

THESIS

A RELIABILITY AND VALIDITY STUDY OF THE PROMIS MEASURES WITH
UNDERSERVED LUNG CANCER AND HEAD-AND-NECK CANCER PATIENTS

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In partial fulfillment of the requirements

For the Degree of Master of Science

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Spring 2019

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ABSTRACT

A RELIABILITY AND VALIDITY STUDY OF THE PROMIS MEASURES WITH UNDERSERVED LUNG CANCER AND HEAD-AND-NECK CANCER PATIENTS

Higher incidence of cancer diagnosis, death, and psychosocial distress are present among traditionally underserved and marginalized populations in the United States. High mortality rates and physical pain are associated with lung cancer and head and neck cancer due to less favorable treatment outcomes and later stage diagnosis that is typical with these types of cancer, and these high rates are observed more often in populations of patients who are identified as underserved. These physical symptoms are coupled with increased psychological distress throughout the course of treatment for underserved cancer patients. Symptoms of anxiety and depression are common and often are associated with poorer treatment adherence and outcomes.

The current study seeks to validate the Patient Reported Outcomes Measurement Information System (PROMIS) measures in a sample of underserved lung cancer and head and neck cancer patients. Data was collected from 92 respondents who were recently diagnosed with lung cancer and/or head and neck cancer and were identified as underserved either by indicating that their household income fell below the Federal poverty line or by indicating that they were uninsured or underinsured. Responses on the PROMIS measures anxiety and depression subscales were correlated with responses on other measures of anxiety and depression in order to establish convergent validity. Predictive validity was determined by exploring the ability of the PROMIS measures to detect the presence of a previously diagnosed mental health concern.

PROMIS anxiety and depression responses were analyzed with responses on a measure of quality of life to establish discriminant validity.

The results of this study imply that the PROMIS measures are valid and reliable in a sample of underserved lung cancer and head and neck cancer patients. In doing so, the study hopes to increase the ease of understanding the psychological distress experienced by underserved lung cancer and head and neck cancer patients and inform future intervention efforts.

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INTRODUCTION

Health disparities in the United States, specifically in relation to underserved populations continue to exist. Health disparities refer to the differences in health outcomes amongst various groups, usually linked to social, economic, or environmental disadvantage (U.S. Department of Health and Human Services [HHS], 2011). For the current study, the term underserved will be utilized to denote those individuals who are socially disadvantaged and have low access to medical resources. Individuals were determined to be underserved if their household income fell below the Federal poverty line and/or if they did not have insurance coverage or identified as underinsured.

Higher rates of cancer diagnosis, death, and psychosocial distress are present among underserved groups in the United States such as those who are underinsured or those who do not speak English as a primary language (Zonderman, Ejiogu, Norbeck, & Evans, 2014). Additionally, low socioeconomic status (SES) has been correlated with high comorbidity of chronic illness in cancer patients and higher rates of death in comparison to higher SES patients with similar cancer diagnosis (Louwman et al., 2010). While cancer is one of the most prevalent diagnoses in the United States, with over 21 distinct types, lung cancer (LC) is the primary cause of cancer death of men and women in the United States (American Cancer Society [ACS], 2015). High rates of death from LC can be attributed to later-stage diagnosis resulting in less treatment options and less favorable outcomes (Siegel, et al., 2012, Ries, et al., 2007). Additionally, many patients with who are diagnosed with LC either present initially with head-and-neck cancer (HNC) or are at risk for developing HNC later in their illness (Center for Disease Control [CDC], 2000). LC and HNC are especially traumatic forms of cancer because their treatments

often lead to long-term physical consequences and/or disfigurement (Frampton, 2001). Surgery, radiation, and chemotherapy are common modes of therapy for cancer and can impact everyday functions such as breathing, speaking, and swallowing, negatively impacting quality of life (Carper, Fleishmen, McGuire, 2004).

Underserved cancer patients may experience higher levels of distress and impact from their illnesses than other patients with greater resources. Barriers in access to quality care include economic, social, and educational barriers; combined with premorbid medical conditions, comorbid mental health conditions, and later stage diagnosis contribute to cancer disparities as well (Bowen, Alfano, McGregor, Kuniyuki, Bernstein, Meeske, & Ganz, 2007; Fagundes, Jones, Vichaya, Lu, Cleeland, 2014). For HNC and LC patients, later stage diagnosis is highly linked to SES and access to insurance (Greenwald et al., 1998). Additionally, for LC patients, low SES was found to be a poorer prognostic factor than late stage diagnosis or lack of treatment options (Ou et al., 2008).

Past research indicates that mental health disparities exist for underserved patients with HNC and LC. Higher rates of depression, anxiety, and overall mental distress have been observed in low SES patients (Fagundes et al., 2014). Due to a lack of resources, systematic marginalization, and other life circumstances, correlates of depression and depressive disorders are likely more common among underserved populations of patients (Miranda, et al., 2003; Ashing-Giwa & Lim, 2009; Chong, Reinschmidt, & Moreno, 2010; Holden, Ramirez, & Gallion, 2014). The social determinants for these disparities have been explored; however, measurement of these underlying psychological mechanisms vary from study to study. A meta-analysis by Luckett et al. (2011) was conducted to determine the psychosocial concerns and psychological morbidity in a sample of cancer patients and survivors with multiethnic and diverse

socioeconomic statuses. The authors found that in the studies reviewed, patients who identified as a cultural minority experienced the most mental health disparities in emotional distress, as well as areas of emotional coping, social functioning and quality of life, compared to other groups included in the study. The authors reviewed 21 articles that included 13 different measures of anxiety, depression, and quality of life. The authors indicated that the heterogeneity of the measures and the information provided from these studies made cross-comparison difficult, creating challenges in drawing conclusions about the experiences of the patients in these studies.

In order to compare mental health conditions among HNC and LC patients who identify as underserved, standard measures must be established first and then validated within these populations. Additionally, some of the measures in Lockett et al. (2011) study did not correlate with diagnostic criteria for either depression or anxiety but simply assessed for symptoms of those disorders. More standard measures that align with diagnostic criteria for psychological disorders would allow for easier detection and diagnosis as well as comparison across groups. The Patient-Reported Outcomes Measurement Information System (PROMIS) was developed by the National Institute of Health as a way to measure diagnostic symptoms and health concepts efficiently and interpretably across chronic health conditions (Cella, et al., 2007). PROMIS includes domains of both mental and physical health and the symptoms included in these measures are consistent with diagnostic criteria for psychological disorders and PROMIS was designed to facilitate easy screening for mental health conditions without including symptomology that is related to the chronic illness that patients experience.

In the current study, a battery of psychological measures were administered to a population of patients newly diagnosed (within a month) with LC and/or HNC who were below

the Federal poverty line, uninsured, or underinsured. Participants were recruited for the study from four hospitals in the Northern Colorado area. Surveys were available in English or in Spanish and were administered online, over the phone, and mailed paper and pencil versions. The set of measures assessed psychological outcomes that effect HNC and LC patients' levels of depression, anxiety, and quality of life. This study provides support for the PROMIS measures validity and reliability in assessing the psychological constructs that impact underserved LC and HNC patients.

Psychological Factors

Some major psychological domains impacted by the diagnosis and treatment of LC and HNC are mood and quality of life. Both depression and anxiety symptoms have been observed to surge during and post treatment for LC and HNC, indicating that this is an area of concern for patients and providers seeking to improve patients quality of life (Duffy, et al., 2007; Alfano & Rowland, 2006; Apollo, Crew, Campbell, Greenlee, Jacobson, Grann, & Hershman, 2007; Ashing-Giwa, Rosales, Lai, Weitzel, 2013). The symptoms of anxiety or depression must cause distress and interfere with normal functioning in order to be considered clinically significant (APA, 2013) and can be measured by self-report or formal diagnosis by mental health professionals. Quality of life (QoL) is a more broad assessment of overall functioning in a variety of life spheres such as physical, social, and emotional functioning. Health Related Quality of Life (HRQoL) examines the same life spheres as they are impacted by health status. QoL is based on self-report and allows researchers a more complete look at the experience of LC and HNC patients when measured as it includes a variety of domains (Levine, Yoo, & Aviv, 2015). Mood and QoL variables fluctuate throughout the journey of a HNC and LC diagnosis and treatment and can be impacted by factors such as type of treatment, stage of cancer, body

image, and clinical symptoms (Hammerlid, Silander, Hornestam, Sullivan, 2001; Zeller, 2006; DiSipio, Hayes, Battistutta, Newman, & Janda, 2011). High levels of distress also come from fear of reoccurrence and high pain and suffering due to treatment (Zeller, 2006). High rates of suicidality have been observed in this population as well, pointing to psychological distress and low coping ability (Sarna, et al., 2002). As such, integrative models like the TMSC which is subjective and individually focused, are needed to understand LC and HNC and their impact on patients due to the distinct nature of each person's experience. Research investigating which psychosocial variables predict adjustment in cancer patients has determined that depression, anxiety, and QoL predicted treatment outcomes consistently and significantly (DiSipio, et al., 2011; Luckett, et al., 2011; Weinberger, Forrester, Markov, Chism, & Kunkel, 2010).

The primary psychological factors in this study were anxiety and depression, and measures assessing patient's self-reported quality of life were also included to establish validity for the measures of interest in this study. Though a wealth of evidence points to the existence of health disparities between populations of underserved cancer patients and higher SES patients (Apollo, et al. 2007; Ashing-Giwa & Lim, 2009; Ashing-Giwa, et al., 2013; Louwman et al., 2008), little research has addressed whether psychological factors further contribute to these health disparities. To explore the rates of psychological distress and its impacts in underserved LC and HNC patients, valid and reliable instruments need to be established. The current study focuses on establishing the validity and reliability of the PROMIS measures in HNC and LC patients who are considered underserved. Establishing these measures as reliable and valid will support research of the extent to which psychological issues are contributing to health disparities within populations of underserved HNC and LC patients.

Depression

Depressive symptoms include feelings of sadness, emptiness, hopelessness, diminished interest or pleasure in activities, disturbances in sleeping and eating patterns, fatigue, and suicidal ideation. (APA, 2013). Studies indicate that half of HNC patients experience depressive symptoms and between 11% and 44% of LC patients show depressive symptoms (Duffy et al., 2007; Alfano & Rowland, 2006). It is challenging to assess actual rates of depression among this population across studies due to discrepancies in measurement (Navari, et al., 2008; Weinberger, et al., 2010) in which some studies use measures that capture clinical depression symptoms while other assess for indicators of distress or dysthymia. Depressive symptoms have been correlated with higher reporting of physical pain and decreased functional wellbeing, as well as increased rates of anxiety (Ell, et al. 2005, Weinberger et al., 2010; Elsheshtawy et al., 2010) which are also common reactions to cancer diagnosis and treatment in general. This overlap makes it challenging to parse out which symptoms are related to clinical depression, which should be treated with therapeutic intervention or medication, and which are appropriate distress levels related to being a cancer patient. There is mixed evidence on whether type of treatment is correlated with depression rates, however a study of patients with early stage breast cancer indicated that the longer term distress a treatment causes, the more depressive symptoms the patient is likely to endorse (Navari, Brenner, & Wilson, 2008). In this study, patients undergoing chemotherapy and antiestrogen treatments had higher rates of depression than those with faster acting interventions. Other studies suggest that education level, social support, and marital status predict depressive symptoms among women with breast cancer (Ell, et al., 2005; Tojal & Costa, 2015; Elsheshtawy et al., 2015).

A recent study found that low SES patients with LC experienced higher levels of distress compared to high SES patients with similar stage diagnosis (Fagundes, Jones, Vichaya, Lu, & Cleeland, 2014). A relationship has been found between barriers to treatment and depressive symptoms in underserved patients (Luckett et al., 2011; Ell, et al., 2005; Chong, Reinschmidt, & Moreno, 2010). Barriers to care, such as lack of understanding of treatment, economic stress, lack of insurance, adverse attitudes towards medicine, and low utilization of medical benefits were highly correlated with depressive symptoms in underserved populations. These barriers can lead to negative outcomes such as noncompliance with treatment, low quality of life, and loss of life (Chong, Reinschmidt, & Moreno, 2010, Ashing-Giwa et al., 2013; Zonderman, et al., 2014). Failure to recognize and treat depression in cancer patients further promote these negative outcomes including decreased quality of life and survival rates (Somerset et al., 2004; Tojal & Costa, 2015) highlighting the importance of accurately measuring and diagnosing clinical depression (Navari et al., 2008).

Measures of Depression

The Hospital Anxiety and Depression Scale (HADS) and the Center for Epidemiological Studies Depression Scale (CES-D) have been the most widely used with cancer patients to assess depression symptoms and have been found to be sensitive to depression, cost effective, and have strong psychometric properties (Mitchell, Meader, & Symonds, 2010; Luckett et al., 2010; Stafford, et al., 2013). The HADS has two subscales, the HADS-D for depression and the HADS-A for anxiety and combined contains fourteen items (Zigmond & Snaith, 1983). Because of its intentioned use in hospital settings, the items on the HADS avoid somatic symptomology to parse out psychological distress beyond physical symptoms. In samples of somatic, psychiatric, and primary care patients the HADS-D was found to be a valid measurement of

depression symptoms using a cutoff score of 8 but is not directly related to DSM diagnosis of Major Depressive Disorder criteria (Bjellen, Dahl, Haug, & Neckelman, 2002).

In cancer patients specifically, the HADS-D has been found to be a useful screening tool, however, the sensitivity for diagnostic purposes is low, between 65-72% sensitivity and concerns about the length of the measure and its specificity have been raised (Mitchell, Meader, & Symonds, 2010). Additionally, questions have been raised regarding the emphasis on anhedonia as an indicator of depression in the HADS and whether or not this is useful for detection of depression (Luckett et al., 2010). The Spanish version of the HADS has been evaluated in medical settings and found to have high internal consistency ($\alpha=0.86$) and high concurrent validity with other measures of depression (Quintana et al., 2003). While the HADS has been widely used, strict and standard cutoffs or percentages for diagnosis have not been established or enforced, leading to lack of clarity in determination of clinical cutoffs (Luckett, et al., 2010).

The CES-D is a 20 item self-report instrument derived from other screening instruments and contains questions regarding key symptoms of depression (Schroevers, Sanderman, Van Sonderen, & Ranchor, 2000). While the items on the CES-D seem to reliably detect symptoms of depression ($\alpha = 0.88-0.91$), the validity of detecting clinically significant depression is questioned due to the measures tendency to capture cancer related somatic distress also (Schroevers, et al., 2000). Additionally, the CES-D requires 20 items to assess only one construct while other measures are shorter and more valid (Luckett et al., 2010). Other researchers have utilized the Zung Self-Rating Depression Scale (SDS or BZSDS for the brief version) which has been found to be useful for screening for depression symptoms but is also not related to DSM criteria (Dugan et al., 1998; Navari et al., 2008).

The Profile of Mood States (POMS) is an assessment used to look at mood states and has been used to assess for depression in cancer patients reliably ($\alpha = 0.63 - 0.91$) however not an accurate tool for diagnosis because it captures transient and fluctuating moods rather than pervasive symptomology (McNair, et al. 1971; Luckett, et al. 2011). The Symptoms Checklist Revised – 90 (SCL-90) is a 90-item checklist that is widely used in clinical settings to screen for psychopathology and psychological symptomology (Derogatis & Unger, 2010). It has been used with cancer patients to screen for both depression and anxiety reliably ($\alpha = .90$) (Fafouti et al., 2010) however is not specific to those constructs as it includes 7 other domains of distress and pathology (Derogatis & Unger, 2010). Similarly, the Patient Health Questionnaire (PHQ) is a screening instrument with sections addressing several domains of psychopathology and contains the PHQ-9, a nine-item section specifically relating to depressive symptoms from DSM criteria that has been found to reliably detect depression symptoms ($\alpha = 0.85$) (Williams, et al. 2002). Both the SCL-90 and the PHQ are available in Spanish and have been found to have good validity and reliability when tested with Spanish speaking participants ($\alpha = 0.7-0.85$ and $\alpha = 0.72$, respectively), though neither have been validated specifically with HNC and LC patients in published research highlighting a gap in the current literature (Huang et al., 2006; Vallejo et al., 2007). Additionally, the PHQ-9 includes items that capture somatic symptoms that may overlap with depression or simply be related to illness, which is problematic for use with cancer patients (Luckett, et al., 2010). The Brief Symptoms Inventory (BSI-18) is widely used in cancer patients to screen for psychological distress and has normative data for cancer patients. It is one of the briefer yet thorough measures for psychological distress and has a three factor structure that has been validated in samples of breast cancer patients and Spanish speaking patients ($\alpha = 0.89$) (Zabora et al., 2001; Reyes-Gibby et al., 2012). The BSI however measures a variety of

psychological subscales other than depression and anxiety and is costly to administer, making it less feasible than other options for screening depression (Lockett et al., 2010).

Overall, the wide variety of measures being used to screen and detect depression make comparison across groups challenging. Beyond the issue of heterogeneity in measuring tools, instruments such as the HADS may not capture the spectrum of depression symptoms or be as sensitive to changes in patient outcomes (Lockett et al., 2011) and have not been validated specifically with LC or HNC patients. The need for standard assessment that reliably and validly capture patient distress in this population may be met by implementing a new set of measures, the Patient Reported Outcomes Measurement Information System or PROMIS. PROMIS was developed for the evaluation of the impact of chronic conditions on HRQoL as reported by the patient in a manner that is consistent, quick, free, and with improved clinical sensitivity (Ader, 2007). Each scale in the PROMIS measures captures a different facet individual's experiences of chronic illness and can be given in short versions for ease of use. PROMIS measures can be used by clinicians to compare across samples of participants due to the regulated structure and are desirable for research outcomes because of this. Under the mental health domain, PROMIS has two scales, one for depression and one for anxiety (National Institute of Health [NIH], 2007). The PROMIS Depression item bank includes diagnostic criteria that differentiates from other psychological issue and excludes somatic symptoms that would be impacted by health status. Additionally, the PROMIS measures were created to be inclusive, meaning that reading level required is lower in attempts to be more widely accessible to populations with lower literacy rates that do not exceed six grade reading levels (NIH, 2007). These measures are available in Spanish and when evaluated for validity and reliability have been found to be adequate tools for measurement of these constructs ($\alpha = 0.90-0.99$).

Anxiety

Beyond depression alone, a strong relationship between depressive episodes and anxiety has been found suggesting overlap between both psychological disorders in people with HNC and LC (Hopwood & Stephens, 2000; Zabora et al., 2001; Burgess, et al., 2005; Stafford, Judd, Gibson, Komiti, Mann, & Quinn, 2013; Hyphantis, Almyroudi, Paika, Degner, Carvalho, & Pavlidis, 2013). Anxiety is characterized by excessive anxiety or worry, apprehensive expectation, restlessness, irritability, muscle tension, sleep disturbance, fatigue, and difficulty concentrating (American Psychological Association, 2013). These symptoms must be interfering with functioning in multiple domains (social, occupational) and cause significant distress to be considered clinically relevant. Assessments of clinical anxiety therefore must include questions regarding symptomology and level of distress in order to determine the presence of clinical anxiety. A distinction can be made between state and trait anxiety, with state anxiety describing more transitory anxiety symptoms and trait anxiety referring to a more stable anxious demeanor (Endler & Kocovski, 2001). Between these two types of anxiety, state anxiety has been found to be positively correlated with QoL in cancer patients and is most amenable to intervention (Hyphantis et al., 2013). While this difference can be relevant for tailoring interventions for patients, most measures do not distinguish between the two.

General anxiety and depression symptoms have been found to be correlated with other negative outcomes beyond QoL such as lack of confidence and lack of intimate relationships indicating the importance of assessment and treatment (Stafford et al., 2013). Rates of anxiety and depression were found to be more related to patient factors (i.e. SES, education, social support, etc.) than factors of treatment or diagnosis (Burgess et al., 2005, Stafford et al., 2013), highlighting the usefulness of the transactional model of stress by way of the inclusion of

psychosocial variables. The prevalence of anxiety symptoms may be slightly lower than depressive symptoms in LC and HNC patients, however the prevalence at which anxiety and depression co-occur is highest, again indicating the importance of assessing for these symptoms (Hammerlid et al., 2001; Hutter, Vogel, Alexander, Baumeister, Helmes, & Bengel, 2013). Moreover, high correlations have been found between symptoms of anxiety and problems in family relationships, pain and fatigue, maladaptive problem solving and conflict management (Lueboonthavatchai, 2007). Untreated, anxiety symptoms may negatively impact the patients' survival rates, emotional functioning, and economic burden, indicating that detection of these symptoms is important for positive outcomes (Stafford et al., 2013; Hutter et al., 2013).

Rates of depression and anxiety in LC and HNC patients appear to be higher for medically underserved populations (HHS, 2001; Aneshensel, 2009; Ell et al., 2005; Lockett et al., 2011; Loi et al., 2013). Mental health disparities in this population reflect higher psychological needs and fewer resources to address these needs fully (Burke, Miller, Saad, Abraham, 2009; Forrest et al., 2013). Studies with Latina cancer patients have found that higher levels of stress and anxiety are related to lower levels of social and emotional support from friends and family, indicating there may be a reciprocal relationship between distress and social support, that more distress early on erodes social support in subsequent months (Alferi et al., 2001; Lopez-Class, Gomez-Duarte, Graves, & Ashing-Giwa, 2012; Gonzalez et al., 2015). Because social support has been researched as a correlate with positive outcomes, it is concerning that social support decreases in samples of underserved patients. Another study indicated that anxiety and other symptoms of psychological distress in underserved cancer patients impacted the psychological distress of their supportive partners to the extent that the rates of symptomology were not significantly different (Montgomery, Gohyea, & Hooeyman,

1985; Nijboer et al., 1998; Segrin & Badger, 2013). These findings highlight the damaging outcomes of mental distress in underserved cancer patients, indicating not only higher rates of distress in this population but higher likelihood of lasting negative outcomes on social support partners, which leads to poorer support for the patient.

Measures of Anxiety

To screen for anxiety symptoms, like depressive symptoms, there is a variety of measures commonly used in the field that vary from global psychological distress measures to anxiety specific tools. As previously mentioned, the HADS, PHQ, SCL-90, and BSI can be used for depressive symptoms as well as anxiety symptoms and have Spanish versions available that have undergone reliability and validity assessments in Spanish speaking populations (Schroevers et al., 2000; Zabora et al., 2001; Williams et al., 2002; Mitchell, Meader, & Symonds, 2010; Derogatis & Unger, 2010; Reyes-Gibby et al., 2012; Stafford et al., 2013). For anxiety specific measures, many options exist as well, although few have been used with underserved cancer patients or validated with that population. The Generalized Anxiety Disorder Screener (GAD-7) is a seven item self-report anxiety questionnaire that assesses generalized anxiety symptoms ($\alpha = 0.89$) but also has been used to detect social anxiety, panic, and post-traumatic stress disorder symptoms in primary care and cancer patients indicating its tendency to capture symptoms beyond general anxiety (Lowe et al., 2008; Brown et al., 2010). A cultural adaptation of the GAD-7 for Spanish speakers is available but has not been used in cancer specific populations (Garcia-Campayo, 2010).

The State Trait Anxiety Inventory (STAI) is a 40-item measure (20 items per subscale) that examines the presence and severity of anxiety symptoms, both transitory and long lasting (Spielberger, 1983). The STAI has been found to have good validity and reliability ($\alpha = 0.86$ -

0.95), though somewhat poor ability to distinguish between anxiety and depression (Spielberger, 1983; Kennedy, Schwab, Morris, & Beldia, 2001; Julian, 2011). The STAI is available in Spanish though has not been used with HNC and LC cancer patients specifically. Additionally, the STAI is designed to distinguish between state and trait anxiety symptoms and does not correlate with diagnostic criteria (Julian, 2011). The Beck Anxiety Inventory (BAI) is a 21 item self-report measure designed to capture symptoms of anxiety distinct from overlapping depression symptoms and has been shown to have high internal consistency reliability ($\alpha = 0.94$) (Leyfer, Ruberg, & Woodruff-Borden, 2006). The BAI is available in Spanish (Magan, Sanz, & Garcia-Vera, 2008) but has not been validated HNC and LC patients and requires 21 items to establish cutoffs for anxiety which may be lengthy when combined with other measures.

These measures of anxiety capture the construct of anxiousness however do not correlate directly with diagnostic criteria for anxiety, have not been used with underserved HNC and LC patients, and may capture information beyond what is necessary for screening for anxiety, creating unnecessary burden by added length. Overall, significant overlap is present in measures looking at anxiety and depression, and as with assessments of depression, a gap in the literature exists for assessment of these symptoms in LC and HNC patients. The use of the PROMIS anxiety subscale addresses fear, anxious misery, hyperarousal, and somatic symptoms that relate to arousal, which are differentiating items between anxiety and threat response (NIH, 2007). These items do not capture behavioral avoidance or other anxious correlates but focus on the fewest number of items needed to detect anxiety (NIH, 2007). In doing so, the PROMIS measures emerge as a more succinct and reliable way of measuring anxiety symptoms ($\alpha = 0.90-0.99$), and as mentioned are standardized and designed to be easily read and understood by

patients. The current study sought to establish validity and reliability of the PROMIS measures for use in this population of LC and HNC patients.

Quality of Life

An important construct discussed in research regarding illness and its impact on the patient is QoL measures. QoL as a construct includes physical, mental, emotional, spiritual, functional and social functioning (Ashing-Giwa & Lim, 2009). Health related quality of life (HRQoL) examines the aforementioned variables as they are impacted by health status, such as chronic illness or disability (US Dept. Health and Human Services, 2014). Cancer patients often experience decreased QoL, which may be related to high prevalence of depression, low socioeconomic status, and persistent life challenges within this population (Reich, Lesur, & Perdrizet-Chevallier, 2008; Ashing-Giwa & Lim, 2009). Compared to other cancer patients, highest pain rates were reported by LC and HNC patients (Sugimura & Yang, 2006). LC and HNC patients also experience high rates of post-treatment distress relating to disfigurement, illness, and mental health distress (Burke, Miller, Saad, & Abraham, 2009). A study by Hutter et al. (2013) investigated the relationship between quality of life and psychosocial variables in first time cancer patients, found that those with low QoL scores reported more depression, anxiety, anger, hostility, and general emotional distress. Social support appears to be a major predictor of depression, anxiety, and is measured by many QoL assessments (Lueboonthavatchai, 2007). Underserved patients tend to have lower reported social support and fewer financial resources, which is predicted to lead to less favorable outcomes (Ashing-Giwa, Tejero, Kim, Padilla, & Hellemann, 2007).

Research on QoL and health related QoL among underserved patients has been somewhat inconsistent, with some researchers indicating significantly lower rates of QoL (Ashing-Giwa et

al., 2007, Janz et al., 2009) and others reporting no significant differences based on medically underserved status (Ganz, Kwan, Stanton, Krupnick, Rowland, Meyerowitz, et al., 2004). More valid and reliable measurement methods may allow this connection to become clearer and highlight areas of improvement for researchers to address.

Measures of Quality of Life

The assessment tools that have been used more widely for QoL include the Functional Assessment of Cancer Therapy (FACT-General, FACT-L for lung cancer specific, FACT-HN for head and neck cancer specific), the Satisfaction with Life Domains Scale for Cancer (SLDS-C), and the World Health Organization Quality of Life Scale (WHOQOL). The FACT-G is a 28 item scale developed for assessment of QoL in patients undergoing general cancer treatment with strong internal reliability ($\alpha = 0.90$) (Cella et al., 1993). The measure includes sections on physical, functional, social, and emotional well-being, as well as a section addressing satisfaction with the treatment relationship with medical providers (Cella et al., 1993). The FACT-G is available in Spanish and has been evaluated for reliability and validity with Uruguayan patients with strong results ($\alpha = 0.78-0.91$) (Dapueto, et al., 2003). The FACT-L was found to be valid and reliable among LC patients ($\alpha = 0.68-0.89$) and FACT-HN to be valid and reliable among HN patients ($\alpha = 0.74- 0.86$). The SLDS-C uses response format of seven smiling faces and seven frowning faces in order to assess QoL in cancer patients (Baker, 2014). It is particularly useful for individuals with low literacy due to its simpler wording and picture-based response format. The WHOQOL-100 consists of 100 items was developed with the goal of cross-cultural relevance in QoL assessment and was been piloted in 15 different cultural settings and 12 different languages, including Spanish ($\alpha= 0.90$) (Group, 1998). Due to its length which lowers practicality of use, there is also a brief version available (WHOQOL-BREF) which includes 26

items, is available in 12 languages, and has comparable psychometric properties as the full version ($r = 0.90$) (Skevington, Lotfy, & O'Connell, 2004).

With the exception of the WHOQOL, other assessments have not been developed with a consideration of cultural relevance or consideration. PROMIS measures of QoL include social functioning, ability to participate in social roles, measures of physical health, and self-efficacy which may capture more culturally salient experiences. As stated, the PROMIS measures were created in an effort to reduce burden of time and mental capacity on the patient, allowing for more effective assessment. The measures mentioned prior to the PROMIS measures may provide a comprehensive picture of the experience of QoL among HNC and LC patients, however for purposes of comparison across studies it would be useful for one concise measure to be used consistently and to be established as valid and reliable in populations of underserved LC and HNC patients specifically. These discrepancies may be related to discrepancies in how QoL is measured and assessed, one meta-analysis stating that no single instrument was used in more than 10% of the studies, indicating the further the need for consistency in assessment tools (Mandelblatt et al., 2004).

PROMIS Measures

PROMIS is the product of an NIH roadmap project to improve patient reported outcomes by developing items that are sensitive to change and inclusive of many domains relevant to the experience of chronic illness. The PROMIS measures have been gaining acceptance and are becoming the clinical standard measurement protocol for research institutions such as the NIH and the Patient Centered Outcomes Research Institute (PCORI). PROMIS measures were developed using Item Response Theory (IRT) and Computerized Adaptive Testing (CAT). These methods were utilized in order to reduce the number of items in the PROMIS scale which were

taken from input of hundreds of experts as well as national and international organizations in the “health” field including physical, mental, and social domains. Questions in each domain were generated and then analyzed via IRT in order to construct unidimensional domains that are mutually exclusive and exhaustive. Items that were redundant or not domain specific were left out of the final item bank, allowing quick and easy testing. To further reduce the difficulty and amount of time for patients, CAT allows for screening questions that reduce domain specific items based on individual’s responses to the screening question (Fries, Bruce, & Cella, 2005). Ongoing and rigorous measures of content and concurrent validity are tested as well to ensure the items are accurate representations of the constructs intended to be measured (Riley, Pilkonis, & Cella, 2011). The PROMIS measures include eight profile domains and fifteen additional domains that were normed on a sample matched demographically to the U.S. Census data from 2007, with 12.5% of participants identifying as Latino/Hispanic (Cella, et al., 2010). The PROMIS measures have been found to have comparable psychometrics as with non-Hispanic white and English speaking populations, indicating their usefulness for this study (Paz, Spritzer, Morales, & Hays, 2013; Hahn et al., 2014; Viligut, et al., 2015). The number of items administered is flexible and adaptable in terms of number of questions and content based on researcher preference and CAT data (National Institutes of Health, 2013). For example, domains that are not applicable to a certain individual can be omitted, allowing for more succinct testing.

The domain of emotional distress includes scales relating to symptoms of both anxiety and depression that correlate to DSM 5 diagnostic criteria, however exclude the somatic symptoms mentioned in DSM 5 (Riley, Pilkonis, & Cella, 2011). This exclusion is based on the overlap between somatic symptoms and other effects of illness as well as the notion that somatic symptoms can both predate and linger beyond affective symptoms and therefore may not capture

pure anxiety or depression states (Riley, Pilkonis, & Cella, 2011; Clarke & Kuhl, 2014). The usefulness of the PROMIS measures in detecting depression and anxiety as defined by DSM 5 is unique compared to many of measures commonly used in assessment in cancer patients.

Current Study

In the current study a battery of assessments measuring depression, anxiety, and QOL were administered to a sample of underserved HNC and LC patients as part of a larger intervention study. Participants were identified as underserved based on their self-reported SES and level of insurance coverage. Results of the survey responses were analyzed for internal consistency reliability, predictive validity, as well as convergent and divergent validity. Many assessment tools have been used to assess these concepts in other patients that do not correlate with clinical indices of these disorders and symptoms. For proper diagnosis and care, standard measurement across agencies and domains is needed. To better understand the mental health disparity gap in LC and HNC patients and collect data that is useful, it is necessary to establish whether valid and reliable measures of these factors exist.

Depression, anxiety, and quality of life are important mental health indicators of the experience of underserved HNC and LC patients as discussed and must be measured in ways that create low level burden for patients and provide information that is clinically valid and useful. As evidenced by the literature, several measures are commonly used to assess these constructs but are not consistent used across studies. To establish a more standard measure of these mental health constructs in LC and HNC patients the PROMIS measures are proposed as better and more efficient means to assess global, physical, mental, and social health in this population.

METHODS

Procedures

Participants were consented to the study as part of a larger longitudinal study examining psychological distress interventions in HNC and LC patients. All participants were recruited at one of four hospitals in Northern Colorado (Denver Health Medical Center, Saint Mary's Medical Center, Saint Joseph Hospital, and National Jewish Health) and eligibility for participation was determined by baseline assessment of eligibility criteria. Inclusion criteria included those who were: over 18 years old, English or Spanish speaking, low income (below the Federal poverty line) or uninsured/underinsured, and newly diagnosed (within one month from first oncology appointment). Participants were either emailed links to the survey to complete the surveys online or mailed paper versions that were then mailed in and entered by the research team, depending on patient preference. The survey included demographic information (Appendix A and Appendix B), the PROMIS measures, the HADS, the FACT-L and FACT-HN (Appendices C-L) in addition to a measure of perceived stress and a measure of coping skills that were not analyzed as part of the current study. Each participant received a \$25 gift card following completion of the survey.

All procedures and methods employed throughout the study were approved through the Colorado Multiple Institutional Review Board (Protocol # 16-2621) on March 17, 2017 and given continuing review approval on March 6, 2018. Patient information was entered into a password protected database and all study materials were kept in a secure and locked facility in compliance with the Health Insurance Portability and Accountability Act (HIPAA) standards.

Participants

There were 93 LC and/or HNC patients who were consented to participate in the study. One participant did not complete the survey past the demographic information, therefore 92 participants completed the survey. Of those 92, there were 64% who self-identified as males and 36% who self-identified as females, ranging in age from 43-87 years of age ($M = 65.93$, $SD = 9.34$). Regarding primary racial background 84% of the participants self-identified as White, 6% as Black, 1% as Asian and 7% declined to answer. When asked to self-identify their primary ethnic background, 80% of participants identified as non-Hispanic and 19% identified as Hispanic. Of the participants, 88 individuals indicated English as their preferred language and 4 indicated Spanish as their preferred language; participants were administered surveys in their preferred language (See Table 1 for demographic statistics).

Diagnoses of women with these cancers is on the rise while male rates of diagnosis have stabilized in underserved patients, suggesting that this sample may not be representative of underserved HNC and LC patients in the larger population (Saba et al. 2011). Additionally, underserved and underinsured patients nationally tend to be more ethnically and racially diverse than what was collected for this sample (Anderson, et al. 2004; Ward, et al. 2004). The demographic information of this sample is not typical of underserved HNC and LC patients from other studies conducted on this population. Furthermore, the hospitals in this study were largely in urban areas and likely did not reach participants living and receiving treatment in more rural areas, impacting the representativeness of the sample.

Power Analysis

An observed power analysis was conducted using the software package GPower (Faul & Erfelder, 1992) for the most complex analysis, logistical regression, to be performed in this study

and determined that a minimum of 82 participants were needed to achieve 80% power (critical $z = 1.644$). The post-hoc power analysis was conducted and demonstrated that with $N=92$ (one-tailed z -test, odds ratio of 1.2, $p < .05$), observed power was equal to 0.85. Based on this analysis, enough participants were part of the study to find significance in both the correlational analyses and logistic regression.

Measures

PROMIS. PROMIS was developed by a National Institute of Health roadmap initiative to provide a more streamlined evaluation of impact of chronic conditions on HRQoL. PROMIS measures have been normed and validated using a sample of individuals with a variety of self-reported chronic illness via YouGovPoll. They include measures of global health, physical health, mental health, and social health and both short and long versions of each domain. The items require low literacy levels, leading to more accessibility and applicability to populations with lower education levels. PROMIS measures correlate with clinical domains of psychological disorders from the DSM 5. The PROMIS system is considered a mature instrument because of continued modification relating to studies in diverse clinical populations. (Fries, Bruce, & Cella, 2005). PROMIS measures are scored on a T-score metric ($\mu = 50$, $SD = 10$) and is referenced to the US general population (2007 Census).

The NIH has also developed the PROMIS-Ca that includes additional items related to physical functioning and is designed to be used with any kind of cancer. The PROMIS-Ca measure has different calibrations from the standard adult measure and is not available in a short form yet (NIH, 2015). PROMIS measures provide a variety of form lengths to choose from including the full item banks (between 50 and 55 items per subscale), broad profile assessments (57 items, 43 items, or 29 items each) and short form options (ranging 4-8 items per subscale).

The profiles provide a dimensional picture of HRQoL and include the subscales for depression and anxiety (NIH, 2007). For the purpose of this study, the 30-item depression and the 23-item anxiety subscale will be administered, in an effort to capture the full picture of psychological distress while also reducing participant burden. All PROMIS scales have been translated to Spanish, except the sexual functioning domain. PROMIS measures have been used with samples of patients with cancer (Cella, et al., 2014; Paz, Spritzer, Morales, & Hays, 2013; Badger, Heitkemper, Lee, & Bruner, 2014; Hahn, et al., 2014; NIH, 2015; Viligut, et al., 2015), however they have not been used specifically with underserved LC and HNC patients in published research for evaluations of validity and reliability. The PROMIS Anxiety displayed good convergent validity with a historical assessment of anxiety, the Mood and Symptom Anxiety Questionnaire ($\alpha = .81$) and PROMIS Depression exhibited good convergent validity as well with the CESD ($\alpha = .84$) (NIH, 2013). The ability of the PROMIS measures to predict presence of anxiety and depression was assessed by determining the ability of the PROMIS measures to predict group membership into those participants who identified as having been previously diagnosed with either an anxiety disorder or depressive disorder prior to participation in the study.

HADS. To assess for convergent validity of the PROMIS measures, the Hospital Anxiety and Depression Scale (HADS) was given to participants and was expected to be highly correlated with the PROMIS measures for depression and anxiety. The Hospital Anxiety and Depression Scale is a 14-item questionnaire broken up into two subscales, the HADS-A for anxiety and the HADS-D for depression. Responses are self-scored from 0-3, 3 indicating more severe symptoms. The HADS has been found to have high internal consistency and sensitivity to these constructs in both chronic illness patients and cancer patients. HADS has high convergent

validity with longer and more established scales such as the BAI, BDI, and SCL-90 ($\alpha = .6-.8$). On average, the HADS takes patients between 2-5 minutes. (Bjelland, Dahl, Haug, & Neckelmann, 2002). The HADS and PROMIS measures have been correlated (Yost, Eton, Garcia, & Cella 2011) with results indicating high levels of relatedness, however the two measures have not yet been compared in samples of LC and HNC patients.

FACT. In addition to the HADS, the FACT-L, and FACT-HN was also administered to participants and expected to differ from scores on the PROMIS, to determine divergent validity. The FACT assesses health related quality of life measures specific to cancer patients which should differ from constructs of anxiety and depression, captured by PROMIS. The assessment is a valid and reliable 48-item health related quality-of-life questionnaire with high internal consistency ($\alpha = .90$) and high levels of test-retest reliability, as well as convergent and divergent validity (Brady, Cella, Mo, Bonomi, Tulsky, Lloyd, & Shiimoto, 1997). Domains assessed are physical, functional, social and family, and emotional well-being (Daputo, et al., 2003; Ell et al., 2005). The FACT-L and FACT-HN include the FACT-G and 20 items addressing the individual concerns of the specific cancer, with FACT-L retaining 8 additional items and FACT-HN retaining 12 additional items.

RESULTS

All data was examined for missing cases. Data that reflected patterns of error, for example skipping one of the measures entirely or not reporting cancer status, was discarded so 1 case was removed. Analyses began with assessing the reliability via Cronbach's alpha of the PROMIS, FACT, and HADS measures. Reliability for the PROMIS scale were assessed separately for each subscale, the 30-item depression subscale and 23-item anxiety subscale were both found to have acceptable reliability (see Table 2 for all reliability statistics). The 35-item FACT-L, 39-item FACT-HN and 14-item HADS scales. Histograms were run on the PROMIS, FACT, and HADS and revealed a pattern of positive skew. All three measures were somewhat positively skewed but determined to be within the acceptable limits as demonstrated by skew and kurtosis being inside the limits of -1 to 1 (see Table 2).

Although a confirmatory factor analysis (CFA) was proposed to confirm the factor structure of the PROMIS measure with this population, the sample size of the current study did not meet the necessary minimum of participants required to run this analysis. It is recommended that at least 200 participants (Hoelter, 1983) or a minimum of 5-10 participants per item (Floyd and Whidaman, 1995), neither of which were met. Analysis that require less participants were used to further explore the validity of the PROMIS measure.

Reliability. Analysis using Cronbach's Alpha Test was used to test the internal consistency reliability of the three scales included in the study. Reliability for the total PROMIS scale, as well for the depression and anxiety subscales separately was found to be highly reliable ($\alpha = 0.97$, $\alpha = 0.97$, and $\alpha = 0.98$ respectively). Reliability for the HADS ($\alpha = 0.88$) and FACT ($\alpha = 0.72$) scales were also found to be acceptable (DeVellis, 2012).

Validity. Convergent validity was determined by computing Pearson's product moment correlation coefficients to understand the strength and relationship between the PROMIS and HADS. Table 3 shows the means, standard deviations and intercorrelations for all scales. Specifically, strong positive correlations between the overall PROMIS score and overall HADS score ($r= 0.76, p<.01$), between PROMIS anxiety subscale and HADS anxiety subscale ($r=0.78, p<.01$), and between the PROMIS depression subscale and HADS depression subscale ($r=0.59, p<.01$). This finding demonstrates that PROMIS scores and HADS scores are capturing the same constructs of depression and anxiety within this sample of participants. Discriminant validity was also investigated using Pearson's product moment correlation coefficients. Non-significant negative correlations were observed between the overall PROMIS score and the FACT-HN ($r=-0.21, p= 0.4$) and the FACT-L ($r=-0.26, p= 0.19$) indicating that the PROMIS measures and FACT-HN and FACT-L were possibly not capturing the same construct (See Table 4).

In order to test predictive validity of the PROMIS assessment in this population, logistic regression analysis methods was used to investigate whether self-reported psychological diagnosis can be predicted by scores on the PROMIS by regressing group membership (dichotomous yes/no responses to the question "Have you been diagnosed with a depressive disorder?" or "Have you been diagnosed with an anxiety disorder?") on PROMIS depression anxiety scores subscale scores. The dependent variable of psychological disorder was coded such that 0= no anxiety disorder diagnosed previously and 1= previous diagnosis of an anxiety disorder for one item in the regression and 0 = no depressive disorder diagnosed previously and 1 = previous diagnosis of a depressive disorder for the second item in the analysis. Assumptions of logistic regression were tested for the analyses. No evidence of multicollinearity was found (variance inflation factor, tolerance values, and correlations between variables all fell in the

acceptable range) and assumptions of independence of errors and linearity were also met (Field, 2009).

A test of the PROMIS depression model against a constant only model was statistically significant, indicating that the PROMIS depression items as a set reliably distinguished between those who were previously diagnosed with a depressive disorder and those who were not (chi square = 19.550, $p < .001$, $df = 1$). Nagelkerke's R^2 of .334 indicated a small relationship between predictor and grouping. Prediction success overall was 89.1% and the Wald criterion demonstrated that the PROMIS depression scale is a small but significant contribution to prediction of depressive disorder ($p < .001$). Exp(B) value indicates that when PROMIS depression score is raised by one unit (one point on the scale) the odds ratio is 1.12 times as large (See Tables 5 and 6).

Similarly, a test of the PROMIS anxiety model against a constant only model was statistically significant, indicating that the PROMIS anxiety items as a set reliably distinguished between those who were previously diagnosed with an anxiety disorder and those who were not (chi square = 4.775, $p < .05$, $df = 1$). Nagelkerke's R^2 of .113 indicated a very small relationship between predictor and grouping. Prediction success overall was 89.1% and the Wald criterion demonstrated that the PROMIS anxiety scale is a small but significant contribution to prediction of depressive disorder ($p < .001$). Exp(B) value indicates that when PROMIS anxiety score is raised by one unit (one point on the scale) the odds ratio is 0.95 times as large.

DISCUSSION

The purpose of this project was to examine the reliability and validity of the PROMIS measures in a sample of underserved, low-income, under-insured head, neck, and lung cancer patients. The PROMIS measures were found to be valid and reliable with the study's sample of LC and HNC patients from four hospitals in Colorado. More specifically, when compared to the HADS, the PROMIS measures demonstrated high convergent validity and adequately captured the domains of depression and anxiety symptoms in this sample. When compared to the FACT, the PROMIS scores were inversely related, indicating that the two measures are likely capturing distinct constructs thus demonstrating discriminant validity for the PROMIS measures. The relationship between FACT and PROMIS measures was nonsignificant, possibly due to sample size of those participants who completed each version (lung or head and neck versions were split into two groups), reducing the overall sample size for comparison.

PROMIS Measures

To understand how PROMIS measures capture the experience of LC and HNC patients, measures from different domains related to psychological outcomes were included in the study. The investigation revealed that the PROMIS measures were positively correlated with scores on the HADS, which was anticipated based on the literature indicating the overlap in content of the scales. Depression and anxiety subscales from the PROMIS were strongly and positively correlated with the respective subscales on the HADS, and overall scores from both measures were also positively correlated. Discriminant validity was demonstrated by exploring the relationship between the PROMIS measures and a health-related quality of life measure, the FACT. Specific batteries from the FACT scales measure for head and neck cancer and lung

cancer were included in the study to capture the unique experience of these patients. The relationship between the PROMIS and the FACT scores was negative and nonsignificant, supporting the hypothesis that the measures are capturing separate constructs and measuring distinct aspects of the impacts of cancer.

Although validity and reliability for the PROMIS measures was established using the measures included, not enough participants utilized the Spanish version of the survey to make comparisons regarding translation. Conclusions could have been drawn about the Spanish translation of PROMIS measures for LC and HNC patients had the sample been more variable in language proficiency. The PROMIS measures also included several subscales that assessed cancer related distress and quality of life domains that could have been added and compared to existing measures of HRQoL. Though inclusion of these additional subscales would increase the number of items administered, it may have provided a broader picture of the distress that is experienced by LC and HNC patients. More information on the distinct aspects of distress endured by patients could have better informed interventions and treatment as part of the larger intervention study. The depression and anxiety subscales, however, did prove to be valid measures of psychological distress in the sample of underserved LC and HNC patients surveyed in this study.

To understand the power of the PROMIS measures to predict psychological distress, a logistic regression was conducted. Findings indicated that the PROMIS measures increase the probability of predicting the presence of a psychological disorder in the participants. Based on the literature, the PROMIS measures are expected to significantly predict psychological distress. However, items used in the logistic regression for the current study were chosen based on the inclusion in the larger intervention study that this data was extracted from. The demographic

question in the survey asked participants whether they had ever previously been diagnosed with a depressive or anxious disorder. Because this information was taken from the baseline survey in the study, the implication was that this diagnosis would have taken place prior to cancer diagnosis and treatment. PROMIS measures are designed to capture the distress related to the cancer experience and therefore are not directly addressing the question posed in the demographic question section. A change in methodology such as including a second time point at which participants are asked whether they meet criteria for an anxious or depressive disorder post-diagnosis and treatment would better demonstrate the predictive validity of the PROMIS measure and possibly lead to a more significant effect in the regression equation.

Additional analyses were proposed to confirm that the factor structure found in the PROMIS measures when administered to the normed sample matched the factor structure observed within responses of the current sample. However, these analyses require a higher number of participants than what was recruited at the time of analysis and consequently, the confirmatory factor analysis was not conducted.

Implications and Contributions

Through this study, PROMIS anxiety and depression subscales were determined to be valid and reliable measures of psychological distress in a sample of underserved LC and HNC patients. The PROMIS measures were designed to be straight forward, domain specific, and correlated to DSM-5 criteria of diagnosis in both English and Spanish versions for cancer patients in general (Riley, Pilkonis, & Cella, 2011). The current study is the first to utilize these measures with this specific population of LC and HNC who do not receive medical access at the same rates as more socioeconomically affluent patients. The study adds to the utility of the

PROMIS measures with diverse groups of patients and demonstrates its efficacy in detecting patients in mental distress.

Interventions that target mental distress and symptomology in cancer patients are increasing in number as understanding of the relationship between distress and health outcomes continues to grow (Lopez-Class, Gomez-Duarte, Graves, & Ashing-Giwa, 2012; Gonzalez et al., 2015). Identification of patients who are struggling with psychological symptoms can lead to early mental health interventions, reducing negative outcomes such as increase in symptom severity, distress, and mortality rates. As part of a larger intervention study, the current project sought to inform the interventions used later with participants by licensed mental health professionals. By establishing PROMIS measures as valid and reliable, the current study may contribute to the successes of the overall intervention designed to reduce the mental distress experienced by underserved and underinsured HNC and LC patients.

Future Directions

Future studies should seek to direct more attention to recruitment and retention efforts to ensure that eligible participants are able and comfortable contributing to the knowledge base of this field. Gathering information from groups who are traditionally underserved can often present challenges that lead to exclusion from larger research studies (Shavers, Lynch, & Burmeister, 2002). Reasons for this lack of inclusion have been reported to include: lack of patient awareness of the benefit of participation, poor patient well-being, poor physician/researcher and patient relationships, lack of institutional support, low literacy of patients, and lack of understanding of the nature of the project that leads to fear or concern about safety and/or confidentiality (Sygna, Johansen, & Ruland, 2015; Bower, et al. 2014; Denicoff, et al. 2013). Studies on recruitment and retention of participants in cancer clinical trials also suggest increased communication about the

study and ways participation can help others, increased advertising, an emphasis on development of culturally sensitive study materials, and recruitment of physicians and research team members who reflect patient population of underserved and minority identities (Sygna et al., 2015; Bower, et al. 2014; Denicoff, et al. 2013). Future studies should seek to focus on these areas because without research to inform treatment interventions, the concerns of underserved patients will not get addressed, furthering already existing health disparities. Continued efforts are needed to reach out to and treat those patients who are traditionally underserved and reduce the lack of access to quality mental health care and intervention.

TABLES

Table 1
Sample Demographic Characteristics

Characteristic	N	Mean or %	Std. Deviation
Female	32	34.4%	-
Male	60	64.5%	-
Age	93	65.93	9.34
Hispanic	18	19.4%	-
Non-Hispanic	75	80.6%	-
Primarily English Speaker	89	95.7%	-
Employed	22	23.7%	-
Retired	50	53.8%	-
Income less than \$4,000 monthly	58	63%	-
Income less than \$8,000 monthly	13	15.2%	-
More than \$12,000 monthly	12	13.1%	-
High school graduate	42	46.2%	-
Some college	27	29.1%	-
College graduate	8	8.6%	-
Post-graduate	14	15.1%	-
Private Insurance	37	40.2%	-
Medicare	55	59.8%	-
Medicaid	24	26.1%	-
VA Insurance	13	14.1%	-

Table 2
Reliability Statistics for PROMIS Scores

Measure	Cronbach's Alpha	Skewness	Kurtosis
PROMISdep	.971	.859	-.436
PROMISanx	.968	.752	-.207
PROMIStot	.984	.687	-.627

Table 3

Pearson Correlations for Determining PROMIS Convergent Validity

	PROMISdep	PROMISanx	PROMIStot	HADSdep
PROMISdep	1	.812	.946	.593
PROMISanx	.812	1	.957	.508
PROMIStot	.946	.957	1	.576
HADSdep	.593	.508	.576	1
HADSanx	.648	.778	.754	.567
HADStotal	.701	.733	.755	.872

Table 4

Pearson Correlations for Determining PROMIS Discriminant Validity

	PROMIS _{tot}	PROMIS _{anx}	PROMIS _{dep}	FACTL	FACTHN
PROMIS _{tot}	1	.957	.946	-.262	-.212
PROMIS _{anx}	.957	1	.812	-.181	-.095
PROMIS _{dep}	.946	.812	1	-.313	-.316
FACTL	-.262	-.181	-.313	1	-
FACTHN	-.212	-.095	-.316	-	1

Table 5

Do scores on the PROMIS predict patient-reported diagnosis of depressive disorders? Logistical Regression Analyses

Source	<i>B</i>	SE <i>B</i>	Wald χ^2	<i>p</i>	OR
PROMIStotal	.117	.031	14.177	.000	1.124

Note. OR= odds ratio.

Table 6

Do scores on the PROMIS predict patient-reported diagnosis of anxiety disorders? Logistical Regression Analyses

Source	<i>B</i>	SE <i>B</i>	Wald χ^2	<i>p</i>	OR
PROMIS total	.066	.031	4.547	.033	1.068

Note. OR= odds ratio.

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APPENDICES

Appendix A

Demographic Survey

Section I: Personal Information

First Name:

Last Name:

What is today's date?

What hospital are you associated with?

- Denver Health
- St. Joe's
- St. Mary's
- National Jewish

How are you completing this survey?

- Online
- Paper and pencil
- Phone call
- Onsite

What is your age in years?

What is your gender?

- Male
- Female
- Other

Are you currently pregnant?

What is your primary racial/ethnic background?

- Hispanic/White
- Hispanic/Black
- Hispanic/Asian
- Hispanic/Other
- Non-Hispanic/White
- Non-Hispanic/Black
- Non-Hispanic/Asian
- Non-Hispanic/Other

For "other", what do you consider your primary ethnic background to be?

Do you speak:

- Only Spanish
- Spanish better than English
- Both Spanish and English equally well
- English better than Spanish
- Only English

Do you read:

- Only Spanish
- Spanish better than English
- Both Spanish and English equally well

- English better than Spanish
- Only English

What is your current marital status?

- Never married
- Married
- Divorced
- Separated
- Living partner
- Widowed

Are you now employed?

- Yes
- No

Are you retired?

- Yes
- No

For health insurance, do you have (check all that apply):

- Medicare
- Medicaid
- VA coverage
- Private Insurance

Pick the category that best describes where your monthly income after taxes falls:

- Less than \$4000
- Less than \$5400
- Less than \$7100
- Less than \$8100
- Less than \$9500
- Less than \$10900
- Less than \$12300
- Less than \$13700
- Less than \$13701

How many people in your household (including you) depend on your monthly income?

What is the highest level of education you have completed?

Section II: Cancer Diagnosis and Treatment Information

Which is your primary cancer diagnosis?

- Lung cancer
- Head and neck cancer
- Other

For “other”, please list what your primary cancer diagnosis is, or indicate if “cancer of Unknown Primary”

What is your secondary cancer diagnosis?

- Lung cancer
- Head and neck cancer
- Other
- Not applicable

When were you first diagnosed with lung and/or head and neck cancer (pathologic tissue diagnosis)?

- MM-DD-YYYY

Does your treatment plan involve surgery?

- Yes
- No
- Pending

Does your treatment plan involve chemotherapy?

- Yes
- No
- Pending

Does your treatment plan involve radiation therapy?

- Yes
- No
- Pending

Does your treatment plan involve biological therapy?

- Yes
- No
- Pending

Have you already started your first cancer treatment?

- Yes
- No
- Pending

When did you start your first cancer treatment (any treatment: surgery, chemotherapy, radiation)?

- MM-DD-YYYY

Are you currently participating in a treatment or related cancer clinical trial?

- Yes
- No
- Pending

Section III: Behavioral Health Information

Have you ever been diagnosed with a cognitive impairment such as (check all that apply):

- Alzheimer's or Dementia
- Traumatic Brain Injury
- Other
- Never

For "other" please describe

Have you ever been diagnosed with any of the following? (Check all that apply)

- Schizophrenia or psychotic disorder
- Personality disorder (e.g. Borderline)
- Intellectual disability (e.g. retardation)
- Bipolar or related disorder
- Depressive disorder
- Anxiety disorder

- Trauma stressor disorder (e.g. PTSD)
- Substance or addictive disorder
- Other mental health disorder
- Never

For “other”, please list which mental disorders

Have you ever taken a prescription drug (such as anti-depressants) for a mental condition in the past month?

- Yes
- No

Have you actively participated in counseling or therapy sessions for behavioral reasons in the past month?

- Yes
- No

Have you sought social support services or resources related to your cancer diagnosis in the past month?

- Yes, a cancer support group (in person or online)
- Yes, information resources (e.g. websites, cancer associations)
- Other
- None

How many times did you have six or more drinks on one occasion in the past month?

- Never
- Once a month
- 2-4 times a month
- 2-3 times a week
- 4 or more times a week

How often did you use “abusable” (e.g. prescriptions) or illegal drugs (e.g. cocaine) in the past month?

- Never
- Once a month
- 2-4 times a month
- 2-3 times a week
- 4 or more times a week

If you have smoked in the past month, how many cigarettes have you consumed a day?

- Have not smoked in the past month
- 1-10 cigarettes
- 11-19 cigarettes
- 20 or more cigarettes

In the past month, did you smoke or use marijuana?

- Yes, recreationally
- Yes, for medical reasons
- Yes, for both medical reasons and recreationally
- No

Have you been homeless (i.e. no housing to dwell) for the past 30 days?

- Yes
- No

Are you currently serving time in incarceration, a detainee awaiting trial, or on probationary status?

- Yes
- No

Have you thought about hurting yourself or ending your life in the past month?

- Yes
- No

Appendix B

Demographic Survey

Spanish Version

Seccion I: Informacion Personal

Primer nombre:

Apellido:

¿Cual es la fecha de hoy?

¿Con cual hospital esta asociado?

- Denver Health
- St. Joe's
- St. Mary's

¿Como esta llenando este cuestionario?

- En linea (correo electronico, telefono movil)
- En la casa/papel y lapiz
- Llamada por telefono
- En el hospital

¿Cual es sue dad?

¿Cual es su sexo?

- Masculino
- Femenino
- Otro

¿Esta actualmente embarazada?

- Si
- No

¿Cual considera que es su origen etnico y su raza?

- Hispano/Blanca
- Hispano/Negra
- Hispano/Asiatica
- Hispano/Otro
- No-Hispano/Blanca
- No-Hispano/Negra
- No-Hispano/Asiatica
- No-Hispano/Otro

Para 'Otro', ¿cual consideras su perimer origen etnico?

¿Que idioma habla?

- Solo espanol
- Espanol major que ingles
- Tanto ingles como espanol
- Ingles major que espanol
- Solo ingles

¿Usted sabe leer?

- Solo espanol
- Espanol major que ingles
- Tanto ingles como espanol
- Ingles major que espanol

- Solo ingles

¿Cual es su estado civil actual?

- Nunca casado
- Casado
- Divorciado
- Separado
- En pareja
- Viudo/a

¿Esta usted actualmente trabajando?

- Si
- No

Para el Seguro de Sauld o medico, ¿tiene usted:

- Medicare
- Medicaid
- Cobertura del VA
- Seguro privado

¿Que categoria se aproxima a su ingreso (despues de los impuestos, el total en cash) por mes?

- Menos del \$4000
- Menos del \$5400
- Menos del \$7100
- Menos del \$8100
- Menos del \$9500
- Menos del \$10900
- Menos del \$12300
- Menos del \$13700
- Mas de \$13701

¿Cuantas personas (usted incluido) en su hogar dependen de su ingreso mensual?

- 1
- 2
- 3
- 4
- 5
- 6
- 7
- 8 o mas

Circle el nivel mas alto de educacion que has completado:

- Grado de Escuela-1
- Grado de Escuela-2
- Grado de Escuela-3
- Grado de Escuela-4
- Grado de Escuela-5
- Grado de Escuela-6
- Grado de Escuela-7
- Grado de Escuela-8
- High school/secundaria-9
- High school/secundaria-10

- High school/secundaria-11
- High school/secundaria-12
- College/universidad-1
- College/universidad-2
- College/universidad-3
- College/universidad-4
- Años de educación después de la graduación universitaria-5
- Años de educación después de la graduación universitaria-6
- Años de educación después de la graduación universitaria-7
- Años de educación después de la graduación universitaria-8+

Sección II: Diagnóstico y tratamiento del cáncer

¿Cuál es su diagnóstico de cáncer primario?

- Cáncer de pulmón
- Cáncer de cabeza y cuello
- Otro tipo de cáncer

Para ‘Otro tipo de cáncer’, por favor liste cuál fue su diagnóstico de cáncer primario o indique “Cáncer de Origen Primario Desconocido”.

¿Cuál es su diagnóstico de cáncer secundario?

- Cáncer de pulmón
- Cáncer de cabeza y cuello
- Otro tipo de cáncer
- No aplica

Para ‘Otro tipo de cáncer’, por favor liste cuál fue su diagnóstico de cáncer secundario o indique “Cáncer de Origen Primario Desconocido”

¿Cuándo fue diagnosticado por primera vez con su diagnóstico primario (fecha cuando recibió el diagnóstico de tejido patológico o biopsia)?

¿Su plan de tratamiento incluye cirugía?

- Sí
- No
- Pendiente

¿Su plan de tratamiento incluye quimioterapia?

- Sí
- No
- Pendiente

¿Su plan de tratamiento incluye radiación?

- Sí
- No
- Pendiente

¿Su plan de tratamiento incluye terapia biológica?

- Sí
- No
- Pendiente

¿Ya empezó su primer tratamiento de cáncer?

- Sí
- No

- Pendiente

¿Cuándo comenzo su primer tratamiento contra el cancer (cualquiera de los tratamientos de cirugía, quimioterapia, o radiación)?

¿Actualmente esta participando en un tratamiento para cancer o en un “ensayo clínico” (clinical trial)?

- Si
- No
- Pendiente

Sección III: Información sobre la salud del comportamiento del paciente

¿Le han diagnosticado un deterioro cognitivo como

- Alzheimer o Demencia
- Lesión cerebral traumática
- Otro
- Nunca

Para ‘otro’ por favor describalo

¿Alguna vez le han diagnosticado alguna de las siguientes enfermedades?

- Esquizofrenia o Trastorno Psicótico
- Trastorno de la personalidad (límite o “borderline”)
- Discapacidad intelectual (retardo mental)
- Trastorno bipolar u otro relacionado
- Trastorno depresivo
- Trastorno de ansiedad
- Trastorno de estrés post-traumático (PTSD)
- Sustancias o Adicciones
- Otros Trastornos Mentales
- Nunca

Para ‘otros trastornos mentales’ por favor liste cuales trastornos

¿Ha tomado medicamentos recetados (como antidepresivos) por una condición mental en el último mes?

En caso que si, ¿que tipo de medicación ha tomado?

¿Ha participado activamente en consejería o terapia por razones de comorbilidad en el último mes?

¿Ha buscado servicios de apoyo o recursos relacionados con su diagnóstico de cancer en el último mes?

¿Cuántas veces en una misma ocasión bebió o más bebidas alcohólicas en el último mes?

- Nunca
- Una vez al mes
- 2-4 veces al mes
- 2-3 veces a la semana
- 4 o más veces a la semana

¿Que tan seguido ha usado drogas recetadas (como medicinas) o ilegales (como cocaína) en el último mes?

- Nunca
- Una vez al mes
- 2-4 veces al mes

- 2-3 veces a la semana
- 4 o mas veces a la semana

Si usted ha fumado en el mes pasado, ¿cuantos cigarrillos ha consumido al dia?

- No fumo en el ultimo mes
- 1-10 cigarrillos
- 11-19 cigarrillos
- 20 o mas cigarrillos

En el mes pasado, ¿fumo o uso marihuana?

- Si recreativamente
- Si por razones medicinas
- No

¿Ha estado sin hogar (es decir, no tiene donde vivir) durante los ultimos 30 días?

- Si
- No

¿Actualmente esta cumpliendo condena en prision, es detenido a la espera de juicio o esta a prueba?

- Si
- No

¿Ha pensado en hacerse un dano fisico o en terminar su vida en el ultimo mes?

- Si
- No

Appendix C

PROMIS – 29 Profile v2.0 Items

Please respond to each question or statement by marking one box per row.

Physical Function

Are you able to do chores
such as vacuuming or yardwork?

(1) (2) (3) (4) (5)

Are you able to go up and down
stairs at a normal pace?

(1) (2) (3) (4) (5)

Are you able to go for a walk at least 15 minutes?

(1) (2) (3) (4) (5)

Are you able to run errands and shop?

(1) (2) (3) (4) (5)

Anxiety

In the past 7 days...

I felt fearful	1	2	3	4	5
----------------	---	---	---	---	---

I found it hard to focus on anything other than my anxiety	1	2	3	4	5
---	---	---	---	---	---

My worries overwhelmed me	1	2	3	4	5
---------------------------	---	---	---	---	---

I felt uneasy	1	2	3	4	5
---------------	---	---	---	---	---

Depression

In the past 7 days....

I felt worthless	1	2	3	4	5
------------------	---	---	---	---	---

I felt helpless	1	2	3	4	5
-----------------	---	---	---	---	---

I felt depressed	1	2	3	4	5
------------------	---	---	---	---	---

I felt hopeless	1	2	3	4	5
-----------------	---	---	---	---	---

Fatigue

During the past 7 days...

I felt fatigued	1	2	3	4	5
I have trouble starting things because I am tired	1	2	3	4	5

In the past 7 days...

How run down did you feel on average?	1	2	3	4	5
How fatigued were you on average?	1	2	3	4	5

Sleep Disturbance

In the past 7 days...

My sleep quality was	5	4	3	2	1
----------------------	---	---	---	---	---

In the past 7 days...

My sleep was refreshing	5	4	3	2	1
I had a problem with my sleep	1	2	3	4	5
I had difficulty falling asleep	1	2	3	4	5

Ability to Participate in Social Roles and Activities

I have trouble doing all of my regular leisure activities with others
5 4 3 2 1

I have trouble doing all of the family activities I want to do
5 4 3 2 1

I have trouble doing all of my usual work (include work at home)
5 4 3 2 1

I have trouble doing all of the activities with friends that I want to do
5 4 3 2 1

Pain Interference

In the past 7 days...

How much did pain interfere with your day to day activities? 1 2 3 4 5

How much did pain interfere with work around the home? 1 2 3 4 5

How much did pain interfere with your ability to participate in social activities? 1 2 3 4 5

How much did pain interfere with your household chores? 1 2 3 4 5

Pain Intensity

In the past 7 days...

How would you rate your pain on average?
0 1 2 3 4 5 6 7 8 9 10

Appendix D

PROMIS – 29 Profile v1.0 Items

Spanish Version

Responda a cada pregunta o enunciado marcando una casilla por linea.

Capacidad de funcionamiento fisico

¿Puede realizar tareas, como pasar la aspiradora o trabajar en el jardín?	5	4	3	2	1
¿Puede subir y bajar escaleras a un paso normal?	5	4	3	2	1
¿Puede salir a caminar durante 15 minutos por los menos?	5	4	3	2	1
¿Puede hacer mandados y compras?	5	4	3	2	1

Ansiedad **En los ultimos 7 dias...**

Senti miedo	1	2	3	4	5
Tuve dificultad para concentrarme en otra cosa que no fuera me ansiedad	1	2	3	4	5
Mis inquietudes fueron demasiado para mi	1	2	3	4	5
Me seit intranquilo/a	1	2	3	4	5

Depresion

En los ultimos 7 dias...

Senti que no valia nada	1	2	3	4	5
Me senti indefenso/a (que no podia hacer nada para					

ayudarme)	1	2	3	4	5
Me senti deprimido/a	1	2	3	4	5
Me senti desesperanzado/a	1	2	3	4	5

Agotamiento

En los ultimos 7 dias...

Me siento agotado/a	1	2	3	4	5
Tengo dificultad para comenzar las cosas porque estoy cansado/a	1	2	3	4	5

En los ultimos 7 dias...

¿Que tan rendido/a se sintio en promedio?	1	2	3	4	5
¿Que tan agotado/a estuvo en promedio?	1	2	3	4	5

Alteracion del sueno

En los ultimos 7 dias ...

La caldidad de mi sueuno fue	5	4	3	2	1
------------------------------	---	---	---	---	---

En los ultimos 7 dias...

Mi sueno fue reparador	5	4	3	2	1
Tuve problemas para dormir	1	2	3	4	5
Tuve dificultad para dormirme	1	2	3	4	5

Satisfaccion con la participacion en roles sociales

En los ultimos 7 dias

Estoy satisfecho/a con la cantidad de trabajo que puedo hacer (incluya el trabajo en el hogar)	1	2	3	4	5
--	---	---	---	---	---

Estoy satisfecho/a con mi capacidad para trabajar (incluya el trabajo en el hogar) 1 2 3 4 5

Estoy satisfecho/a con mi capacidad para ocuparme de mis responsabilidades personales y domesticas regulares 1 2 3 4 5

Estoy satisfecho/a con mi capacidad para desempenar mis actividades de rutina diarias 1 2 3 4 5

Efectos del dolor

En los ultimos 7 dias...

¿En que medida el dolor interfirio En sus actividades diarias? 1 2 3 4 5

¿En que medida el dolor interfirio en el trabajo en el hogar? 1 2 3 4 5

¿En que medida el dolor interfirio en su capacidad para participar en actividades sociales? 1 2 3 4 5

¿En que medida el dolor interfirio en sus tareas domesticas? 1 2 3 4 5

Intensidad del dolor

En los ultimos 7 dias...

En promedio, ¿como calificaria su dolor?
0 1 2 3 4 5 6 7 8 9 10

Appendix E

FACT-Head and Neck Cancer, Additional Concerns

Please circle or mark one number per line to indicate your response as it applies to the past 7 days.

I am able to eat the foods that I like

(0)Not at all (1) A little bit (2) Somewhat (3) Quite a bit (4) Very much

My mouth is dry

(0)Not at all (1) A little bit (2) Somewhat (3) Quite a bit (4) Very much

I have trouble breathing

(0)Not at all (1) A little bit (2) Somewhat (3) Quite a bit (4) Very much

My voice has its usual quality and strength

(0)Not at all (1) A little bit (2) Somewhat (3) Quite a bit (4) Very much

I am able to eat as much food as I want

(0)Not at all (1) A little bit (2) Somewhat (3) Quite a bit (4) Very much

I am unhappy with how my face and neck look

(0)Not at all (1) A little bit (2) Somewhat (3) Quite a bit (4) Very much

I can swallow naturally and easily

(0)Not at all (1) A little bit (2) Somewhat (3) Quite a bit (4) Very much

I smoke cigarettes or other tobacco products

(0)Not at all (1) A little bit (2) Somewhat (3) Quite a bit (4) Very much

I drink alcohol (e.g. beer, wine, etc.)

(0)Not at all (1) A little bit (2) Somewhat (3) Quite a bit (4) Very much

I am able to communicate with others

(0)Not at all (1) A little bit (2) Somewhat (3) Quite a bit (4) Very much

I can eat solid foods

(0)Not at all (1) A little bit (2) Somewhat (3) Quite a bit (4) Very much

I have pain in my mouth, throat or neck

(0)Not at all (1) A little bit (2) Somewhat (3) Quite a bit (4) Very much

Appendix F

FACT-Head and Neck Cancer, Additional Concerns- Spanish Version

Marque un solo número por línea para indicar la respuesta que corresponde a los últimos 7 días.

OTRAS PREOCUPACIONES

Puedo comer lo que me gusta

(0) Nada (1) Un poco (2) Algo (3) Mucho (4) Muchísimo

Tengo la boca seca

(0) Nada (1) Un poco (2) Algo (3) Mucho (4) Muchísimo

Tengo dificultad para respirar

(0) Nada (1) Un poco (2) Algo (3) Mucho (4) Muchísimo

Mi voz sigue siendo la misma

(0) Nada (1) Un poco (2) Algo (3) Mucho (4) Muchísimo

Puedo comer cuanto quiera

(0) Nada (1) Un poco (2) Algo (3) Mucho (4) Muchísimo

Estoy descontento(a) con la manera en que lucen mi cara y mi cuello

(0) Nada (1) Un poco (2) Algo (3) Mucho (4) Muchísimo

Puedo tragar normalmente y sin dificultad

(0) Nada (1) Un poco (2) Algo (3) Mucho (4) Muchísimo

Fumo cigarrillos, cigarrillos (u otros productos derivados del tabaco)

(0) Nada (1) Un poco (2) Algo (3) Mucho (4) Muchísimo

Tomo bebidas alcohólicas (cerveza, vino, etc.)

(0) Nada (1) Un poco (2) Algo (3) Mucho (4) Muchísimo

Puedo comunicarme con los demás

(0) Nada (1) Un poco (2) Algo (3) Mucho (4) Muchísimo

Appendix G

FACT-Lung Cancer, additional concerns

I have been short of breath

(0)Not at all (1) A little bit (2) Somewhat (3) Quite a bit (4) Very much

I am losing weight

(0)Not at all (1) A little bit (2) Somewhat (3) Quite a bit (4) Very much

My thinking is clear

(0)Not at all (1) A little bit (2) Somewhat (3) Quite a bit (4) Very much

I have been coughing

(0)Not at all (1) A little bit (2) Somewhat (3) Quite a bit (4) Very much

I am bothered by hair loss

(0)Not at all (1) A little bit (2) Somewhat (3) Quite a bit (4) Very much

I have a good appetite

(0)Not at all (1) A little bit (2) Somewhat (3) Quite a bit (4) Very much

I feel tightness in my chest

(0)Not at all (1) A little bit (2) Somewhat (3) Quite a bit (4) Very much

Breathing is easy for me

(0)Not at all (1) A little bit (2) Somewhat (3) Quite a bit (4) Very much

Have you ever smoked?

No ___ Yes ___ If yes:

I regret my smoking

(0)Not at all (1) A little bit (2) Somewhat (3) Quite a bit (4) Very much

Appendix H

FACT-Lung cáncer, additional concerns – Spanish Version

Marque un solo número por línea para indicar la respuesta que corresponde a los últimos 7 días.

OTRAS PREOCUPACIONES

Me ha faltado el aire para respirar

(0) Nada (1) Un poco (2) Algo (3) Mucho (4) Muchísimo

Estoy bajando de peso

(0) Nada (1) Un poco (2) Algo (3) Mucho (4) Muchísimo

Pienso con claridad

(0) Nada (1) Un poco (2) Algo (3) Mucho (4) Muchísimo

He estado tosiendo

(0) Nada (1) Un poco (2) Algo (3) Mucho (4) Muchísimo

Me molesta la pérdida de cabello

(0) Nada (1) Un poco (2) Algo (3) Mucho (4) Muchísimo

Tengo buen apetito

(0) Nada (1) Un poco (2) Algo (3) Mucho (4) Muchísimo

Siento el pecho presionado

(0) Nada (1) Un poco (2) Algo (3) Mucho (4) Muchísimo

Respiro bien

(0) Nada (1) Un poco (2) Algo (3) Mucho (4) Muchísimo

¿Ha sido fumador(a)?

No___ Sí___ En caso afirmativo:

Me arrepiento de haber fumado

(0) Nada (1) Un poco (2) Algo (3) Mucho (4) Muchísimo

Appendix I

Hospital Anxiety and Depression Scale

Choose the reply that is closest to how you have been feeling in the past week. Don't take too long over your replies, your immediate answer is best.

(A) 1. I feel tense or "wound up"

3-Most of the time

2-A lot of the time

1-From time to time

0-Not at all

(D) 2. I still enjoy the things I used to enjoy

0-Definitely as much

1-Not quite so much

2-Only a little

3-Hardly at all

(A) 3. I get a sort of frightened feeling as if something awful is about to happen

3- Very definitely and quite badly

2-Yes but not too badly

1-A little, but it doesn't worry me

0-Not at all

(D) 4. I can laugh and see the funny side of things

0-As much as I always could

1-Not quite so much now

2-Definitely not so much now

3-Not at all

(A) 5. Worrying thoughts go through my mind

3-A great deal of the time

2-A lot of the time

1-From time to time, but not too often

0-Only occasionally

(D) 6. I feel cheerful

3-Not at all

2- Not often

1-Sometimes

0-Most of the time

(A) 7. I can sit at ease and feel relaxed

0-Definitely

1-Usually

2-Not often

3-Not at all

(D) 8. I feel as if I am slowed down

3-Nearly all of the time

2-Very often

1-Sometimes

0-Not at all

(A) 9. I get a sort of frightened feeling like "butterflies" in the stomach

0-Not at all

1-Occasionally

2-Quite often
3- Very often

(D) 10. I have lost interest in my appearance

3-Definitely
2-I don't take as much care as I should
1-I may not take quite as much care
0-I take just as much care as ever

(A) 11. I feel restless as if I have to be on the move

3-Very much indeed
2-Quite a lot
1-Not very much
0-Not at all

(D) 12. I look forward with enjoyment to things

0-As much as I ever did
1-Rather less than I used to
2-Definitely less than I used to
3-Hardly at all

(A) 13. I get sudden feelings of panic

3-Very often indeed
2-Quite often
1-Not very often
0-Not at all

(D)14. I can enjoy a good book or radio or TV program

0-Often
1-Sometimes
2-Not often
3-Very seldom

Total Score: (D) Depression _____ (A) Anxiety _____

0-7 Normal Range

8-10 Borderline Abnormal Range

11-21 Abnormal Range

Appendix J

Hospital Anxiety and Depression Scale, Spanish Translation
Translation Castresana, Perez, & de Rivera (1995)

Este cuestionario ha sido diseñado para ayudarnos a saber cómo se siente usted. Lea cada frase y marque la respuesta que más se ajusta a como se sintió durante la semana pasada. No piense mucho las respuestas. Lo más segura es que si responde de prisa sus respuestas se ajustaran mucho más a como realmente se sintió.

(A) Me siento tenso o nervioso
3-Todos los días
2-Muchas veces
1-A veces
0-Nunca

(D) Todavía disfruto con lo que antes me gustaba
0-Como siempre
1-No lo bastante
2-Solo un poco
3-Nada

(A) Tengo una sensación de miedo, como si algo horrible me fuera a suceder
3- Definitivamente y es muy fuerte
2-Si, pero no es muy fuerte
1-Un poco, pero no me preocupa
0-Nada

(D) Puedo reírme y ver el lado divertido de las cosas
0-Al igual que siempre lo hice
1-No tanto ahora
2-Casi nunca
3-Nunca

(A) Tengo mi mente llena de preocupaciones
3-La mayoría de las veces
2-Con bastante frecuencia
1-A veces, aunque no muy a menudo
0-Solo en ocasiones

(D) Me siento alegre
3-Nunca
2- No muy a menudo
1-A veces
0-Casi siempre

(A) Puedo estar sentado confortablemente y sentirme relajado

0-Siempre

1-Por lo general

2-No muy a menudo

3-Nunca

(D) Me siento como si cada día estuviera más lento

3-Por lo general, en todo momento

2-Muy a menudo

1-A veces

0-Nunca

(A) Tengo una sensación extraña, como si tuviera mariposas en el estomago

0-El nunca

1-En ciertas ocasiones

2-Con bastante frecuencia

3- Muy a menudo

(D) He perdido interés en mi aspecto personal

3-Totalmente

2-No me preocupe tanto como debiera

1-Podria tener un poco más de cuidado

0-Me preocupo al igual que siempre

(A) Me siento inquieto, como si no pudiera parar de moverme

3-Mucho

2-Bastante

1-No mucho

0-Nada

(D) Me siento optimista respecto al futuro

0-Igual que siempre

1-Menos de lo que acostumbraba

2-Mucho menos de lo que acostumbraba

3-Nada

(A) Me asaltan sentimientos repentinos de pánico

3-Muy frecuentemente

2-Bastante a menudo

1-No muy a menudo

0-Rara vez

(D) Me divierto con un buen libro, la radio, o un programa de televisión

0-A menudo

1-A veces

2-No muy a menudo

3-Rara vez

Total Score: (D) Depression _____

(A) Anxiety _____

0-7 Normal Range

8-10 Borderline Abnormal Range

11-21 Abnormal Range