because they may represent more accurately the complete experience of the individual than do indices based solely on clinical measures. In the specific case of evaluating outcomes for patients with IBD, HRQOL has been indicated as an appropriate outcome measure for treatment (Cohen, 2002) since health status cannot be explained adequately by symptom and disease-related measures. Psychosocial factors such as illness worry and daily functioning impairment would otherwise be missed using only medical benchmarks for disease activity (Drossman et al., 1999). Identifying the factors associated with poor quality of life can aid clinicians in anticipating problems that patients may have and in targeting therapeutic interventions more appropriately (Han et al., 2005).

Measures of HRQOL among patients with IBD, even those with minimal symptoms, show markers of distress not only due to systemic and bowel symptoms, but functional

impairment, social impairment and emotional functioning compared to age and sex matched controls (Love, Irvine, & Fedorak, 1992). This indicates a broad-reaching negative impact on quality of life.

In an apparent contradiction to these results, one study found that, among patients admitted to a hospital, those with Crohn's Disease, a specific form of IBD, had higher socioeconomic level, lower unemployment, greater job stability and fewer absences due to sick leave than age and sex matched controls (Sørensen, Olsen, & Binder, 1987). This finding seems contrary to the previously discussed impairments associated with IBD. Although research has suggested a relationship between IBD and various forms of impairment, it seems logical that the looming, unpredictable threat of hospitalization could cause patients with IBD to use sick days judiciously, whereas non-ill patients feel more comfortable with less of a buffer. Similarly, patients with IBD may be less likely to leave the security of jobs that offer health insurance, paid time off for medical leave, disability insurance, retirement plans and other such benefits. Job stability in this context could be viewed as an indicator of fear of job loss rather than high performance or job satisfaction. In line with this interpretation of absences, unemployment and socioeconomic status, 54% felt that their disease strained their professional and personal life, 23% reported decreased working capacity, and 21% reported decreased leisure activities (Sørensen et al., 1987). It is plausible, then, that just as physiological markers sometimes fail to capture the subjective impact of chronic illness-related distress, some common markers used in work-related studies (e.g., socio-economic status, unemployment, and number of medical leave days used) may miss the nuances of workrelated impairment due to MUS.

Given the complex nature of symptom experience, the impact of symptoms on quality of life, and the risk for somatosensory amplification, IBD presents an ideal opportunity to study the relationship of body vigilance in the development and maintenance of medically unexplained symptoms. The following sections will elaborate on the CBT Model of MUS, and provide an in-depth discussion of the component factors and their relationship with HRQOL.

Predisposing factors. Among the factors believed to predispose one to medically unexplained illness are genetics, personality types and early experiences. Deary et al., describe genetics as one of the less understood links to MUS (Deary et al., 2007). This is understandable given the broad spectrum of conditions that are included under the umbrella of MUS. There is support, however, for individual medically unexplained and under-explained conditions, including: chronic fatigue (Afari & Buchwald, 2003), fibromyalgia (Buskila & Sarzi-Puttini, 2006), irritable bowel syndrome (Gonsalkorale, Perrey, Pravica, Whorwell, & Hutchinson, 2003; Levy et al., 2001) and inflammatory bowel disease (Bonen & Cho, 2003; Bouma & Strober, 2003; Yang & Rotter, 2005).

Genetics are widely believed to contribute to IBD (Kalibjian, 2003; Sklar & Sklar, 2007). A study investigating the genetic influence of IBD found that monozygotic twins with Crohn's disease have a concordance rate of 58%, while dizygotic twins exhibited a rate of is only 3.9%. A similar pattern was observed in ulcerative colitis in which a 50% concordance rate in monozygotic and none of the dizygotic participants had twins with UC (Tysk, Lindberg, Järnerot, & Floderus-Myrhed, 1988). This evidence strongly supports a genetic component to the development of IBD, though it is likely that the

interaction is complex and involves interaction with both environmental and dispositional factors (Bouma & Strober, 2003).

Gender. Though a specific genetic marker for IBD is elusive, gender, which reliably coincides with chromosomal sex, is a risk factor for MUS in general (Nimnuan, Hotopf, & Wessely, 2001; Wool & Barsky, 1994). Social factors may explain some of this effect, including lower barriers to admitting discomfort, greater willingness to seek medical attention and differences in prevalence of psychiatric conditions with somatic features, and increased risk of childhood physical or sexual trauma and resulting differences in bodily perception (Nimnuan et al., 2001; Wool & Barsky, 1994).

A study of medically unexplained symptoms of pain in women undergoing laparoscopic surgery showed that a history of severe sexual abuse was positively associated with psychiatric disorders and unexplained chronic pelvic pain (Walker, Katon, Roy-Byrne, Jemelka, & Russo, 1993). Walker followed this study with an investigation of the influence of childhood sexual abuse on irritable bowel syndrome and inflammatory bowel disease and found significant differences between the conditions on rates of victimization and subsequent mental health issues including depression, panic and generalized anxiety disorders (Walker, Gelfand, Gelfand, & Katon, 1995). Fifty-four percent of women with IBS reported histories of sexual assault, 76% depression, 41% panic disorder and 58% generalized anxiety. In contrast, 42% of the women with IBD reported sexual abuse, 45% reported histories of depression, 25% panic disorder, and 35% generalized anxiety disorder (Walker et al., 1995). Of note in this study, patients without pathological inflammation of the gastrointestinal tract, that is, those with IBS, showed a level of functional disability equal to or greater than patients with severe

organic symptoms of IBD. Female gender is also associated with increased symptom severity and lower HRQOL in IBD (Casellas et al., 2002), although the relationship is diminished controlling for perceived symptom severity (Han et al., 2005).

Personality factors. Personality factors are known to influence medical patients' reports of symptoms and health (Costa, 1987; Larsson, Lööf, Rönnblom, & Nordin, 2008; Lawson, Bundy, Belcher, & Harvey, 2010). Most of the literature on personality and MUS has focused on negative affectivity or neuroticism, two similar constructs, to describe a general disposition to experience subjective distress, including aversive mood states such as anger, disgust, scorn, guilt, fearfulness and depression (Moreno-Jiménez et al., 2007; Watson & Clark, 1984; Watson & Pennebaker, 1989). With a heritability of approximately 50% (Matthews, Deary, & Whiteman, 2003), neuroticism could help explain part of the genetic link of IBD.

Neuroticism is associated with several mechanisms of the cognitive model including harm avoidance (Cloninger, 1987), increased generalization of conditioned response (Bergh, Winters, Devriese, & Diest, 2002), increased experience of physical symptoms after an aversive stimulus (Petrie, Moss-Morris, Grey, & Shaw, 2004), disproportionate attention to pain or fear (Matthews et al., 2003), compromised immune activity (Marsland, Cohen, Rabin, & Manuck, 2001), increased instances of negative life events (Kendler et al., 2003; Magnus, Diener, Fujita, & Payot, 1993), and greater reactivity to negative life events (Bolger & Schilling, 1991).

Neuroticism is related to poorer HRQOL in general populations (Kressin, Spiro III, & Skinner, 2000) and in patients with chronic health conditions (Patten, 2001). Negative affect is an important determinant for the development and maintenance of MUS (De

Gucht et al., 2004). Among patients with IBD, Neuroticism is correlated with selfesteem (r = -.50; p < .001), the predisposing factor alexithymia (r = -.48; p < .001), and all four domains of HRQOL including bowel symptoms (r = -.45; p < .001), systemic symptoms (r = -.52; p < .001), emotional functioning (r = -.62; p < .001) and social functioning (r = -.41; p < .001) (Moreno-Jiménez et al., 2007).

Alexithymia is a second dimension of personality that relates to one's ability to recognize and regulate emotional distress. Literally meaning "no words for feelings," alexithymia has three facets, difficulty identifying and describing feelings (DIF), difficulty in distinguishing between feelings and bodily sensations of emotional arousal (DDF), and the tendency to focus on the concrete details of external events (EOT) (Lesser, 1981; Nemia et al., 1976; Taylor 1984). Higher levels of alexithymia are associated with greater somatic distress, both among patients receiving medical care and in nonclinical populations (Bailey & Henry, 2007; Deary et al., 1997).

Alexithymia and emotional control are negatively related constructs that address one's ability to access, recognize and express one's emotional state. In a study investigating the influence of both variables on HRQOL on patients with IBD, Verissimo, Mota-Cardoso, and Taylor (1998) found that, although they did not predict duration of illness and level of disease activity, emotional control and alexithymia independently predicted HRQOL. Emotional control was related to a composite score of HRQOL (r =.37; p < .01) as well as each of its component domains: bowel symptoms (r = .26; p <.01), systemic symptoms (r = .42; p < .01) and emotional symptoms (r = .43; p < .01). This shows that greater emotional control is associated with improvement in symptoms, functioning and well-being. Not surprisingly, alexithymia, measured by the Toronto Alexithymia Scale (TAS-20) showed an inverse correlation with total HRQOL (r = -.34; p < .01) as well as each of its component domains: bowel symptoms (r = -.28; p < .01), systemic symptoms (r = -.37; p < .01) and emotional symptoms (r = -.38; p < .01), indicating that as difficulty identifying and describing feelings, and externally oriented thinking increase, symptoms increase and functioning and well-being decrease.

Predisposing factors gender, neuroticism and alexithymia are all predictive of greater illness-related distress evidenced by lower scores on HRQOL among people diagnosed with IBD. The CBT Model of MUS holds that once the illness-related distress is present, perpetuating factors maintain and even amplify this distress. The following section will address perpetuating factors in the case example of people with IBD.

Perpetuating factors. The CBT model of MUS holds that cognitive and behavioral factors predict both the development and maintenance of medically unexplained symptoms in a self-reinforcing autopoietic system. These perpetuating factors include the development of illness-related cognitions, coping strategies to reduce the effects of distressing symptoms and the process of sensitization to aversive stimuli and precipitants to distress (Deary et al., 2007).

Cognitive representation of illness. Illness representation is a concept that describes an individual's cognitive and emotional representations used to make sense of one's illness. The interpretation of this information is instrumental in shaping the way a person affected by illness adapts to and engages with his or her condition (Hagger & Orbell, 2003). The "common sense model" (CSM), originally proposed by Leventhal, Meyer, and Nerenz (1980), proposes that individuals construct cognitive representations of their illness from their cultural knowledge of illness, from persons holding authority,

and from their own experience with illness, and organize this representation along dimensions of cause, consequences, identity and timeline (Hagger & Orbell, 2003).

The "cause" dimension represents a person's beliefs regarding the origin and etiology of the illness. An example would be the belief that one's condition is the result of pathogens, stress, or environmental pollutants. The "consequences" dimension of illness representation refers to a person's belief of the impact that illness will have on his or her functional capacity and quality of life. The belief that illness will prevent a person from engaging in pleasurable activities or performing activities of daily living would indicate high consequences. The "identity" dimension refers to the particular label a person ascribes as the source of illness. A person with cancer who attributes nausea to chemotherapy would have a markedly different representation from a person whose nausea is idiopathic and mysterious to him or her. The "timeline" dimension refers to the belief in the chronicity of the condition, or in other words the likelihood that it will be resolved or persistent. Recent research has added a fifth dimension assessing the controllability of an illness (Hagger & Orbell, 2003; Moss-Morris et al., 2002).

The common sense model has been operationalized by the illness perception questionnaire (IPQ-R; Moss-Morris et al., 2002) with demonstrated use in many conditions including rheumatoid arthritis, COPD and psoriasis (Scharloo et al., 1998), asthma (Leventhal et al., 1992), chronic fatigue syndrome (Heijmans & de Ridder, 1998), irritable bowel syndrome (Rutter & Rutter, 2002), and IBD (Dorrian et al., 2009).

Dorrian and Dempster (2009) investigated whether illness perception predicted psychological distress, health-related quality of life and functional independence among patients with IBD. In this study, the IBD-Q, an IBD-specific measure of quality of life,

was reverse-coded, and positive correlations indicated inverse relationships. The authors found that scores on the "identity" scale of the IPQ-R, which measures belief in an attributable cause of symptoms, was related with poorer quality of life (r = .50; p <.001). Likewise higher scores on the "acute/chronic" scale, indicating belief in a chronic rather than acute timeframe for illness, were related to poorer quality of life (r = .33; p <.002). Higher scores on the "cyclical timeline" scale, indicating belief in a variable and unpredictable course of illness (r = .42; p < .001), and the "consequences" scale, indicating belief of severe consequences of illness (r = .58; p < .001), were both related to poorer quality of life. These results support the role of cognitive representations as an influence in the experience of illness as predicted by the CSM of illness representation and the CBT model of MUS.

Sensitization. Deary et al. (2007) define sensitization as the tendency for an individual to have a heightened response to stimuli because of prior experience, most likely in the presence of painful or stressful stimuli that are both uncontrollable and unpredictable, (Rygh et al., 2005). The process of sensitization in the context of MUS was first described by Barsky and Wyshak, in reference to hypochondriasis (Barsky & Wyshak, 1990). Termed somatosensory amplification, patients with unexplained somatic symptoms disproportionately attend to benign somatic sensations, misinterpreting them as serious threats and amplifying both attention and resulting distress. The CBT model of MUS predicts that a similar process takes place among non-hypochondriac population with MUS. In the predicted model, greater perception of and attention to distress mutually and reciprocally influence cognitions, and the result of this feedback loop is a lowered physiological threshold and greater reactivity to aversive experience (Deary et

al., 2007). Thus, sensitization is both an effect of, and secondary cause of prolonged distress. The following section will discuss the role of sensitization in precipitating distress.

Precipitating factors. The CBT model of MUS, illustrated in chapter 1, page 10, outlines the relationship between predisposing, precipitating and perpetuating factors in the development and maintenance of illness-related distress, including a mutual and reciprocal relationship between perpetuating and precipitating factors. In the proposed study, sensitization serves this function, as both a result of prolonged distress which increases the likelihood of future detection of symptoms, resulting in distress.

Overmier and Murison (2005) found support for this feedback cycle in persons exposed to trauma or chronic stress. Among the effects observed were greater reactivity in the hypothalamic-pituitary-adrenal axis, and greater gastrointestinal vulnerability to ulcers, impaired cognition, suppressed emotional expression, and exacerbations in IBD (Overmier & Murison, 2005). For patients with IBD, whose disease induces gastrointestinal ulcers, and whose symptoms include frequent unpredictable and uncontrollable pain, the effect of stress appears remarkably similar to disease activity, thus providing the ideal conditions for the cycle of somatosensory amplification.

Although no studies to date have addressed somatosensory amplification in IBD, Keough et al. have studied the process in irritable bowel syndrome (IBS). In IBS, many of the symptoms are similar, including pain and altered bowel habits; however in IBS, no underlying physiological pathology is present (North, Hong, & Alpers, 2007). Psychiatric comorbidity is common in IBS, with between 50 and 90% of affected patients meeting criteria for a psychiatric disorder (Lydiard, 2001). Individuals with IBS also

report elevated levels of worry, distress, neuroticism and somatization (Gros, Antony, McCabe, & Swinson, 2009; Hazlett-Stevens, Craske, Mayer, Chang, & Naliboff, 2003; Van der Veek, Van Rood, & Masclee, 2008), making this study an appropriate functional analog to IBD. Keough et al. found significant relationships between IBS and distress intolerance (r = .12; p < .01), anxiety (r = .12; p < .05), depression (r = .09; p < .05) and body vigilance (r = .13; p < .01). The elevated vigilance to internal bodily sensations was not accounted for by symptoms of anxiety or depression, lending support to the mechanism of somatosensory amplification and the independent role of affect, avoidance behaviors, and body vigilance (Keough et al., 2011).

Purpose of the Study

Medically unexplained symptoms, particularly those associated with chronic illness, are common occurrences that cause physical discomfort and frustration to patients, increase the likelihood of clinically significant psychological distress, and negatively impact multiple aspects of quality of life. Although literature exists describing the development and maintenance of MUS, the body of research is currently incomplete, lacking any published test of sensitization, a key component in the context of the conceptual model. This study attempts to close this gap in the literature by testing body vigilance as a marker of sensitization, in line with the CBT model of MUS.

Given demographic and epidemiological trends, the likelihood that psychologists--even those in general practice--will encounter clients with MUS is very high. Further, pressure by managed care organizations to employ empirically supported treatments, and psychologists' ethical duty to provide the best possible care, makes evident the need for research in this area. Cognitive behavioral therapy has produced the most empirically

validated treatments for the population with MUS, and the CBT model of MUS is the predominant guiding theory for treatment. Evidence that increased body vigilance is associated with greater MUS severity will give valuable insight to psychological interventions that could reduce subjective distress.

Given the complex nature of symptom experience, the impact of symptoms on quality of life, and the risk for somatosensory amplification, IBD presents an ideal opportunity to study the influence of body vigilance in the development and maintenance of medically unexplained symptoms. By testing this model in a population with IBD, this study attempts to clarify entry points to behavioral health treatment for people living with a complex and dynamic illness, and potentially improve patient care and patients' subjective and physical well-being. In the process, use of this population avoids some of the pitfalls of previous research by eliminating the possibility of purely psychogenic distress.

Chapter 3

Method

The purpose of the study is to test whether body vigilance predicts unique variance in health-related quality of life, and thereby shed light on whether body vigilance may serve as a precipitating factor of illness-related distress as suggested by Deary et al.'s (2007) cognitive model of medically unexplained symptoms, using the case example of inflammatory bowel disease. Prior to data collection, the investigation was approved by the University's Institutional Review Board.

Participants

Eligible participants were a non-random sample of adult volunteers who selfidentified as having a diagnosis of inflammatory bowel disease, defined as either Crohn's disease or ulcerative colitis (CCFA, 2009). Since diagnosis typically involves a combination of blood tests, radiological imagery, and colonoscopy or endoscopy with tissue biopsy, self-report of diagnosis from a gastroenterologist was assumed to be an accurate indication of disease status. Participants under the age of 18 or over the age of 70 were excluded due to potential age related confounds, in line with similar studies (De Gucht et al., 2004; Moreno-Jiménez et al., 2007).

Sample Size

Sample size for the regression analysis in the present study was determined following the recommendations made by Cohen (1998) in the second edition of his book on power analysis. Cohen's recommendation makes use of a combination of power tables with adjustments based on approximate effect size of predictor variables.

Cohen offers an operational definition for small, medium and large effect sizes represented by R^2 s of .02, .13, and .26 respectively. By this definition, previous research has shown, moderate effect sizes connecting neuroticism to MUS (De Gucht et al., 2004) and health-related quality of life (Moreno-Jiménez et al., 2007), alexithymia to MUS (De Gucht et al., 2004) illness perception to health-related quality of life (Kiebles et al., 2010) and body vigilance to severity of MUS (Keough et al., 2011).

Using his base recommendation of 139, adjusted by (m-1) where m equals the number of predictor variables, with a power of .80 and alpha of .05, a sample size of approximately 153 participants is indicated. An alternative rule of thumb was proposed by Harris (1975) suggests a sample size of 50 + 8m, where m equals the number of predictor variables. This rule of thumb for the present study would indicate a sample size of 170. Given the tendency of Harris's rule to overestimate sample size when m > 6 (Green, 1991), the lower of the two recommendations was used and a goal of 153 participants was set. The anticipated sample of 153 exceeded the size of previous published regression analyses investigating similar constructs (Dorrian et al., 2009; Kiebles et al., 2010; Moreno-Jiménez et al., 2007).

An a priori power analysis was performed using G*Power software (Franz, 2012) for an additional estimate of sample size. Prior to this study, there was no basis for estimating the increase in variance explained by the addition of body vigilance to the other variables being tested. With a conservative estimated effect size of .05 additional variance explained by the addition of body vigilance, a power of .80 and alpha of .05, the G*Power software indicated a sample size of 152 would be required. If the effect size is changed to include a .10 increase in variance explained, the indicated sample size drops

to 74. Therefore, a sample size of 154 was assumed to be sufficient to show statistical significance. The present study included 199 participants in the final analysis, exceeding all estimates for minimum sample size. A demographic breakdown can be found in the following chapter.

Recruitment

Participants were recruited in two ways. First, members of the Crohn's and Colitis Foundation of America (CCFA) were invited to participate in a study about factors contributing to health-related quality of life through a posting in the research section of the CCFA website (Appendix A). CCFA maintains a listing of active research studies including clinical medical trials and non-medical outcome research such as the current study. CCFA requires that all projects have statements of compliance with Health Insurance Portability and Accountability Act (HIPAA) regulations, and requires informed consent from participants (CCFA, 2011). Each study included in the CCFA registry has a unique webpage within the CCFA domain and includes a brief description of the nature of the study and contact information of the lead investigator, should participants have any questions. A direct link to the online survey was included and a statement of risks and benefits was included (Appendix A). Consent was implied by navigating to and completing the survey.

The second method of recruitment involved posting to online IBD-related interest and support groups with permission of the appropriate group moderator. Groups were found on Facebook, Google+ as well as state and local CCFA chapters and affiliated groups. Once approval was granted, a message inviting members to participate,

including a link to the above referenced study specific website contained on the CCFA research page was posted to the respective group message board.

With both methods of solicitation, the descriptions included a statement of incentives which gave participants the option of a small (\$3.00) credit to Amazon.com, or the addition of the same amount to a group donation made by the investigator to the CCFA at the conclusion of the study.

Measures

Participants were asked to complete the following measures: a demographics questionnaire, the 12-item Neuroticism subscale of the NEO Five Factor Inventory (NEO FFI), the Toronto Alexithymia Scale (TAL-20), the Illness Perception Questionnaire (IPQ-R), the Body Vigilance Scale (BVS) and the IBD specific measure of health related quality of life (IBDQ). Time to complete all of the instruments is approximately 45 minutes. Previous research in condition-specific measures of quality of life have not indicated any effect of instrument order on response outcomes, therefore the likelihood of order effects in the proposed study is assumed to be low (Mccoll et al., 2003).

Demographic variables. Demographic information (Appendix B) collected for each participant included background information: age, race, gender, education level; and disease-specific information including: particular diagnosis, length of time the participant has lived with the diagnosis, self-report of number of flares in the previous 12 and 24 months. Finally the demographics questionnaire incorporated information relevant to treatment including surgical and medical interventions.

Personality variables. Neuroticism and Alexithymia were operationalized by the Neuroticism subscale of the NEO Five Factor Inventory (Costa & McCrae, 1992) and the Toronto Alexithymia Scale (Appendix C), respectively.

Neuroticism. Neuroticism, defined as the stable tendency toward negative affect and cognition, is one of five dimensions of personality proposed by Costa and McCrae's five factor model (1992). The NEO Five Factor Inventory (NEO –FFI) is a brief measure of personality designed to measure the five basic personality factors including Neuroticism (Costa & McCrae, 1989). The NEO-FFI was derived from the NEO-PI, taking 12 items per factor from the pool of 180 items on the full NEO Personality Inventory (NEO-PI) (McCrae & Costa, 1989). The instrument uses a 5-point Likert scale format with scores ranging from 1 (not very true of me) to 5 (very true of me) for statements that indicate Neuroticism (e.g., "I often feel tense and jittery.") In the present study, only the Neuroticism scale was used.

The NEO-FFI has demonstrated acceptable internal consistency and reliability. Among adults exhibiting MUS, internal consistency for the Neuroticism scale of the NEO-FFI is .83 (De Gucht et al., 2004a), similar to young adults in general (Robins, Fraley, Roberts, & Trzesniewski, 2001). Test-retest reliability was .89 over a span of two weeks (Robins et al., 2001).

Among the general population, the Neuroticism scale of the NEO-FFI has been shown to correlate negatively with measures of subjective well-being including the Oxford Happiness Inventory (r = -.72; p < .001), the Depression-Happiness Scale (r = -.61; p < .001) and the Satisfaction with Life Scale (r = -.54; p < .001) (Hayes & Joseph, 2003). Neuroticism is also linked with symptom severity in populations with

MUS (Costa, 1987; Vassend, 1994). In the current study, the Cronbach's alpha for the Neuroticism scale of the NEO-FFI in an adult population with IBD was .860.

Alexithymia. Alexithymia is a construct characterized by difficulty identifying and articulating emotions and distinguishing them from bodily sensations (Nemiah et al., 1976). The Toronto Alexithymia Scale, TAS-20 (Bagby, Parker, & Taylor, 1994), is a 20-item measure of alexithymia, This well-established personality construct is believed to inhibit affect regulation (Taylor, Bagby, & Parker, 1999). The TAS-20 has a three-factor structure comprising the core dimensions of the alexithymia construct including difficulty identifying feelings (DIF) measured by seven items (e.g., "I am often confused about what emotion I am feeling"), difficulty describing feelings (DDF) assessed with 5 items (e.g., "It is difficult for me to find the right words for my feelings"), and externally oriented thinking (EOT) assessed with 8 items (e.g., "I prefer talking to people about their daily activities rather than their feelings") (Bagby et al., 1994). The TAL-20 has been used in research studies examining influences of MUS in general (Bailey & Henry, 2007; De Gucht et al., 2004a; De Gucht, et al., 2004b; Deary et al., 1997; Jones, Wessinger, & Crowell, 2006) and with IBD specifically (Moreno-Jiménez, et al., 2007; Porcelli, Zaka, Centoze, & Taylor, 1981; Verissimo et al., 2000).

Prior to the current study, internal consistency and reliability data were not presented in published studies in patients with IBD; however, among patients with MUS, internal consistency was similar to internal consistency among non-ill peers (De Gucht et al., 2004; Parker et al., 2010). Among patients with MUS, internal consistency was represented by Cronbach's alphas of .83 (DIF), .73 (DDF), .and 61 (EOT) (De Gucht, et al., 2004), estimates that are similar to estimates in other studies of alexithymia in young adult populations (Parker et al., 2010). Test-rest reliability is shown by correlations with a second measure of Alexithymia taken six months later. Correlation coefficients at 6 months for DIF, DDF and EOT were .61, .66, and .73 respectively. In the current study, internal consistency on the three scales of the TAL-20 among adults with IBD are represented by Cronbach's alphas of .843 (DIF), .792 (DDF), and .571 (EOT).

Illness Cognitions. Illness cognitions are the cognitive and emotional representations that a person forms in response to his or her state of health. The most common conception of illness cognition derives from the "common sense model" of illness representation (Leventhal et al., 1980; Leventhal et al., 1984). The Revised Illness Perceptions Questionnaire (IPQ-R) (Moss-Morris et al., 2002) was used to assess participants' cognitive representations of illness (Appendix D). The IPQ-R, a measure derived from Leventhal's "common sense model," organizes cognitive representation of illness into seven subscales: timeline acute/chronic, timeline cyclical, consequences, personal control, treatment control, illness coherence, and emotional representation.

The 6-item "timeline acute/chronic" scale measures one's belief in the chronicity of the illness (e.g., "my illness will last for a long time," and "this illness will pass quickly," which are reverse-coded.) The 4-item "timeline cyclical" scale addresses variability in illness over time; sample items include "my symptoms come and go in cycles" and "my illness is very unpredictable." The 6-item "consequences" scale measures the perceived severity and includes "my illness is a serious conditions" and "my illness strongly affects the way others see me." The 6-item "personal control" scale assesses belief in one's ability to influence the course and severity of symptoms, and includes "what I do can determine whether my illness gets better or worse" and "I have

the power to influence my illness." The 5-item "treatment control" scale measures belief in the efficacy of current treatment and includes "my treatment will be effective in curing my illness" and "the negative effects of my illness can be prevented by my treatment." The 5-item "illness coherence" scale is a measure of understanding of one's illness and includes "my illness is a mystery to me" (reverse coded), and "I have a clear picture or understanding of my condition." Finally the 6-item "emotional representations" scale asks for specific emotional reactions such as "I get depressed when I think about my illness" and "my illness makes me feel afraid."

Since its initial publication, the IPQ and subsequent revision have been validated and used with numerous illness populations (Moss-Morris et al., 2002) including chronic fatigue and rheumatoid arthritis (Moss-Morris & Chalder, 2003), multiple sclerosis (Jopson & Moss-Morris, 2003) chronic obstructive pulmonary disease and psoriasis (Scharloo et al., 2007, 1998) and recently IBD (Dorrian et al., 2009; Kiebles et al., 2010) The IPQ-R, when used with individuals with IBD, has generally similar internal reliability (Cronbach's alphas ranging from .70 to .83) except for the "treatment control" scale which, contrary to previous research, showed low internal consistency ($\alpha = 20$) (Dorrian et al., 2009). The authors noted that their sample differed from previous research both in the low internal consistency and in the lack of a relationship between the "treatment control" scale and their outcome measure of adjustment. They proposed two possible explanations for the unacceptably low reliability: First, that no validation study had been conducted with the IBD population, and it is possible that the scale may not fit this population, particularly given "the incongruence between controllability and curability" (Dorrian et al., 2009, p. 53). Although it is possible to control symptoms for

periods of time, IBD is notoriously unpredictable, and there is currently no cure. The authors noted that other factors including frequency of relapse and hospitalizations were not assessed in that study, which may influence perception of treatment control. Test-retest reliability was not reported and is a possible limitation of using this instrument. In the current study, the Cronbach's alpha for the seven subscales of the IPQ-R in an adult population with IBD were .817 (Timeline: Acute/Chronic), .767 (Consequences), .853 (Personal Control), .704 (Treatment Control), .897 (Illness Coherence), .742 (Timeline: Cyclical), .894 (Emotional).

Body vigilance. Body vigilance refers to the focusing of conscious attention to internal somatic sensations including monitoring for disturbance. Schmidt, Lerew, and Trakowski (1997) conceptualized body vigilance as the learning that takes place, a "natural consequence" of chronic exposure to aversive stimuli. Body vigilance was operationalized by the 4-item Body Vigilance Scale (BVS) (Schmidt et al., 1997), (Appendix E). The first three items assess on a 10-point Likert scale the degree of attentional focus (e.g., "I am the kind of person who pays close attention to internal bodily sensations"), perceived sensitivity to changes in bodily sensations (e.g., "I am very sensitive to changes in my internal bodily sensations") and the average amount of time spent attending to bodily sensations ("On average, how much time do you spend each day 'scanning' your body for sensations (e.g., sweating, heart palpitations, dizziness)?"). A fourth item identifies 15 distinct sensations including all of the symptoms of panic attack as defined by the DSM-IV-TR (American Psychiatric Association, 2000). Participants are instructed to rate how much they attend to each of these sensations from none (0) to extreme (10), and an average is computed. The BVS total score is the sum of these four

items. Principal component analysis of BVS items support a single factor on which all items load (Schmidt et al., 1997; Vujanovic, Zvolensky, Bernstein, Feldner, & McLeish, 2007). Internal consistency and test-retest reliability are good, with an average Cronbach's alpha of .83 in non-clinical samples and a 5 week test-retest coefficient of r=.68 (Schmidt et al., 1997). No studies to date have validated the BVS for use with IBD patients; however high internal consistency (Cronbach's alpha of .95) has been shown in use with its functional analog, IBS (Keough et al., 2011). The total score (sum of the four items) will be used for evaluation in this study. In the current study, the Cronbach's alpha for the BVS in an adult population with IBD was .771.

Illness distress. Illness distress is a construct encompassing subjective health status, notably the negative experience of one's medical condition. In the context of the CBT model of MUS, illness distress includes the direct discomfort of physical symptoms, as well as the physical and emotional distress that may be fueled by negative beliefs, potentially aided by increased detection through higher body vigilance. Whereas physiological measures often correlate poorly with measures of functional capacity and well-being, illness distress more accurately captures the total impact of chronic disease (Guyatt, Mitchel, & Irvine, 1989).

Illness distress in the present study was measured by the 32-item IBD Quality of Life (IBDQ) scale (Guyatt et al., 1989). Participants were asked to respond to each question using a 7-point Likert scale ranging from 1 "worst" to 7 "best." Scores range from 32 to 224, with higher scores representing better perceived health and functioning. Developed as an outcome measure for patients with IBD, the IBDQ assesses perceived functioning and symptom severity across domains including systemic symptoms, bowel

symptoms, social factors and emotional functioning. The IBDQ is correlated with the Crohn's disease activity index (CDAI) (-.50), a common measure of physiological symptoms, and internal consistency is acceptable for both UC and CD shown by Cronbach's alphas of .89 and .85 respectively (Hyphantis et al., 2010). The IBDQ has greater test-retest reliability at .70 compared to the CDAI's .66 (Irvine, 1999). Although comparatively low, the variance in test-retest reliability may indicate that IBD-specific well-being measured by the IBDQ is a state rather than trait characteristic. This questionnaire is commonly used in clinical trials as a primary clinical endpoint (Casellas et al., 2005; Dorrian et al., 2009; Han et al., 2005; Kiebles et al., 2010).

Procedure

Following approval by the University of Memphis Institutional Review Board (IRB), the study went through an additional review process with the Crohn's and Colitis Foundation of America for inclusion on their research study website. Participants were recruited by the methods described earlier in this chapter and were directed to the study website with an embedded survey, powered by surveymonkey.com.

Data Analysis

This study used hierarchical multiple regression analysis to determine the relative contribution of body vigilance as a predictor of health-related quality of life, in line with the cognitive model of medically unexplained symptoms (Deary et al., 2007). Hierarchical multiple regression is used to determine the effects of predictors whose order may be determined a priori by theoretical rationale. The CBT model of MUS provides such a rationale by organizing factors into temporally distinct categories: predisposing, precipitating and perpetuating factors. Inherent in this model are

assumptions of a temporal order. By definition, predisposing factors influence the likelihood of developing illness and resulting distress that has not yet occurred. Likewise, precipitants are the proximal triggers to illness distress that may be influenced by predisposing factors. As a result of the distress, perpetuating factors reinforce the systemic conditions that created them. Because support exists for all elements of the CBT Model of MUS except for the influence of sensitization in the form of body vigilance, in the present study, variables will be entered in the hierarchical regression in two blocks. The first block included all the variables that current research supports, including demographic, predisposing and perpetuating variables. Specifically, this included gender, specific diagnosis, length of time since diagnosis, neuroticism, alexithymia, as well as all seven dimensions of illness perception illness cognitions. The second block consisted of the measure of body vigilance. Changes in variance explained when the second is added can be attributed to body vigilance in the context of all other elements in the CBT Model of MUS. It is hypothesized that, after controlling for the variance in health related quality of life explained by predisposing factors (gender, specific diagnosis, neuroticism, and alexithymia,) and perpetuating factors (chronicity, cyclical timeline, consequences, personal control, treatment control, illness coherence, and emotional representation), the precipitating factor (body vigilance) will account for significant additional variance.

Chapter 4

Results

This study tested whether body vigilance predicts unique variance in healthrelated quality of life, serving as a precipitating factor of illness-related distress as suggested by Deary et al.'s (2007) cognitive behavioral model of medically unexplained symptoms, using the case example of inflammatory bowel disease. This chapter provides a summary of the statistical analyses used to evaluate the hypothesis established in the previous chapters, followed by the results of these analyses.

Preliminary Analysis

Hierarchical multiple regression was used to address the research question and determine whether body vigilance uniquely and significantly explains variance in health related quality of life. SPSS software v. 21 was used to perform a two-step, hierarchical multiple regression to determine the influence of body vigilance on health related quality of life. A three-step regression was then run to determine if non-significant variables, when entered together in blocks derived from the CBT model of MUS explained significant variance, supporting the organization of the theoretical model.

After descriptive statistics were reviewed, preliminary analyses were conducted in order to examine the data for accuracy, missing values, appropriate ranges and frequencies and normality of distributions. Tests for outliers were conducted to examine the possibility of potential influential data points.

Prior to analyzing the data, responses were checked for missing, incomplete or inconsistent data that would warrant exclusion. Of the 300 initial contacts for the survey, 230 participants attempted all survey instruments. Due to incomplete responses or

missing information, 27 responses were excluded from analysis. Two additional participants entered responses, which appeared to be typographical errors (entering the date in which they were diagnosed as a future date). There was no other indication that these participants were atypical, therefore they were retained in the analysis, and erroneous scores were replaced with the mean score for length of time since diagnosis.

To assess for curvilinearity and the assumption of homoscedastisity of variance, a regression was run on the dependent variable (IBDQ). Review of the scatterplot suggested that curvilinearity was not present in the data and no pattern in the plot suggested a violation of the assumption of homoscedastisity.

To determine if outliers were influencing the data, a multiple regression was run and the results were examined to determine if any data points had a Cook's D value greater than 1 or a leverage value (n = 203, k = 15) greater than 0.241 (Stevens, 2002). Regression results indicated that no Cook's D was greater than .043, and no leverage value greater than .215. It was determined therefore that there was no significant bias introduced by outliers. Of the independent variables with significant influence on the dependent variable, only one scale showed outliers, the consequences scale on the IPR-R (CONSEQ), which measures the belief of severe consequences because of the participant's illness. The distribution of scores on this scale showed a positive skew, indicating that the majority of participants viewed their disease as having serious consequences in their lives with four outliers on the low end. Low scores on the CONSEQ scale suggest that these four participants viewed the consequences of their disease as notably less serious than the rest of the sample. Each of these participants also indicated that they were on no maintenance medications, which was atypical for the population. Consequently these cases were removed from the final analysis yielding a sample of 199.

Preliminary analysis indicated there were no multicollinearity problems in the data as evidenced by variance inflation factors (VIF) of less than 10 (Stevens, 2002), with the largest VIF being 2.836. Visual review of the scatter plots indicated no curvilinearity in the data. No pattern suggested a violation of the assumption of homoscedastisity.

Demographic variables including sex (Sex), diagnosis (Dx) and time since diagnosis (MoSinceDx) were operationalized using demographic information provided by the participants and are summarized in Table 1. Descriptive statistics for study variables are presented in Table 2.

Table 1

Demogr	anhic	Var	iables
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	I	Frequency	Percent	Cumulative Percent
Dx	Crohn's Disease	123	61.8	61.8
	Ulcerative Colitis	76	38.2	100.0
Sex	Female	161	80.9	80.9
	Male	38	19.1	100
	Caucasian	186	93.5	93.5
Race	African American	1	0.5	94.0
	Hispanic/Latino	5	2.5	96.5
	Native American/Alaska Nat	ive 1	0.5	97
	Other	6	3.0	100
	High School / No College	11	5.5	5.5
	Associate's Degree	48	24.1	29.6
Education	Bachelor's Degree	14	7	36.7
	Master's Degree	75	37.7	74.4
	Doctoral/Professional Degree	e 51	25.6	100

	N	Minimum	Maximum	М	SD
Age	199	18	66	35.08	12.31
MoSinceDx	199	2	600	109.50	114.48
Ν	199	14	57	35.45	9.34
DIF	199	7	35	17.31	6.42
DDF	199	5	24	12.42	4.62
EOT	199	8	32	17.56	4.43
TLAC	199	12	30	25.75	3.79
CONSEQ	199	13	30	23.47	4.17
PRCTRL	199	6	30	21.03	4.96
TXCTRL	199	6	24	16.42	3.70
ILLCOHER	199	5	25	18.22	5.24
TLCYCL	199	4	20	14.33	3.39
EMOT	199	7	30	20.19	5.93
BVSTotal	199	5.07	40	24.61	6.94

Table 2Descriptive Statistics

Sex was given values of 1 (male) and 2 (female). Dx was coded as 1 (Crohn's disease) and 2 (ulcerative colitis). For both Sex and Dx, values were chosen arbitrarily. Time since diagnosis was calculated by subtracting the approximate date of diagnosis from the date on which the survey was completed.

Participants for the present study were majority female, at 80.9 % (n = 161) as compared to male at 19.1 % (n = 38), with a diagnosis of Crohn's disease, 61.8 % (n =123) as opposed to ulcerative colitis, 38.2 % (n = 76). Self report of race was predominantly Caucasian at 93.5 % (n = 186), followed in descending order by responses marked "Other" 3 % (n = 6), "Hispanic/Latino" 2.5 % (n = 5), "African American" and "Native American/Alaska Native" each with 0.5 % (n = 1). This relative lack of racial diversity is a potential limitation in the study and is addressed in the discussion section. Previous research sampling adults with IBD yielded similar mean age (40) and time since diagnosis (10.9 years) (Dorrian et al., 2009).

Participants tended to skew disproportionately to higher levels of education with 5.5 % (n = 11) endorsing a highest level of education as "high school with some college," 24.1 % (n = 48) endorsing "associate's degree," 7 % (n = 14) endorsing "bachelor's degree," 37.7 (n = 75) endorsing "master's degree" and 25.6 % (n = 51) with a "doctoral or professional degree."

Internal consistencies for all scales used in the regression analysis were consistent with those in previous research studies, and are summarized in Table 3. Cronbach's alpha of .86 for the Neuroticism scale of the Neo-FFI (N) was similar to the .83 shown in other MUS populations (DeGucht et al., 2004). Internal consistency for alexithymia scales of DIF ($\alpha = .84$), DDF ($\alpha = .79$) and EOT ($\alpha = .57$) were likewise similar to populations with MUS (alphas equal to .83, .73 and .61 respectively) (DeGucht et al., 2004). Currently the only study to publish internal consistency of IPQ-R scales in IBD populations, Dorrian et al., (2009) reported alphas ranging from.70 to .83, though did not specify which alpha applied to particular scales with the exception of treatment control, for which they found low internal consistency ($\alpha = .20$). In the present study, all subscales showed internal consistencies between .70 and .90, including the treatment control scale. In this way, the current study improves upon existing literature for the use of the IPQ-R with populations with IBD. Internal consistency for the Body Vigilance Scale was notably lower with an alpha of .77 as compared to .95 when used in IBS, a similar but separate medical condition (Keough, et al., 2011). The outcome measure of

health related quality of life, normed for those with IBD (IBDQ) previously showed

internal consistencies of .89 and .85 for ulcerative colitis and Crohn's disease

respectively (Hyphantis et al., 2010). Internal consistency for the combined group in the

present study is higher at ($\alpha = .94$).

Reliability Statistics		
	Cronbach's	Number of Items
	Alpha	
NEO-FFI: Neuroticism	.86	12
TAL-20: DIF	.84	7
TAL-20: DDF	.79	5
TAL-20: EOT	.57	8
IPQ-R Timeline Acute/Chronic	.82	6
IPQ-R Consequences	.77	6
IPQ-R Personal Control	.85	6
IPQ-R Treatment Control	.70	5
IPQ-R Illness Coherence	.90	5
IPQ-R Timeline: Cyclical	.74	4
IPQ-R Emotional Reasoning	.89	6
Body Vigilance Scale (BVS)	.77	32
Health Related Qualify of Life (IBDQ)	.94	32

Table 3 Reliability Statistics

Statistical Analysis

To examine the ability of body vigilance to predict health related quality of life among the sample population with IBD, study variables were entered into a multiple regression analysis in two steps, with variables currently supported by research based on the CBT model of MUS entered in the first step and the study variable, BVS entered in the second step to determine additional predictive value reflected in change in R squared. In the first step, predisposing and perpetuating variables were entered. Predisposing variables included demographic variables of gender (Sex), specific diagnosis (Dx), and length of time since diagnosis in months (MoSinceDx), along with personality variables of neuroticism (N), alexithymia which includes difficulty identifying feelings (DIF), difficulty describing feelings (DDF) and externally oriented thinking (EOT). Perpetuating variables included scales of the Illness Perception Questionnaire Revised (IPQ-R), specifically timeline acute/chronic (TLAC), timeline cyclical (TLCYCL), consequences (CONSEQ), personal control (PRCTRL), treatment control (TXCTRL) emotional (EMOT), and illness coherence (ILLCOHER). Body vigilance (BVS) was entered in the second step as the precipitating factor being tested. An alpha level of $\alpha = .05$ was used to assess for statistical significance.

Findings in the current study support previous research that shows correlations among personality variables, neuroticism and alexithymia. Neuroticism showed significant correlations with each of the subscales of alexithymia, including DIF (r = .59, p < .01), DDF (r = .49, p < .01), and EOT (r = .19, p < .01). In this sample, higher scores on neuroticism were related to increased difficulty identifying and describing feelings as well as more externally oriented thinking.

Neuroticism also correlated significantly with all scales on the IPQ-R reflecting a relationship with belief that the illness will be long lasting (r = .15, p < .05), have serious consequences (r = .38, p < .01). Beliefs that one has personal control (r = -.19, p < .01), or that treatment will be effective (r = -.22, p < .01), are negatively correlated with neuroticism. Higher neuroticism was related with a less cohesive understanding of one's illness (r = -.26, p < .01), beliefs that symptoms will repeatedly reappear (r = .28, p < .01).

.01) and greater emotional distress (r = .59, p < .01). Neuroticism also showed a significant correlation with body vigilance (r = .18, p < .01), and health related quality of life (r = -43, p < .01). Likewise, alexithymia, a construct that incorporates difficulty identifying and articulating emotions as well as externally oriented thinking, showed strong correlations with illness cognitions. Correlations can be seen in Table 4.

Table 4

Hierarchical Regression Correlations	Hierarchical	Regression	Correlations
--------------------------------------	--------------	------------	--------------

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
1) IBDQ		2	5		5	0	1	0	,	10	11	12	15	11	10	10
2) Sex	.02															
3) Dx	06	.04														
4) MoSinceDx	06	07	18**													
5) N	43**		02	.05												
6) DIF	44**	.00	09	03	.59**											
7) DDF	31**	11	.01	07	.49**	.68**										
8) EOT	12	12*	00	.07	.19**	.29**	.44**									
9) TLAC	13*	.13*	17**	.10	.15*	.09	.06	.05								
10) CONSEQ	46**	02	07	.04	.38**	.34**	.21**	.03	.31**							
11) PRCTRL	.31**	13*	.07	.01	19**	19**	05	19**	33**	13*						
12) TXCTRL	.31**	.05	.16*	18**	22**	24**	11	22**	41**	25**	.60**					
13) ILLCOHER	R .28**	.02	.03	.08	26**	41**	20**	26**	.00	19**	.21**	.24**				
14) TLCYCL	42**	.02	04	.04	.28**	.42**	.33**	.18**	.04	.24**	18**	15*	24**			
15) EMOT	52**	.11	.00	08	.59**	.49**	.32**	.15*	.20**	.53**	34**	30**	43**	.36**		
16) BVSTotal	25**	.04	03	06	.18**	.23**	.07	15*	.07	.14*	.04	.03	07	.07	.21**	

Note. IBDQ = Health Related Quality of Life in IBD; Sex = reported gender; Dx = diagnosis as either Crohn's Disease or Ulcerative Colitis; MoSinceDx = time since diagnosis in months; N = Neuroticism; DIF = difficulty identifying feelings; DDF = difficulty describing feelings; EOT = externally oriented thinking; TLAC = timeline acute/chronic; CONSEQ = consequences; PRCTRL = personal control; TXCTRL = treatment control; ILLCOHER = illness coherence; TLCYCL = timeline cyclical; EMOT = emotional consequences; BVSTotal = composite score of Body Vigilance Scale; *p < .05. **p < .01.

Variables entered in step 1 were significant, as shown in Tables 5 and 6, with $R^2 =$.442, *F* (14, 184) = 10.426, *p* < .01. The addition of body vigilance accounted for an additional 2.4 % of variance explained, $R^2 = .466$, *F*(1, 183) = 10.644, *p*>.01.

Model Summary of 2-Step Regression R^2 Adjusted R^2 Std. Error of R R^2 Change the Estimate F df2Sig. F df1Change Change Step 1 .665 .442 .400 26.37718 .442 10.426 14 184 .000 Step 2 .683 .466 .422 25.88428 .024 1 183 8.074 .005

Table 5

Results of the regression analysis support the hypothesis that body vigilance has a significant relationship with health related quality of life in addition to what is already accounted for by variables supported by current IBD research. Effect size for the additional variance explained is represented by a Cohen's f^2 of .025. In the context of the full model tested, significant relationships were found between perception of serious consequences of illness ($\beta = -.234$), cyclical timeline ($\beta = -.204$), personal control ($\beta = ..168$), body vigilance ($\beta = -.165$), and specific diagnosis ($\beta = -.123$). Personality variables including neuroticism and all scales of alexithymia, which previously have been associated with higher distress and lower quality of life among people with MUS, were not individually significant in this analysis. This appears to contradict previous research on personality and MUS.

	Unstand	lardized	Standardized	t	Sig.
	Coeff	icients	Coefficients		
	В	Std. Error	Beta		
Step 1					
1. Sex	5.017	5.107	.058	.982	.327
2. Dx	-8.503	4.018	122	-2.116	.036
3. MoSinceDx	022	.018	075	-1.269	.206
4. N	267	.287	073	930	.354
5. DIF	571	.482	108	-1.186	.237
6. DDF	382	.630	052	606	.545
7. EOT	.629	.501	.082	1.255	.211
8. TLAC	.544	.586	.061	.929	.354
9. CONSEQ	-1.881	.566	230	-3.324	.001
10. PRCTRL	1.045	.510	.152	2.048	.042
11. TXCTRL	.709	.712	.077	.996	.320
12. ILLCOHER	.187	.431	.029	.434	.665
13. TLCYCL	-1.997	.630	199	-3.168	.002
14. EMOT	924	.483	161	-1.915	.057
Step 2					
1. Sex	4.701	5.013	.054	.938	.350
2. Dx	-8.613	3.943	123	-2.184	.030
3. MoSinceDx	024	.017	082	-1.409	.161
4. N	244	.282	067	863	.389
5. DIF	299	.482	056	619	.537
б. DDF	518	.620	070	836	.404
7. EOT	.403	.499	.052	.808	.420
8. TLAC	.677	.577	.075	1.174	.242
9. CONSEQ	-1.911	.555	234	-3.440	.001
10. prctrl	1.152	.502	.168	2.295	.023
11. TXCTRL	.810	.699	.088	1.158	.248
12. ILLCOHER	.219	.423	.034	.518	.605
13. TLCYCL	-2.045	.619	204	-3.304	.001
14. EMOT	771	.477	134	-1.617	.108
15. BVSTotal	811	.285	165	-2.842	.005

Table 6Summary of Hierarchical Regression Analysis

The regression analysis was re-run in three steps (Table 7) corresponding to the grouping of variables in the CBT Model of MUS with the first step containing only predisposing variables, the second step adding perpetuating variables and the third step adding the precipitating variable and completing the model. When run as a three-step regression, each step showed a significant contribution to variance explained, indicating that while specific variables which were used as predictors did not explain significant unique variance in MUS, the conceptual model and theoretically defined grouping of variables still appears to fit this population.

Table 7

Model Summary of Three-Step Regression

Model	R	R^2	Adjusted	Std. Error	Change Statistics				
			R^2	of the	R^2	F	df1	df2	Sig. F
				Estimate	Change	Change			Change
Step 1	.503	.253	.226	29.96	.253	9.257	7	191	.000
Step 2	.665	.442	.400	26.38	.189	8.911	7	184	.000
Step 3	.683	.466	.422	25.88	.024	8.074	1	183	.005

Chapter 5

Discussion

Medically unexplained symptoms (MUS), defined as sets of symptoms which physical pathology does not adequately explain (Swanson et al., 2010), are both commonplace and problematic to health care providers (Kroenke, 2000; Swanson et al., 2010). In the U.S. between 15% (Aiarzaguena et al., 2008) and 20% (Hartz et al., 2000) of patients presenting to general practitioners have somatic symptoms with no clear physiological basis. MUS are particularly challenging to treat for health care providers (Kroenke, 2000; Raine et al., 2002). Patients with MUS use more health care services and often receive more tests and treatments at greater cost than may be necessary (Aiarzaguena et al., 2008). They also experience significant psychological distress and poorer quality of life (Koch et al., 2007). The impact of MUS extends beyond patient and provider, as it accounts for a significant proportion of disability in the workforce (Kroenke et al., 1994; Reid et al., 2001).

The cognitive behavioral model of MUS (Deary et al., 2007) outlines the relationships between sets of factors believed to be relevant in the development and maintenance of MUS. These factors are organized into three categories of variables: predisposing factors which influence likelihood of the symptom first occurring, precipitating factors which influence the direct triggering of the symptom and perpetuating factors, those which determine the detection and reactivity to stimuli which are both effects and secondary causes of the symptom.

While the literature on treating MUS has a solid theoretical grounding in the CBT Model of MUS, research to date based in this theory has largely neglected precipitating

factors, a key component in the theoretical framework. Existing studies which show support for measures of reactivity to MUS in the form of body vigilance (Keough et al., 2011) have done so without other essential parts of the model, leaving the body of research incomplete.

This study tested whether body vigilance predicts variance in health-related quality of life, serving as a precipitating factor of illness-related distress as suggested by Deary et al.'s (2007) cognitive behavioral model of medically unexplained symptoms, using the case example of inflammatory bowel disease. By doing so, this study adds depth to the body of literature on CBT model of MUS, and fills a critical gap by demonstrating both the role of precipitating factors in the model, and that body vigilance scale specifically may serve this function.

Research Question

It was hypothesized that in the current study, after controlling for the variance in health-related quality of life explained by predisposing factors (gender, diagnosis, neuroticism and alexithymia,) and perpetuating factors (chronicity, cyclical timeline, consequences, personal control, treatment control, illness coherence, and emotional representation), the precipitating factor body vigilance would account for significant additional variance in health-related quality of life.

The results of the multiple regression analysis supported the research hypothesis. The extent to which adults with inflammatory bowel disease (IBD) attended to internal sensations and monitored for symptoms explained a significant portion of the variance in symptom severity, even when controlled for sex, diagnosis, personality and illness perceptions. The full model accounted for 47% of the variance in symptom severity as

measured by the IBDQ and the addition of the precipitating factor, body vigilance accounted for roughly 2.4% of the total variance. The strength of correlation between body vigilance and symptom status was nearly twice that of previous research in irritable bowel syndrome (IBS) (Keough et al., 2011). Although this relationship is consistent with the CBT model of MUS, it does not necessarily indicate that the additional variance explained by body vigilance is due to sensitization, and in fact some evidence suggests the opposite process occurs.

Whereas measures of pain detection thresholds show sensitization to rectal pain among patients with IBS, attenuated pain perception has been observed in patients with IBD (Chang et al., 2000) suggesting important differences between IBS and IBD in the etiology of pain, and potential fit of the CBT model of MUS. However the breadth of symptoms and the impact of illness extend far beyond the experience of pain. For example the IBDQ, the widely accepted measure of disease status in IBD used in the current study, also assesses for fatigue, nausea, social and emotional consequences, embarrassment, impairment in sexual functioning among the numerous areas that that the disease impacts people. Each of these negative consequences could potentially contribute to changes in body vigilance. Further analysis using structural equation modeling or path analysis as well as longitudinal studies may add clarity to the nature of the relationship of body vigilance to other variables in the CBT model of MUS.

Although personality variables showed significant correlations with illness cognitions, body vigilance and with health related quality of life, when all variables were entered in the regression equation, neither neuroticism nor any of the scales of alexithymia individually explained significant portions of variance in health related

quality of life. This is in contrast to previous research on MUS which showed associations between neuroticism for instance, and harm avoidance (Cloninger, 1987), increased experience of physical symptoms after an aversive stimulus (Petrie et al., 2004), disproportionate attention to pain or fear (Matthews et al., 2003), and poorer health related quality of life in general populations (Kressin et al., 2000) and in patients with chronic health conditions (Patten, 2001). Likewise, alexithymia had previously been shown to predict health related quality of life among adults with IBD (Verissimo et al., 1998). In the current study, the association between both personality variables and health related quality of life was non-significant, however, when predisposing variables were entered together in a single block, the variance explained was significant. Likewise, when all illness perceptions were entered in block two of the three step regression as perpetuating factors, significant additional variance was explained. This supports the organizational structure of the CBT model of MUS by showing that non-significant predictors when applied in combination can explain significant variance.

Limitations

Although the current study provides support for the CBT model of MUS, it must be interpreted in light of several limitations. An intended strength of this study was the use of a population with IBD, a medical illness with a rigorous and definitive diagnostic process to illustrate the role of body vigilance in the CBT model of MUS, thus eliminating the confounds of purely psychogenic disorders such as conversion and somatization. This was in keeping with a liberal definition of MUS (Swanson et al., 2010). In selecting this sample population however, it was ensured that some degree of

medical explanation was present which may account for some differences in the present results and other studies of MUS populations.

Another limitation in the present study is the omission of some variables suggested in the theory. The CBT model of MUS also leaves open the possibility for classes of variables such as coping, which, if included in their entirety, would make the survey prohibitively long. Wherever possible, redundancy in conceptually and statistically related variables was eliminated, while maintaining the constructs identified in the model (Deary et al., 2007). Although the cognitive model suggests an order of influence and causal direction, since this study is a non-experimental, correlational design, results cannot demonstrate causal relationships between variables.

Another potential limitation in this study lies in the sampling method. Since participants were recruited from online support organizations, it is possible that the sample over-represented younger and more technologically fluent people or that members of the Crohn's and Colitis Foundation of America (CCFA) would be overrepresented. CCFA, however, is currently the most comprehensive source of national data on IBD (Kalibjian, 2003); therefore an overrepresentation of members will be unlikely to introduce any bias that would limit the validity of the results. Furthermore, IBD affects primarily young adults (Loftus, Schoenfeld, & Sandborn, 2002), the same age groups that would be expected to have the greatest access to online forums. Skew in age then, would likely mirror the age distribution of IBD and would be unlikely to introduce bias.

The sample drawn in the current study was heavily weighted towards female participants, and those with Crohn's disease relative to ulcerative colitis. It does not

appear that this influenced the results, which were in line with previous research that had more balanced samples.

At first glance, the lack of racial diversity appears troubling; with over 93% of the sample reporting race as Caucasian. IBD has traditionally been diagnosed at much higher rates among people whose lineage points to Northern Europe, Scandinavia, and United Kingdom (Loftus et al., 2002) so some skew towards Caucasian participants may be expected. These differences in disease appearance seem to be waning over time however as populations migrate and diagnostic screening improves (Basu, Lopez, Kulkarni, & Sellin, 2005) Basu et al. (2005) note differential patterns of diagnosis according to race with African American and White identified people being diagnosed with CD whereas Mexican-Americans tended to be diagnosed with UC. The current sample had insufficient numbers of African American and Mexican American participants for any substantive analysis or race and diagnosis. Future studies would benefit from a more diverse sample.

As with any self-report measures, the instruments used in this study are subject to individual participants' idiosyncratic interpretation and response biases. Responses regarding specific illness identity may be assumed to be accurate since multiple imaging including endoscopy and or colonoscopy with tissue biopsy is generally required for a diagnosis of Crohn's disease or ulcerative colitis (Kalibjian, 2003). Since these diagnostic tests can only be performed by physicians qualified to diagnose either condition, the danger of ambiguous or incorrect self-diagnosis is minimal. Social desirability and potential embarrassment may influence self-report responses; however,

the anonymous nature of the tests and the stated purpose of advancing research that will benefit those with IBD likely encouraged honest, non-biased answers.

Responses in this data collection showed evidence of both idiosyncratic interpretation and also limitations in the instruments when applied to IBD. For instance, several participants who had diagnoses of ulcerative colitis, had ileostomies or "jpouches" after surgical removal of the large intestine. For these participants, the symptom profiles they experience are drastically different, with "flares," pain, and the sensation of urgency subsiding and chronic maintenance becoming more of a focal concern. One participant commented: "I have a permanent ileostomy due to UC …it has resolved many of the negative quality of life issues of IBD." Whether this participant viewed continued care for the ileostomy as related to the IBD that necessitated the surgery was unclear. Although the IBDQ is currently the best available instrument for assessing subjective distress of IBD, some important facets of the disease experience are omitted which may lead to under-reporting of severity.

Similarly, participant comments related to the BVS scale suggested that specific wording related to "scanning" one's body for symptoms was problematic. One participant commented "I feel what I feel, I don't 'scan my body' for it," and another wrote "I don't 'scan' my body; symptoms are so strong that there is no need." In contrast, several participants commented about the importance of being "in tune" with one's body, particularly in light of absorption issues, which are common in IBD. Idiosyncratic interpretation of "scanning" may have caused an under-reporting of vigilance as several participants wrote that they were constantly aware, yet never intentionally scanning their bodies. This also may lead to underreporting of symptoms.

Several participants indicated comorbid medical diseases, which they believed to be secondary to their IBD. Likewise, several participants indicated concurrent psychological diagnoses including major depression, posttraumatic stress disorder and unspecified eating disorders, which could cloud interpretation of these test results. In the current study, the number of participants reporting comorbid medical and mental health conditions was small; however, the feedback from these participants was valuable.

Relevance to the Field of Counseling Psychology

The likelihood of counseling psychologists encountering a client with a medically unexplained symptom is high, particularly for those working in primary care settings, in collaboration with medical providers in behavioral health and preventive medicine settings or in practices organized as part of a patient-centered medical home. As the instance rate of chronic conditions increases and the number of patients whose distress exceeds medical explanation continues to grow, the importance of psychologists in integrated care will likewise increase, particularly as chronic and complex health conditions become increasingly more common and even normative.

Further, pressure by managed care organizations to employ empirically supported treatments, and psychologists' ethical duty to provide the best possible care makes evident the need for research in this area. Cognitive behavioral therapy has produced the most empirically validated treatments for the population with MUS, and the CBT model of MUS is the predominant guiding theory for treatment. Evidence that increased body vigilance is associated with greater MUS severity gives potentially useful insight to interventions that could reduce subjective distress. Complementary alternative medicine modalities such as prayer, guided imagery, meditation, relaxation, and yoga are becoming

popular among patients and healthcare providers, and are gaining empirical support for symptom management (Cotton et al., 2010; Gaylord et al., 2011).

Many counseling psychologists in general practice therefore are likely to encounter a client with MUS, and will also likely be subject to pressure to use empirically supported treatment such as CBT in their work. In that sense, the findings from this study will be directly applicable to counseling psychology practice. Perhaps more importantly, this study highlights the dynamic nature of stressors of chronic illness, and the importance of including measures of precipitating factors such as body vigilance, which can account for differences in sensitivity and reactivity to symptoms when assessing overall distress.

Implications for Education

Medically unexplained symptoms are notoriously dysregulating to the individuals who experience them, and difficult for health care providers to treat effectively. The present study shows that the addition of a the body vigilance scale, a psychometric measure of sensitization to the CBT model of MUS explains significant additional variance in health related quality of life, a widely accepted benchmark for both psychological and physical health among people with IBD. The full model accounted for nearly half of the variance observed. This is strong support of the role of psychological theory in describing, and predicting well-being in this population and further support of the role of psychologists in contributing to effective and comprehensive health care. It will be increasingly important for counseling psychologists to be fluent in a wide range of health functioning including MUS, and to be able to communicate this information to other health care providers and patients.

Central to the education of counseling psychologists is training in critical evaluation of research, and translation of findings into treatment recommendations that are grounded in empirical support, personalized to the needs of the patient. This often involves adapting previously established theories to novel population groups or settings. The present study shows that although the CBT model of MUS is useful in describing categories of predictors to explain variance in health related quality of life among adults with IBD, differences still exists between this population and other medical populations that have been studied through this model.

Future Research

By using the sample population of adults with IBD, it was possible to eliminate purely psychogenic sources of MUS. It is also possible that in doing this, some degree of medical explanation was essentially guaranteed which may separate IBD from other populations studied through the lens of the CBT model of MUS. This difference may also be related to variable definitions of MUS as noted in chapter 2. As research in MUS continues, it will be helpful to make explicit the particular definition of MUS being used to ease application of results across studies.

In response to confounds identified in the previous sections, researchers might screen for and exclude comorbid conditions which might introduce bias. Doing so however could systematically exclude the more severe cases, and those who may potentially benefit the most from research. Several participants in the current study included comments indicating severe emotional and financial strain as a result of IBD which in turn may in turn increase the susceptibility to distress through strained relationships, insecure housing or access to healthcare. This highlights the importance of

including a broad spectrum of participants, and whenever possible, expanding the ways in which we in the field of counseling psychology assess and treat illness distress.

Among the important findings of the current study is the evidence that the CBT model of MUS can be used to organize influences of subjective distress related to disease among people with IBD, a population that has received proportionally little attention. Future research both in MUS and in IBD would benefit from more diverse samples, particularly among racial and ethnic minorities as well as disease specific measures. Comments from participants in the current study highlight the particular need for customization of existing measures to particular populations and "ground-up" measures. A full report of the psychometric properties of the assessment tools used is outside the scope of this study, but would be useful in directing future research.

Additionally, the CBT model of MUS implies the potential of a recursive model in which precipitating factors may be a method of feedback in a more dynamic system than this study assumed. More in-depth statistical analysis using structural equation modeling may shed light on possible mediation or moderation effects.

Conclusion

Overall, the hypothesis that body vigilance would predict health related quality of life and serve as a precipitating factor of illness-related distress as suggested by Deary et al.'s (2007) cognitive behavioral model of medically unexplained symptoms was supported by the analyses. Body vigilance was found to significantly increase the variance explained by the set of variables derived from the theory. In addition, the threestep regression showed support for the theoretical structure of the model by showing that variables which individually were non-significant, when used in combination explained

significant variance. This study provided additional support for the use of inflammatory bowel disease as a model population to study illness distress which exceeds medical explanation. Significant correlations between both personality variables and illness cognitions, and illness distress which were previously documented were observed in this study. Neither measure of personality accounted for significant variance in symptom severity, indicating that dimensions of personality do not explain to MUS among people with IBD. Among illness cognitions, belief in the chronic recurrence, severe consequences and personal control all explain significant variance.

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Appendix A

Electronic Solicitation and Informed Consent

Health-Related Quality of Life in Patients with Inflammatory Bowel Disease.

People with a diagnosis of Crohn's Disease or Ulcerative Colitis and who are 18 years of age or older are invited to participate in a study examining health related quality of life in inflammatory bowel disease. By answering a series of brief questionnaires, you will be contributing to research efforts in understanding how to prevent unnecessary distress and improve subjective quality of life for people living with IBD. In addition to our sincere gratitude, eligible participants will have the option of a \$3 Amazon.com credit, or a \$3 donation to the CCFA on your behalf.

The present study is being conducted as part of a doctoral dissertation in counseling psychology at the University of Memphis. The person in charge of this study is Aron Katz, under the supervision of Douglas Strohmer, Ph.D., chair of the department of Counseling Education Psychology and Research. The purpose of this study is to expand our understanding of the factors that contribute to health-related quality of life in medically complex illnesses by applying the cognitive behavioral model of medically unexplained and under-explained symptoms to people with IBD. Those interested in participating are encouraged to go to: <u>https://www.surveymonkey.com/s/IBDstudy</u> to take the survey online. Questions about the research project may be directed to <u>amkatz@memphis.edu</u> and will be answered as quickly as possible.

WHY ARE YOU BEING INVITED TO TAKE PART IN THIS RESEARCH?

You are being invited to take part in a research study about the factors contributing to symptoms of Inflammatory Bowel Disease. If you volunteer to take part in this study, you will be one of about 155 people to do so nationally.

WHO IS DOING THE STUDY?

The person in charge of this study is Aron Katz of University of Memphis Department of Counseling Psychology. He is being guided in this research by Douglas Strohmer, Ph.D. There may be other people on the research team assisting at different times during the study.

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to test the influence of new variables in the cognitive behavioral model of medically unexplained and under-explained symptoms. This is the prevalent model of psychological treatment and complementary care of people with unexplained or under-explained symptoms. By doing this study, we hope to clarify factors contributing to illness related distress in an attempt to improve patient care and reduce illness related distress in medically unexplained symptoms in general and IBD in particular.

ARE THERE REASONS WHY YOU SHOULD NOT TAKE PART IN THIS STUDY?

People under the age of 18, or over the age of 70 are not eligible for this study, and those who believe they have Crohn's disease or ulcerative colitis but have not been diagnosed by a gastroenterologist should not participate.

WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?

The research procedures will be conducted electronically so you, as the participant may take the following survey at a time and location convenient to you. The total amount of time required to take the full survey should be between 30 and 45 minutes.

WHAT WILL YOU BE ASKED TO DO?

You will be asked a series of questions with instructions at the top of every page. Please read the instructions and answer honestly.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

To the best of our knowledge, the things you will be doing have no more risk of harm than you would experience in everyday life.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

Your willingness to take part in this study may, in the future, help health care providers better understand and treat symptoms of medically unexplained and under-explained symptoms including those associated with inflammatory bowel disease.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any benefits or rights you would normally have if you choose not to volunteer. You can stop at any time during the study and still keep the benefits and rights you had before volunteering.

IF YOU DON'T WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

If you do not want to be in the study, there are no other choices except not to take part in the study.

WHAT WILL IT COST YOU TO PARTICIPATE?

There are no costs associated with taking part in the study.

WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?

You will receive a \$3 credit to Amazon.com or comparable service for taking part in this study.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

We will make every effort to keep private all research records that identify you to the extent allowed by law. Your information will be combined with information from other people taking part in the study. When we write about the study to share it with other researchers, we will write about the combined information we have gathered. You will not be personally identified in these written materials. We may publish the results of this study; however, we will keep your name and other identifying information private.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. Electronic data will be stored on password protected media with identifying information removed.

CAN YOUR TAKING PART IN THE STUDY END EARLY?

If you decide to take part in the study you still have the right to decide at any time that you no longer want to continue. You will not be treated differently if you decide to stop taking part in the study.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS, CONCERNS, OR COMPLAINTS?

Before you decide whether to accept this invitation to take part in the study, please ask any questions that might come to mind now. Later, if you have questions, suggestions, concerns, or complaints about the study, you can contact the investigator, Aron Katz at <u>amkatz@memphis.edu</u>. If you have any questions about your rights as a volunteer in this research, contact the Institutional Review Board staff at the University of Memphis at 901-678-3074. We will give you a signed copy of this consent form to take with you.

Appendix B

Demographic Questionnaire

Please complete the following questions about yourself. This information is private and will remain confidential. If you have any comments, you are welcome to write them in the box provided and they will be taken into consideration. Please mark the appropriate field to answer the questions below:

- 1. I am: Male / Female
- 2. My age is:_____.
- 3. I am (mark those that apply) Caucasian/White African American Asian/Pacific Islander Hispanic/Latino Native American/Alaskan Native Other: _____
- 4. Highest level of education completed: High School / no college High School / some college Associates degree Bachelor's degree Master's degree Doctorate or professional degree
- I have been diagnosed by a gastroenterologist with: Crohn's Disease Ulcerative Colitis Neither
- 6. Approximate date of diagnosis
- 7. Current medications:
- 8. In the past twelve (12) months, how many flares have you experienced?
- 9. In the past two (2) years, how many flares have you experienced?
- 10. In the past year, how many times have you been admitted to the hospital due to your IBD?
- 11. How many surgeries have you had related to your IBD?

Appendix C

Toronto Alexithymia Scale (TAL-20)

Please rate how much you agree with the following statements using the scale provided.

1. I am often confused about what emotion I am feeling Strongly Disagree Strongly Agree 1 2 3 4 5 2. It is difficult for me to find the right words for my feelings Strongly Disagree Strongly Agree 2 3 4 5 1 3. I have physical sensations that even doctors do not understand. Strongly Disagree Strongly Agree 3 4 2 5 4. I am able to describe my feelings easily. Strongly Disagree Strongly Agree 2 3 5 4 5. I prefer to analyze problems rather than just describe them. Strongly Disagree Strongly Agree 1 2 3 4 5 6. When I am upset, I do not know if I am sad, frightened or angry. Strongly Disagree Strongly Agree 4 5 2 3 7. I am often puzzled by sensations in my body. Strongly Disagree Strongly Agree 4 2 3 5 8. I prefer to just let things happen rather than to understand why they turned out that way. Strongly Disagree Strongly Agree 2 3 4 5 9. I have feeling that I cannot quite identify Strongly Disagree Strongly Agree 2 3 4 5 10. Being in touch with emotions is essential. Strongly Disagree Strongly Agree 3 2 4 5 11. I find it hard to describe how I feel about people. Strongly Disagree Strongly Agree

1 2 3 4 5

Strongly Disagree				Strongly Agree
1	2	3	4	5
. I do not know what is goin	g on insid	e me.		
Strongly Disagree				Strongly Agree
1	2	3	4	5
. I often do not know why I	am angry.			
Strongly Disagree				Strongly Agree
1	2	3	4	5
. I prefer talking to people a	bout their	· daily acti	ivities ratl	ner than their feeling
Strongly Disagree				Strongly Agree
1	2	3	4	5
. I prefer to watch "light" e	ntertainm	ent shows	rather the	an psychological dra
Strongly Disagree				Strongly Agree
<u>1</u>	2	3	4	5
. It is difficult for me to reve	eal my inn	ermost fee	elings, eve	n to close friends.
	eal my inn	ermost fee	elings, eve	
. It is difficult for me to reve Strongly Disagree	-			Strongly Agree
Strongly Disagree	eal my inn	ermost fee	elings, eve	
Strongly Disagree	2	3	4	Strongly Agree
Strongly Disagree 1 . I can feel close to someone	2	3	4	Strongly Agree 5
Strongly Disagree 1 . I can feel close to someone, Strongly Disagree	2 , even in n	3 noments of	4 f silence.	Strongly Agree 5 Strongly Agree
Strongly Disagree 1 . I can feel close to someone	2	3	4	Strongly Agree 5
Strongly Disagree 1 . I can feel close to someone, Strongly Disagree	2 , even in n 2	3 noments of 3	4 f silence. 4	Strongly Agree 5 Strongly Agree 5
Strongly Disagree 1 • I can feel close to someone, Strongly Disagree 1	2 , even in n 2	3 noments of 3	4 f silence. 4	Strongly Agree 5 Strongly Agree 5
Strongly Disagree 1 . I can feel close to someone , Strongly Disagree 1 . I find examination of my fe	2 , even in n 2	3 noments of 3	4 f silence. 4	Strongly Agree 5 Strongly Agree 5 nal problems.
Strongly Disagree 1 I can feel close to someone, Strongly Disagree 1 I find examination of my for Strongly Disagree	2 , even in n 2 eelings use	3 noments of 3 eful in solv	4 f silence. 4 ving perso	Strongly Agree 5 Strongly Agree 5 nal problems. Strongly Agree
Strongly Disagree 1 I can feel close to someone, Strongly Disagree 1 I find examination of my for Strongly Disagree	2 , even in n 2 eelings use 2	3 noments of 3 eful in solv 3	4 f silence. 4 ring perso 4	Strongly Agree 5 Strongly Agree 5 nal problems. Strongly Agree 5
Strongly Disagree 1 I can feel close to someone, Strongly Disagree 1 I find examination of my fe Strongly Disagree 1	2 , even in n 2 eelings use 2	3 noments of 3 eful in solv 3	4 f silence. 4 ring perso 4	Strongly Agree 5 Strongly Agree 5 nal problems. Strongly Agree 5

12. People tell me to describe my feelings more.

Difficulty Identifying Feelings: Sum of responses for items:

- 1 _____
- 3 _____ 6 ____
- 6 _____ 7 ____ Total ____
- 9
- 13 _____
- 14 _____

Difficulty Describing Feelings: Sum of responses for items:

- 2 _____ 4* ____ 11 ____ Total ____
- 12
- 17 _____

Externally Oriented Thinking: Sum of responses for items:

* Denotes an item which is reverse scored.

Appendix D

Illness Perception Questionnaire-Revised

YOUR VIEWS ABOUT YOUR IBD

Listed below are a number of symptoms that you may or may not have experienced since your IBD. Please indicate by circling *Yes* or *No*, whether you have experienced any of these symptoms since your IBD, and whether you believe that these symptoms are related to your IBD.

	I have experie	nced this	This s	ymptom is
	symptom since	e my IBD	relate	d to my IBD
Pain	Yes	No	Yes	No
Sore Throat	Yes	No		No
Nausea	Yes	No		No
Breathlessness	Yes	No	Yes	No
Weight Loss	Yes	No	Yes	No
Fatigue	Yes	No		No
Stiff Joints	Yes	No	Yes	No
Sore Eyes	Yes	No	Yes	No
Wheeziness	Yes	No	Yes	No
Headaches	Yes	No		No
Upset Stomach	Yes	No		No
Sleep Difficulties	Yes	No	Yes	No
Dizziness	Yes	No	Yes	No
Loss of Strength	Yes	No		No

We are interested in your own personal views of how you now see your current IBD.

Please indicate how much you agree or disagree with the following statements about your IBD by ticking the appropriate box.

Views about your IBD	Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree
My IBD will last a short time					
My IBD is likely to be permanent rather than Temporary					
My IBD will last for a long time					
This IBD will pass quickly					
I expect to have this IBD for the rest of my life					
My IBD is a serious condition					
My IBD has major consequences on my life					
My IBD does not have much effect on my life					
My IBD strongly affects the way others see me					
My IBD has serious financial consequences					
My IBD causes difficulties for those who are close to me					
There is a lot which I can do to control my symptoms					

What I do can determine whether my IBD gets			
better or worse			
The course of my IBD depends on me			
Nothing I do will affect my IBD			
עמו			
I have the power to influence my IBD			
My actions will have no affect on the outcome of my IBD			
My IBD will improve in time			
There is very little that can be done to improve my IBD			
My treatment will be effective in curing my IBD			
The negative effects of my			
IBD can be prevented (avoided) by my			
treatment			
My treatment can control my IBD			
There is nothing which can help my condition			
The symptoms of my condition are puzzling to me			
My IBD is a mystery to me			
I don't understand my IBD			
My IBD doesn't make any sense to me			
I have a clear picture of understanding of my condition			

The symptoms of my IBD change a great deal from day to day			
My symptoms come and go in cycles			
My IBD is very unpredictable			
I go through cycles in which my IBD gets better and worse.			
I get depressed when I think about my IBD			
When I think about my IBD I get upset			
My IBD makes me feel angry			
My IBD does not worry me			
Having this IBD makes me feel anxious			
My IBD makes me feel afraid			

CAUSES OF MY IBD

We are interested in what you consider may have been the cause of your IBD. As people are very different,

there is no correct answer for this question. We are most interested in your own views about the factors that

caused your IBD rather than what others including doctors or family may have suggested to you. Below is a

list of possible causes for your IBD. Please indicate how much you agree or disagree that they were causes for

you by ticking the appropriate box.

Possible Causes	Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree
Stress or worry					
Hereditary - it runs in my family					
A Germ or virus					
Diet or eating habits					
Chance or bad luck					
Poor medical care in my past					
Pollution in the environment					
My own behavior					
My mental attitude e.g. thinking about life negatively					
Family problems or worries					
Overwork					
My emotional state e.g. feeling down, lonely, anxious, empty					

Ageing			
Alcohol			
Smoking			
Accident or injury			
My personality			
Altered immunity			

In the table below, please list in rank-order the three most important factors that you now believe caused <u>YOUR IBD</u>. You may use any of the items from the box above, or you may have additional ideas of your own.

The most important causes for me:

- 1.

 2.
- 3. _____

Appendix E

Body Vigilance Scale (BVS)

Instructions: This measure is designed to index how sensitive you are to internal bodily sensations such as heart palpitations or dizziness. Fill it out according to how you have felt for the past week.

		person	who pu	lys close				ouny s	ensations.
0 1	2	3	4	5	6	7	8	9	10
Not Like	Me		Mode	rately L	ike Me		I	Extrem	ely Like M
2. I am v	ery sensit	ive to cl	nanges	in my in	iternal bo	odily se	ensatior	ns	
0 1	2	3	4	5	6	7	8	9	10
Not Like	Me		Mode	rately L	ike Me		E	Extrem	ely Like M
	erage, hov s (e.g. swo						cannin	g your	body for
0 1		3	<u>4</u>	<u>5</u>	6	7	8	9	10
Not Like	Me		Mode	rately L	ike Me		F	Extrem	ely Like M
0 1		3	4	5	6	7	8	9	10
-								-	
None	Sligh	t	Ν	Aoderat	te	Su	bstanti	al	Extreme
1 11 4	nolnitotio	ns							
I. Heart	Daiditatio								
 Heart Chest 									
	pain/disco								
2. Chest	pain/disco ness								
 Chest j Numbrie Tinglin 	pain/disco ness	mfort	ring						
 Chest j Numbrie Tinglin 	pain/disco ness ng of breath /	mfort	ring	-					
 Chest j Number Tinglin Short of 	pain/disco ness ng of breath / ess	mfort	ring						
 Chest j Number Tinglin Short of Faintne Vision 	pain/disco ness ng of breath / ess	mfort smothe	ring						
 Chest j Number Tinglin Short of Faintne Vision Feeling 	pain/disco ness ng of breath / ess changes	mfort smothe ality	-						
 Chest j Number Tinglin Short of Faintne Vision Feeling 	pain/disco ness of breath / ess changes gs of unrea g detached	mfort smothe ality	-						
 Chest j Number Tinglin Short of Faintne Vision Feeling Feeling 	pain/disco ness of breath / ess changes gs of unrea g detached ness	mfort smothe ality	-						
 Chest j Number Tinglin Short of Faintne Faintne Vision Feeling Feeling Dizzi Hot f 	pain/disco ness of breath / ess changes gs of unrea g detached ness	mfort smothe ality l from se	elf						
 Chest j Number Tinglin Short of Faintne Vision Feeling Feeling Feeling Dizzi Hot f Sweat Storm 	pain/disco ness ng of breath / ess changes gs of unrea g detached ness lash ting/clama ach upset	mfort smothe ality l from se	elf						
 Chest J Number Tingling Short of Faintne Vision Feeling Feeling Feeling Dizzi Hot f Swear Stom Nauss 	pain/disco ness of breath / ess changes gs of unrea g detached ness lash ting/clamm ach upset ea	mfort smothe ality I from so ny hanc	elf Is						
 Chest J Number Tingling Short of Faintne Faintne Vision Feeling Feeling Feeling Dizzi Hot f Swear Stom Nauss 	pain/disco ness ng of breath / ess changes gs of unrea g detached ness lash ting/clama ach upset	mfort smothe ality I from so ny hanc	elf Is						