

DISSERTATION

STRESS, COPING, AND QUALITY OF LIFE OF MEDICALLY UNDERSERVED LUNG
AND HEAD-AND-NECK CANCER PATIENTS

Submitted by

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ABSTRACT

STRESS, COPING, AND QUALITY OF LIFE OF MEDICALLY UNDERSERVED LUNG AND HEAD-AND-NECK CANCER PATIENTS

The intent of this study was to investigate how medically underserved (i.e. uninsured, underinsured, low income) cancer patients responded to a stepped-care cognitive behavioral therapy (CBT) intervention aimed at increasing their ability to cope. The Transactional Model of Stress and Coping (TMSC) was utilized as a theoretical guide to assess outcomes of change in perceived stress, change in coping self-efficacy, and change in general quality of life. A parallel indirect effects model of change scores was tested to assess if this model was a good fit for the data, and results indicated that there was a significant specific direct effect from treatment to change in general quality of life, via change in coping self-efficacy. Further, 40 percent of the variance in change in general quality of life was accounted for by this model, which is a very large effect. Conclusions from this study include the utility of the TMSC to theoretically organize the relations of these outcome variables for lung, head and neck, and thyroid cancer patients who are medically underserved. In addition, this study indicated that the stepped-care CBT intervention increased quality of life for those in the intervention group. Future research should continue to assess for the mental health needs of this specific patient population. Continued resources should be put toward research on the development and implementation of stepped-care therapeutic interventions that increase patient coping skills and thereby increase patient quality of life.

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DEDICATION

*To
Barbara Lee Wright
“Don’t screw up.”*

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Chapter I: Introduction

The intent of this study was to explore how a stepped-care cognitive behavioral therapy (CBT) intervention for patients diagnosed with lung cancer (LC), head-and-neck cancer (HNC) and/or thyroid cancer (TC), impacted coping self-efficacy and patient quality of life (QOL). LC is one of the most common cancer diagnoses and often co-occurs with HNC due to cancer cells spreading between areas of the body. TC has very similar symptoms and treatment side effects to LC and HNC. Side effects of LC, HNC, TC and their treatments include difficulty with breathing, swallowing, and eating. These side effects are often stressful to patients and this stress has been shown to have an impact on patient's quality of life (QOL). Within health psychology research, quality of life is comprised of physical, emotional, social, and functional wellbeing. One way to understand the relations of treatment, perceived stress of a cancer diagnosis, coping, and QOL is by utilizing the Transactional Model of Stress and Coping (TMSC) (Lazarus & Folkman, 1984). This model posits that if an event (i.e. a cancer diagnosis/ cancer treatment) is cognitively appraised as a threat to wellbeing, then efforts are made to cope with that stress. There are personal and environmental factors (e.g. exposure to the intervention) that impact the way one appraises the resources they have to manage a stressful situation. These efforts to manage stress can be adaptive or maladaptive. According to the TMSC, the level of coping mediates the relation of stress to QOL outcomes.

In this study, LC, HNC, and TC patients were recruited to participate in a randomized clinical trial. Once consented, participants were randomized to either the control condition arm or the intervention arm. In the intervention arm, a stepped-care CBT intervention was used to teach adaptive coping skills and to manage stress. Data was gathered on perceived stress, coping

self-efficacy, and quality of life at baseline and at a 3-month follow-up. These outcomes were analyzed based on the TMSC, which states the relation of situational appraisal to QOL is mediated by perceived stress and coping.

Lung Cancer and Head-and-Neck Cancer

Approximately 228,150 new cases of lung cancer were diagnosed in 2019 in the United States (American Cancer Society [ACS], 2019). Those who received this diagnosis also likely received the news that their prognosis was poor, as the 5-year survival rate for LC diagnoses is between 16%-22% (ACS, 2019).

LC and head-and-neck cancer (HNC) often co-occur because HNC cells either metastasize in the lung or LC cells move to the head and neck area (ACS, 2018). HNC is an overarching term for cancers, typically squamous cell cancers, located in the oral cavity, pharynx, larynx, paranasal sinuses, nasal cavity, and salivary glands (NIH National Cancer Institute, 2017). Within the medical field, thyroid cancer (TC) is sometimes classified differently than other HN cancers (Heroiu Cataloiu, Danciu, & Popescu, 2013). However, TC has very similar symptomology and treatment to HNC, therefore patients who were given TC diagnoses were also recruited for this study. LC, HNC and TC diagnoses are ordered based on Stages 0, I, II, III and IV. Earlier stage diagnoses indicate smaller primary tumor size and/or lower presence of metastasis, and later stages indicate larger primary tumor size and higher prevalence of cancer cells that have spread throughout the body (ACS, 2015). LC and HNC have very low survival rates given their intense nature, particularly at later stages (Stage III and Stage IV). Typical treatments for LC and HNC include surgery to remove tumors, chemotherapy which impacts all cells in the body, radiation therapy which can be targeted to one place in the body where a

primary tumor is located, and other biological treatments (e.g. immunotherapy) (ACS, 2016). The side effects of these treatments often impact one's ability to breathe, eat, swallow, or have typical energy to carry out daily tasks. Because of these harsh side effects of treatment, many LC, HNC, and TC patients, especially those given late stage diagnoses, choose to receive, or quickly transition to receiving palliative care (Mallow, Hayes, Semaan, Smith, Hales, Brower, & Yarmus, 2018). Palliative care is aimed at increasing comfort and reducing distress associated with symptoms of cancer, rather than a full recovery from the cancer (Hsieh & Hsiao, 2017). Given the low survival rates and the often deleterious impact that treatment has on functioning, these diagnoses are often highly stressful events which impact one's quality of life.

Quality of Life for LC and HNC Patients

It is difficult to find a singular definition of “quality of life” (QOL) when reviewing health psychology literature. In 1948, the World Health Organization defined “health” as a “state of complete physical, mental, and social well-being, and not merely the absence of disease and infirmity” (World Health Organization, 1948). The inclusion of the word “well-being” within the definition of health introduced confusion about the conceptual difference between “health” and “quality of life” (Post, 2014). “Quality of life” is a term that has been used in health literature since 1960s. Since then, the term “health related quality of life” has also attempted to capture QOL particularly as related to mental and physical health (Center for Disease Control [CDC], 2019). While these definitions vary, each make an attempt to define an important outcome. At present, what is agreed upon in the literature is that each of these concepts—health, quality of life, well-being, health related quality of life—are multi-dimensional and ought to include measures in many domains including physical functioning, mental functioning, and social

functioning. Some definitions also include that these qualities can be measured on individual and community levels. For example, the World Health Organization (WHO) currently defines QOL as

“an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns. It is a broad ranging concept affected in a complex way by the person's physical health, psychological state, personal beliefs, social relationships and their relationship to salient features of their environment.” (WHO, 2011).

Given the variability in definitions, current literature recommends that researchers specify which domains of QOL are being studied on a case-by-case basis rather than relying on QOL as the only description of a measure (Post, 2014). This study utilized a cancer specific QOL measure that had subscales for physical, social, emotional, functional, and specific cancer diagnosis wellbeing. This measure also provided a “General” QOL score that combined physical, social, emotional, functional wellbeing subscales. In this study, differences in mean QOL were also researched as exploratory outcomes based on community level factors: race, ethnicity, sex, and hospital site. Given that this study collected data from patients at five different hospitals, it was important to analyze mean differences in outcomes by each hospital community.

In 1949, researchers Karnofsky and Burchenal first introduced concepts of QOL as related to chemotherapy treatment for cancer. Karnofsky and Burchenal posited that 1) the impact of cancer treatment eliminating cancer cells was important to increasing QOL and they added that 2) the impact of cancer and cancer treatment on appetite, mood, and social role obligations were also of importance to the patient (1948). Current research corroborates that there is a negative relation between QOL and chemotherapy treatment of LC and HNC

(Fernández-Rodríguez, Villoria-Fernández, Fernández-García, González-Fernández, & Pérez-Álvarez, 2019; Akin, Can, Aydiner, Ozdilli & Durna, 2010). Researchers Andrykowski and Kangas found evidence that the harsh side effects of LC and HNC treatment are appraised as traumatic experiences for many (2010). Given this information, it is unsurprising that many patients choose palliative care, especially patients of older age, to increase their comfort in living rather than undergoing difficult treatment. The QOL measures for this study included treatment side effects and cancer symptomology. In addition, exploratory research questions include assessment of mean differences in the outcome measures based on type of treatment planned for the patient.

Medically Underserved Patients

According to the WHO definition of QOL, one's perception of one's position in life in the context of one's culture, is important to QOL. There is evidence that for LC and HNC patients, socioeconomic or financial position has an impact on emotional aspects of QOL (Fagundes, Jones, Vichaya, Lu & Cleeland, 2014). Looking at health disparities is one way to contextualize differences in QOL. Health disparities encompass the preventable differences in health and health care, that exist among specific populations due to identity variables including race, gender, socioeconomic status, and sexual orientation (CDC, 2018). This study will focus specifically on those who have disparities in health and healthcare because they are medically underserved. In this study, medically underserved refers to individuals who do not have medical insurance or are underinsured (meaning that they receive public insurance such as Medicaid, Medicare, or Veteran's Affairs insurance, but do not have private insurance) and were living at below 400% of the 2016 Federal Poverty Level (FPL). Additionally, patients who live below

200% of the 2016 FPL and are spending at least 10% of their annual income on medical expenses out-of-pocket qualified as medically underserved for this study.

For these medically underserved individuals, receiving a LC and HNC diagnosis has greater-known negative impacts. One of the biggest challenges for medically underserved patients is that they at a higher likelihood for receiving a later stage diagnosis (ACS, 2019). Treatment for later stage diagnoses tend to be more expensive, extensive, and have lower success rates than treatment for earlier stage diagnoses (ACS, 2019). In addition, financial burden is one component of functional wellbeing and QOL (DiGiovanni et al 2015). Those who are medically underserved, by definition, experience greater financial burden of cancer treatment. Patients with LC and HNC typically need to take time away from work to receive treatment, rest, and participate in recovery or palliative care (ACS, 2019). For medically underserved patients, there is a lower likelihood that they hold jobs which offer paid medical leave. As such, the impact of not working and paying for costly medical treatment can be a major burden. Because of the challenges that medically underserved LC and HNC patients face, this study focused on how their QOL was impacted by the stress of a cancer diagnoses, a psychotherapeutic intervention, and their belief in their ability to cope.

In addition to being medically underserved, other demographic variables have been connected to decreased QOL as related to LC and HNC. Research indicates that race and ethnicity are factors that impact someone's likelihood for being insured. According to the ACS, 16% of Hispanic people are uninsured, and 11% of Black people are uninsured compared to the 6% of uninsured non-Hispanic White people in America (ACS, 2019). Age has been shown to impact cancer survivability, with older people having a lower chance of survival than younger people (Zeng, Wen, Morgans, Pao, Shu, Zheng, 2015). As such, race, ethnicity and age were

used in exploratory analyses to assess for mean differences in groups included within this medically underserved population. As discussed in the above sections, mean differences in the outcome variables by sex and hospital site were analyzed based on research that indicates differences in QOL differing at community group levels. Mean differences were explored based on ways that that medical covariates of stage of cancer and type of treatment impacted cancer survivability and stress, coping ability, and QOL.

Transactional Model of Stress and Coping

The theory behind the Transactional Model of Stress and Coping (TMSC) is a helpful guide to organize the relation of a psychotherapeutic treatment condition to QOL outcomes. Richard Lazarus and Susan Folkman began to write about the TMSC in the 1980s as theoretical way to connect stress, coping, and health outcomes. Lazarus and Folkman define psychological stress as “a relationship between the person and the environment that is appraised by the person as taxing or exceeding his or her resources and endangering his or her well-being” (Lazarus and Folkman, 1984, p. 19). By this definition, a LC, HNC, or TC diagnosis is an environmental stimulus, as is the treatment condition of this study. Given the discussion above about the way cancer endangers well-being and cancer treatment taxes resources, a cancer diagnosis is likely to be appraised as stress. Once an event or an environmental factor is appraised as stress, the TMSC posits that people engage in a process of appraising and managing that stress. Other “influencing factors” come into the picture as well during the appraisal process (e.g. treatment condition). The appraisal and the subsequent actions taken to manage stress are defined as “coping”. Actions of coping, as described by the TMSC, can be either adaptive or maladaptive. The TMSC posits that the outcome variable, in this case QOL, changes based on the amount of stress and the adaptive

or maladaptive coping utilized to manage the stress. The TMSC theorizes that the path from appraisal of an environmental stimulus to health-related outcomes is mediated by perceived stress and coping. This model is presented in Figure 1 (Lazarus and Folkman, 1984).

Based in this theory, and previous health psychology research that supports it, coping is an influential mediator of quality of life outcomes (Hinz, Friedrich, Kuhnt, Zenger & Schulte T, 2019). Some types of coping have been measured to have positive impacts on QOL for cancer patients like moderate exercise and carrying out simple tasks of daily living rather than avoiding them (Fernández-Rodríguez et al, 2019; Ha, Ries, Mazzone, Lippman & Fuster, 2018). Other reactions to stress have been shown to be maladaptive, meaning they result in distressing outcomes. Examples of coping that lead to maladaptive outcomes include problematic alcohol use and disengagement from life (Alcoholism, 2018; Tallman, 2013). A previous study from this author showed that with this same patient population, adaptive coping moderated the effects of perceived stress on emotional distress (e.g. anxiety and depression symptoms) (Peterson, 2019). Promisingly, there are large bodies of research to demonstrate that it is possible to teach adaptive coping techniques and to minimize maladaptive coping by utilizing psychotherapeutic interventions, thereby increasing quality of life.

Intervention

Cognitive Behavioral Therapy (CBT) is a widely utilized and extensively researched psychotherapy modality (Beck, 1979; Beck 1993). CBT posits that thoughts, feelings, and behaviors related to oneself, others, and the future, are parts of what impacts a person's QOL. CBT addresses automatic thoughts, feelings, and behaviors in an attempt to change internal core beliefs about oneself that are driving thoughts, feelings and behaviors. Research indicates that

CBT has utility in increasing adaptive coping across many populations (Miranda et. al, 2003). However, there is literature that indicates traditional approaches to CBT may not appropriately meet the needs of cancer patients, due to fear based thoughts, feelings, and behaviors that are understandable given the threat of death presented by cancer (Greer, Park, Prigerson, & Safren, 2010). Results of this study will add to the literature a clinical trial with a CBT intervention solely for cancer patients, with Master's level counselors administering a protocol that was tailored for the needs of this population. In the intervention arm of this study, CBT was used at a stepped-care level to address distress. Stepped-care is a research-supported treatment approach that attempts to match the level of care that is given, to the level of care that is needed on a case-by-case basis (Bower & Gilbody, 2005). Stepped-care interventions are tiered such that the lowest level of intervention can be given to the patient by the simplest means necessary, thereby utilizing the fewest resources necessary while delivering proper, accessible care. Patients with moderate to high of distress receive more specialized care and resources specified to their needs.

In this study, which focuses on quality of life within a health and oncological psychology context, behavioral health care is "stepped" based on self-report of symptoms of emotional distress (i.e. symptoms of anxiety and symptoms of depression) reported at baseline. Symptoms of anxiety and depression vary from mild to severe (American Psychiatric Association, 2013). As such, stepped-care has been an appropriate intervention for helping cancer patients manage emotional distress by matching the level of emotional distress to the level of care given (Krebbel 2012; Bower & Gilbody, 2005).

Purpose of Study

Broadly, this study explored the relations of treatment conditions (i.e. stepped-care CBT interventions vs control) to change in perceived stress, change in coping self-efficacy, and change in QOL for medically underserved LC, HNC, and TC patients. One purpose of this study was to explore the relation of these variables by utilizing the TMSC as a theoretical guide. A secondary purpose of this study was to assess if these relations changed over time between a baseline and three-month follow-up. The final purpose of the study was to compare the stepped-care intervention groups to the control group. The intervention arm received the stepped-care CBT intervention described above. Patients randomized to the control arm received “enhanced usual care” which included a packet of resources available to the participant.

Hopefully, the findings of this study will guide future research and intervention for LC, HNC, and TC patients because it provides longitudinal information about the ways change in perceived stress, change in coping self-efficacy and change in QOL were related within this highly specified population of medically underserved cancer patients. This study also provides information about the way LC, HNC, and TC patients respond to a stepped-care model for addressing emotional distress. Lastly, the study provides information about the utility of a CBT intervention for exclusively medically underserved LC, HNC, and TC patients.

The overarching research question and two secondary questions were:

1. Does the data support the TMSC framework?
 - a. Does change in CSES mediate the relation of treatment type to change in QOL?
 - b. Does change in PS mediate the relation of treatment type to change in QOL?

Exploratory research questions of this study were:

1. If significant mediations are present, does treatment step (Step 1, 2, 3, or 4) impact the effects of the mediators?
2. If significant mediations are present, do the effects of the mediators vary by demographic variables including: race/ethnicity, gender, age, stage of cancer at diagnosis, type of treatment, and hospital site?

Hypotheses guiding this data analysis included:

1. Change in coping will mediate the relation of treatment condition to change in quality of life.
2. Change in perceived stress will mediate the relation of treatment condition to change in quality of life.
3. Intervention groups will have more positive change in coping and better QOL outcomes than the control group.

Chapter II: Methods

This current study was a part of a large, randomized controlled trial (RCT). The larger study was funded by the Patient-Centered Outcomes Research Institute (PCORI) (Evelinn Borrayo, PI). “A Stepped-Care Intervention to Reduce Disparities in Mental Health Services among Underserved Patients and Caregivers with Lung and Head and Neck Cancer” was the name of this larger study which focused on comparing the intervention arm of CBT stepped-care treatment to the control arm of enhanced usual care. The larger study is focused on outcomes of anxiety symptoms and depression symptoms over four time points. Standardized protocol between multiple sites was used to maintain consistency in training, participant recruitment and administration of measures. This current study focused on the relation of change in perceived stress, change in coping-self efficacy, and change in QOL over two time points.

Participants

All participants in this study qualified as medically underserved by the definition stated previously. Spanish and English-speaking participants were recruited and given survey materials in their preferred language. Each participant was recruited from one of five Colorado Hospitals including: Denver Health Hospital in Denver, Saint Mary’s Hospital and Reginal Medical Center in Grand Junction, Saint Joseph Hospital in Denver (St. Joe’s), National Jewish Health in Denver and the University of Colorado Cancer Center (UCCC) in Aurora. All patients were recruited to the study within 30 days of their first oncology appointment after receiving their LC, HNC, or TC diagnosis.

Measures

Demographic variables were collected from all participants. These variables include age, sex, race, ethnicity, primary cancer diagnosis, cancer treatment planned. Demographic variables including income, insurance status, pregnancy status, severe mental illness, homelessness and incarceration/detainee status were utilized as exclusion criteria.

The Perceived Stress Scale (PSS) is a 10-item scale that assesses for perceived stress in the past month. Participants responded on a 5-point Likert scale that ranged from “never” to “always” in response to statements like “In the last month, how often have you felt that things were going your way?” and “In the last month, how often have you been angered because of things that were outside of your control?”. On this scale, higher PSS scores are related to higher levels of perceived stress.

The PSS was developed in 1983 and now has multiple versions. A principle components analysis (PCA) demonstrated that the PSS used in this study has one factor (with a .42 factor loading) for positively worded questions and a second factor for negatively worded questions. When the two factors are combined, 48.9 percent of the total variance was explained (Cohen, Kamarck, & Mermelstein, 1983).

The PSS has been widely utilized as a measure appropriate for audiences with at least a junior high-level education. With cancer patients the PSS has an internal consistency between .80 and .89 (Cohen, Kamarck, & Mermelstein, 1983). This version of the PSS had predictive validity for 4-8 weeks (Cohen, Kamarck, & Mermelstein, 1983; Cohen & Williamson, 1988). In this study, the PSS had an internal consistency reliability of $\alpha=.83$ at baseline and $\alpha=.89$ at 3-month follow-up. The test-retest reliability coefficient was .60 between baseline and 3-month follow-up.

The Coping Self Efficacy (CSE) scale is a 26-item scale that measures an individual's confidence in their ability to utilize adaptive coping. The scale is used to measure the construct of coping self-efficacy in the context of when "life is not going well or when you're having problems" (Chesney et al., 2006). Exploratory and confirmatory factor analysis previously completed indicates that this scale has three factors which are: problem-focused coping (6 items, $\alpha=.91$); emotion-focused coping (4 items, $\alpha=.91$); and social support (3 items, $\alpha=.80$). Chesney et al.'s research on the measure in 2006 indicated that as scores on the CSE scale increase over time, measures of psychological distress decline. In this study, the CSES had an internal consistency reliability of $\alpha=.96$ at baseline and $\alpha=.96$ at 3-month follow-up. The test-retest reliability was coefficient .61 between baseline and 3-month follow-up.

The participants in this study are medically underserved which is a proxy for lower socioeconomic status (SES). Research indicates that lower SES is correlated with lower literacy levels (Buckingham, Wheldall, & Beaman-Wheldall, 2013). Given this information, the original 10-point Likert scale was modified to a response scale which includes three possible responses. The modified responses are "Certainly cannot do", "Maybe can do", and "Certainly Can Do".

Quality of life was assessed for using the Functional Assessment of Cancer Therapy (FACT) measures specifically for Lung Cancer (FACT-L Version 4) or Head-and-neck cancer (FACT-HN) depending on the patient's primary diagnosis. These measures are comprised of the FACT General (FACT-G) and each have additional questions related specifically to cancer therapies for LC or HNC. The FACT-G has 27 questions and four subscales including physical, social/family, emotional, functional quality of life. The FACT-L has an internal consistency of .68 (DiGiovanni et al 2015). In this study, the FACT-G had an internal consistency reliability of

$\alpha=.76$ at baseline and $\alpha=.83$ at 3-month follow-up. The test-retest reliability was coefficient .73 between baseline and 3-month follow-up.

Procedures

The PCORI-funded RCT was run through the University of Colorado Denver and as such Institutional Review Board (IRB) approval was obtained through the Colorado Multi-Institutional Review Board (COMIRB). Eligible participants were identified via monthly audits of medical records at each hospital site reported above. Newly diagnosed LC, HNC and TC patients were considered eligible participants. In addition to monthly audits of medical records, eligible participants were identified by attendance to cancer tumor boards which physicians and Site Research Coordinators (SRCs) attended. Daily reviews of LC, HNC, and TC patients who had appointments with oncology clinics, ear-nose-and-throat (ENT) clinics, and radiation oncology units at each hospital were also conducted.

Once a possible participant was identified, SRCs would discuss the RCT with the patient at their first oncological appointment in a private and comfortable medical room. In order to recruit and consent patients to the study, SRCs followed Health Insurance Portability and Accountability Act (HIPAA) compliant procedures to administer participation agreement and consent forms. These forms were administered electronically, and each participant had the option of receiving a hard paper copy for their personal records.

Once patients were consented, they received a baseline survey in their preferred language (English or Spanish) to complete either online or as a paper copy. This baseline survey included demographic information, PSS, CSE Scale, and FACT-L or FACT-HN as needed based on

primary cancer diagnosis. TC patients completed the FACT-HN. Once baseline surveys were received, patients were randomized to either the control arm or intervention arm.

As discussed, the intervention arm was a CBT stepped-care intervention which was delivered by a master's level counselor. In Step 1, "Watchful Waiting" (PROMIS score <50), one face-to-face Orientation Session was conducted with all intervention participants to establish therapeutic rapport and explain the purpose, design, and content of the study. Participants with no symptoms or mild levels of distress were continually monitored. Step 2 "Self-Help Guide" (PROMIS score 50-59) provided participants with mild levels of distress a self-administered evidence-based stress-management and coping skills techniques packet to practice independently with their counselor available via telephone to answer any questions. The next step, Step 3 the "Coping Skills Training" (PROMIS score 60-69) was provided for participants with moderate levels of distress. For Coping Skills Training, participants spent two sessions with the counselor learning problem-focused and emotion focused coping strategies, and to identify ways to strategically manage stress. Cognitive-Behavioral Therapy was provided in Step 4 (PROMIS score >70). This step was for those reporting high levels of distress, and included up to four CBT sessions focused on cognitive and emotional reactions to distress and correcting cognitive distortions. A visual representation of this information is presented in Figure 2

The control arm was enhanced usual care for which patients received a printed packet of local and national resources for support.

Three-month follow-up surveys included the same measures as the baseline survey but did not include a demographic questionnaire. All responses were recorded in a secure REDCap database. REDCap, according to its website is a "secure web application for building and

managing online surveys and databases” (REDCap. (n.d.). When participants returned each survey a \$25 gift certificate to Walmart was mailed back for their participation.

This author was involved in the development of the demographics survey and choice of measures included in the survey. This author also called participants to remind them to complete surveys after being consented and worked on general administrative tasks for the PCORI project.

Chapter III: Results

Parallel Indirect Effects Model

A parallel indirect effects model, also referred to as a parallel mediation model, was utilized to analyze this data (See Figure 3). When a causal effect is transmitted from an independent variable (X) to a dependent variable (Y) through a mediator (M) it is referred to as mediation (Preacher, Rucker, Hayes, 2007, p. 186). A parallel mediation, or a parallel indirect effects model, measures two paths from the independent variable, to each mediator, and then to the dependent variable. It also measures the direct effect of the independent variable on the dependent variable. One benefit of longitudinal data like this study provides, is the ability to measure casual mechanisms overtime.

Using the TMSC as a theoretical guide, the independent (X) variable was the categorical treatment condition (i.e. intervention vs control) and the dependent (Y) variable was change in QOL from baseline to 3-month follow-up (herein denoted as “ Δ QOL”). Given that the TMSC is reflexive, one mediator (M1) was the change in perceived stress from baseline to 3-month follow-up (herein denoted as “ Δ PSS”). The second mediator (M2) was the change in coping self-efficacy from baseline to 3-month follow-up (herein denoted as “ Δ CSES”).

Rationale for Use of Change Score Analysis

Pearl articulates in a 2016 article that the most important consideration when choosing a statistical analysis for pre-post designs is to assure that the analysis used matches the question being asked. In this study, it is especially important to consider the research on Lord’s Paradox. Lord (1967) discussed a paradox of two correct, yet, contrasting answers to a pre-post design

research question. Important contrasting conclusions in analysis were a result of differences in the statistical analyses used, and the way two separate researchers interpreted the research question. The two types of analyses in question here are the use of change score versus the use of residualized gain scores.

Articles by Allison (1990) and Pearl (2016) expand on the research of Lord and other statisticians since. Allison discussed two questions that are important to answer when a predictor (referred to as X) is measured concurrently with the outcome (referred to as Y). In this study there are three predictor variables (i.e., X_1 , M_1 , and M_2). X_1 the treatment condition which is expected to predict changes in Y , and because this research question also tests an indirect effects model, the indirect effects M_1 (i.e., PSS) and M_2 (i.e., CSES) are also predictors of Y and were measured concurrently with Y (i.e., QOL). Given this, it was important to answer Allison's two questions in regard to the b-path, or the indirect effects to outcome relations. The first question is, "Is there a true causal effect of Y_1 on Y_2 ?" The answer to this is no because QOL at time 1 (baseline) has no causal effect on QOL at time 2 (3-month follow-up). These variables are related given that they are nested within participants. However, the level of QOL at time 1 does not cause QOL at time 2. The second question asks is Time 2 Predictor Variable minus Time 1 Predictor Variable correlated with any omitted Z or V variables? Z , as defined by Allison's article, is "a vector that is constant over time but whose effects change" and V is "a vector whose values and effects both change". In this study, an example of a vector that remains constant over time but whose effects change is insurance status. Type of health insurance has an effect on people's medical care. Medical care changes once someone is diagnosed with cancer, and the patient's insurance status is a major factor that effects the quality and type of care possible. In this study, only people with specific insurance statuses were selected. Because the difference

from Time 1 to Time 2 predictor variables perceived stress and coping self-efficacy may have differed based on insurance status, this was an important part of the research design to restrict inclusion to only certain types of insurance statuses. Second, an example of a vector whose values and effects both change could be income. In the general population, one's income may change in value, and the effect of one's income on their perceived stress and coping self-efficacy could change given changes in life circumstances. That is why the research design took income into consideration when including and excluding patients in the selection process for this study, to focus only on those whose income was low. It is also possible that during the course of the study, participant's income changed due to missing work for cancer treatments, and that this change in income impacted perceived stress and coping self-efficacy. This would likely have been reported to study coordinators. The answer to this question is also no, both Δ PSS and Δ CSES are assumed to be independent of other vectors, yet caused by treatment condition, which is randomly assigned. Any variables that might vary with the outcomes will be examined in exploratory analyses (e.g., demographic variables). Given that these participants were randomly assigned, there existed no plausible reason that there should have been pre-existing differences in their baseline. Analysis of baseline scores determined this was true, there were no significant differences in mean scores for the outcome variables between control (PSS Baseline: $M=12.93$, $SD=6.49$; CSES Baseline: $M=207.64$, $SD=51.13$; QOLg Baseline: $M=76.21$, $SD=16.23$) versus intervention (PSS Baseline: $M=12.3$, $SD=7.04$; CSES Baseline: $M=209.01$, $SD=52.704$; QOLg Baseline: $M=78.57$, $SD=17.717$) (PSS Baseline: $t(202)=0.659$, $p=.511$; CSES Baseline: $t(202)=-0.188$, $p=.851$; QOLg Baseline: $t(202)=-0.993$, $p=.322$). As such, it was deemed appropriate to utilize change scores.

Allison's (1990) article was focused on the two biggest arguments statisticians report against using change scores: 1. unreliability and 2. sensitivity to regression toward the mean. Allison sites myriad authors who conclude that change scores are indeed reliable, particularly when the experimental design includes randomization and when X (in this case X, M1 and M2) is delivered after Y1. In the current study, baseline measures were collected, patients were randomized to either treatment or control and delivered the respective interventions, and then the 3-month follow up measure was completed. As such, the two major components were met. In addition, the two groups are stable, which Allison and Kenny (1975), and Kenny and Cohen (1979) all argued that given this stability, regression to the mean is not a problem. Moreover, these authors argue that there is less bias with changes scores than with the regressor variable/residualized gains method.

Experimental Design Considerations

This study is focused on the overall change in QOL participants experience, regardless of where they began at baseline. The primary research question is "Does the data support the TMSC framework". This question is meant to be interpreted as: Does being in intervention versus control make a difference for participants total positive change in QOL, as indirectly effected by either of these total changes in PSS or total changes in CSES. The TMSC is being used as a theoretical guide, and the intention of the stepped-care CBT intervention is to increase overall coping self-efficacy and teach skills to manage stress, so change in PSS and change in CSES were used as indirect effects.

Because the intervention arm of treatment was given in a stepwise manner, and the control arm was not, it makes conceptual sense that Δ QOL would be most appropriate

measurement given this experimental design. To elaborate, the most important consideration is how the intervention arm compares to the control arm in their change in QOL score from baseline to 3-month follow-up. Further, change in QOL for the intervention arm would be expected to change in a stepwise manner, given the stepwise intervention. On the contrary, the control arm would not be expected to change. The change between the two timepoints and across the two conditions is the focus of this study, rather than a focus on the end point of treatment (i.e., the 3-month follow-up score). Change scores also make the most conceptual sense given the research question, which Pearl (2016) indicated was important.

Regarding the experimental design, patients randomized to the intervention arm received a Step assignment (the level of CBT intervention) based on their Y_1 PROMIS Anxiety and PROMIS Depression measure scores. Step 1 was the lowest level of intervention; Step 4 is the highest level of intervention. The control arm of the study received a Step assignment based on Y_1 anxiety and depression scores as well, however, treatment of the control group was uniform (“enhanced usual care” which was a resource packet). Treatment of the control group did not vary by Step at Y_1 .

The primary aim of this study was to assess differences between the control arm and the intervention arm to assess for impact of treatment condition on ΔQOL . In addition, one exploratory aim is to compare the effects of ΔPSS and $\Delta CSES$ on ΔQOL for each Step of the stepped care treatment. As such, the remainder of this section expands on the different levels of treatment to argue that research design is an important factor in choosing change score analysis to address the exploratory aims. The study included a stepped-care model, such that for those randomized to the intervention, treatment intensity was matched with symptom severity. The intervention arm of the experimental design already takes into account Y_1 scores of PROMIS

Anxiety and Depression (conceptually related to QOL and the whole model tested in this study). If residualized gain scores had been used instead, this process would conceptually double dip the impact of Y_1 scores. Y_1 scores are, in a sense, already conceptually controlled for within the Treatment group because of stepwise experimental design. This was assessed for using a one-way ANOVA which was significant ($F(3, 200) = 61.076, p < .001$). Post hoc tests indicated that mean scores of baseline QOL between each Step were all statistically significantly different from one another except for Steps 3 and 4 (See Table 5).

Considering the exploratory research question about the effects of the mediators ΔPSS and $\Delta CSES$ on ΔQOL , it points conceptually toward using change scores and away from residualized gain scores. To illustrate, when a participant reported anxiety and depression levels at Step 1, which has minimal intervention, their ΔQOL , $\Delta CSES$, and ΔPSS would be expected to be small based on the hypotheses. If someone indicated high levels of anxiety and depression symptoms, that participant gets the highest Step assignment, Step 4, which has the most intensive clinical CBT intervention. For a Step 4 participant, the $\Delta CSES$ and ΔQOL (and possibly ΔPSS) conceptually should be larger if the intervention works, because of the difference from Y_1 (very high) to Y_2 (hopefully low if the intervention works and study hypotheses are supported). Instead, if residualized gain scores were used to control for the initial Y_1 QOL score, Y_1 CSES score, and Y_1 PSS score, part of that analysis would be to compute the direct effect of the c path (treatment on Y_2 QOL controlled for the Y_1 QOL). However, this is not the right question because this question of the c path direct effect is *already* built into the experimental method because participants are getting the level of intervention tailored to their Y_1 anxiety and depression symptom score (which is conceptually related to Y_1 QOL score).

Path Analysis Considerations

Mplus was used to conduct all path analyses (Muthén & Muthén, 1998-2012).

Historically, statisticians measured the effect of the mediation by subtracting the c' path (the path that considers that direct effect as controlled for the by mediator) from the c path (the direct effect of Y on X) (Baron and Kenny, 1987). However, the current best practice approach for testing mediation, called the product of coefficients method, is proposed for this study. The product of coefficients method multiplies the effect of M on X (a_1) and the effect of Y on M (b_1) (MacKinnon et al, 1995) (See Figure 3).

One assumption of this kind of testing is the assumption that a_1 , b_1 , a_2 , and b_2 are all independent and normally distributed. The second assumption is that the product of a_1b_1 and a_2b_2 are normally distributed, but this assumption is often violated. The default setting in Mplus is to assume a normal distribution of the products and conduct a z -test called a Sobel test. However, since this was a smaller sample size, there was a high chance for a Type II error with the Sobel test. To correct for this, asymmetrical bias-corrected bootstrap confidence intervals (ACIs) were used to address this non-normal distribution (Hayes, 2009). In addition to p -values, confidence intervals were reported for each effect size due to p -values not being a sufficient measure of clinical significance (Cumming & Calin-Jageman, 2016). Standard errors were calculated using a sandwich estimator (Muthén & Muthén, 1998-2012). To assess for the potential violation of the independence assumption due to the multiple hospital sites intraclass correlations were calculated. Intraclass correlations less than .05 do not require adjustments.

Because this study aimed to address health disparities that are related to being medically underserved, exploratory aims included assessing for demographic (e.g. race, ethnicity, age, sex)

and medical covariates (e.g. stage of cancer, type of treatment, hospital site) in the form of visualizations, descriptive statistics and effect size reporting.

Data Analysis

Figure 4 includes a CONSORT (Consolidated Standards of Reporting Trials) diagram of the participants in the study, and Table 1 includes study demographic variable information of the final participants. Table 2 and Table 3 include descriptive statistics.

Missing Data

Missing data was assessed for based on recommendations from the authors of each scale. For the PSS, 4 participants had missing data in PSS baseline. Three participants were missing 1 item, and 1 participant was missing 2 items. Mean scores were computed with the remaining items for the participants and used to fill in the missing items. There were 8 participants with missing data in PSS 3 month. All 8 participants were missing 1 item. Mean scores were computed with the remaining items for participants and used to fill in the missing items.

The authors of the CSES recommend using the same method described above to handle missing data (Chesney, Neilands, Chambers, Taylor, & Folkman, 2006). In the CSES, 17 participants had missing data for CSES baseline. The most frequently missed question was Item 23, “Pray or meditate” which has 6 missing items. One participant was missing 2 items, all other participants were missing only 1 item. Mean scores were computed with the remaining items for the participants. These mean scores were rounded to 0, 5, or 10 to match the answer options on the original scale. Mean scores of 8 and 9 were rounded up to 10. Mean scores of 6 were rounded down to 5. Mean scores of 2 were rounded down to 0. Mean scores of 3 and 4 were rounded up to 5. The rounded scores replaced the missing variables.

There were 14 participants with missing data for CSES 3-month follow-up. One participant was missing 4 items, two participants were missing 2 items, and all other participants were missing 1 item. The most frequently missed question was Item 3, “Sort out what can be changed, and what cannot be changed” which had 5 items missing. Mean scores were computed with the remaining items for the participants. These mean scores were rounded to 0, 5, or 10 to match the answer options on the original scale. Mean scores of 8 and 9 were rounded up to 10. Mean scores of 6 and 7 were rounded down to 5. The rounded scores replaced the missing variables.

For the FACT-L and FACT-HN measures, instructions from the author of the measures was used for calculation (Cella, Tulsky, Gray, et al, 1993). To calculate these scales, the score of answers was summed, multiplied by how many were answered, and divided by the number of items in that subscale. FACT-G (herein referred to as QOLg) was calculated by summing the scores of subscales for physical, social/familial, emotional, and functional wellbeing. If any subscale was completely missing, the FACT-G was not calculated and was coded as missing. In total, 2 participants were deleted listwise due to having a missing FACT-G score.

Change scores for each outcome measure were created by subtracting the participants 3-month follow-up score from their baseline score (e.g. $\Delta\text{CSES} = \text{baseline CSES} - \text{3-month follow-up CSES}$), such that positive scores indicate that baseline values were higher and negative scores indicate that 3-month follow-up scores were higher.

Tests of Normality

IBM SPSS Statistics for Windows, Version 26.0 (2019) was used to clean data and to assess normality. Regression assumptions were tested including linearity of the relations,

checking for outliers, multivariate normality, non-multicollinearity, independence of observations, and homoscedasticity.

Linearity was assessed by checking scatter plots of the independent and dependent variables and was determined to be linear by visual inspection. Two cases were deleted listwise due to having outliers beyond 3 standard deviations (SD) of the mean in the Δ CSES scale. No other outliers beyond 3 SDs were detected. Multivariate normality was assessed for using visual inspection of histograms and Q-Q plots with fitted normal curve plots of the dependent variables (Δ PSS, Δ CSES and Δ QOLg). Skew and Kurtosis were within the expected range for each outcome variable (Δ PSS skewness .31, kurtosis .28; Δ CSES skewness -.03, kurtosis .74; Δ QOLg skewness .36, kurtosis .47). None of the observed variables were correlated at a rate that would indicate multicollinearity ($r < .79$). Δ PSS, Δ CSES and Δ QOL were significantly correlated. Δ CSES and Tx were significantly correlated (See Table 4). In addition to the correlations, P-P plots indicate no multicollinearity based on the visual inspection of scatter plots of the standardized residuals. Independence of observations across hospitals was assessed for by examining the intraclass correlations. All intraclass correlations for the variables in the model were less than .05 (range: .001 - .019), i.e., there was no evidence for nesting. In fact, only .1% to 1.9% of the variance was observed to be between hospitals while, 99.9% to 98.1% of the variance was between individuals. Scatter plot of the standardized residuals against the regression standardized residuals indicated there were no differences in values of outcome variables at differing values of the predictor variables, the models does equally well at predicting values of outcome variables at all levels of predictor variables. This reflects homoscedasticity.

Inferential Statistics

Asymmetrical bias corrected bootstrapping confidence intervals (ACIs) were used to assess fit statistics of the specific indirect effects (Hayes, 2009). Bootstrapping is the process by which a sample is resampled many times over, with replacement, to mimic a sampling distribution from which that sample could have come. Once this mimicked population is created, the *a* and *b* paths are estimated from this new sample and the product of their coefficient is recorded. This is then repeated *k* times, in this case 1,000, in order to create a distribution of possible path coefficients from the mimicked population. Once this process is completed, Hayes writes that the distribution of all the *k* paths “functions as an empirical approximation of the sampling distribution of the indirect effect when taking a sample of size *n* from the original population”. From this distribution of 1,000 paths, ACIs are determined by sorting the paths from smallest to largest and creating 95% ACI based on this range. Then, when assessing for the indirect effects of the sample corrected for the study, if the ACI does not include 0, the researcher assumes that the effect is significant because there is less than a 95% chance that the effect could be 0 (Hayes, 2009).

This process mitigates the issues that arise when using traditional Sobel Tests to assess significance of mediation. The Sobel Test assumes normality of the distribution, but typically the distribution of the product of two regression paths is not normal. The advantage of using ACIs is that they are based on the distribution created by the bootstrapping process, and as such do not assume any particular shape of distribution. This is the best practice for assessing significance of specific indirect effects.

The model was saturated *a priori* which precludes estimation of model fit indices. In this parallel mediation model, the *a* paths were Treatment predicting Δ PSS (a_1), and Treatment predicting Δ CSES (a_2) (See Figure 3). The *b* paths were Δ PSS predicting Δ QOL (b_1) and Δ CSES predicting Δ QOL (b_2). The *c* path was Treatment predicting Δ QOL. Given the variation of quality of life subscales, a model was comprised for individual subscale as well as one for the FACT-G (i.e. Δ QOLg). Data from all models is presented in Table 6 through Table 12. However, because the model for Δ QOLg had the most variance explained in Δ QOL scores, it is expanded upon below and discussed at length throughout the rest of the results and discussion (See Table 6).

Δ QOLg

Direct Effects. Some direct effects specified in the model were significant. Specifically, Treatment significantly and negatively predicted Δ CSES ($b = -14.10$, $SE = 5.97$, $p = .02$). This suggests that the intervention group had lower values of Δ CSES (baseline-3months). Δ QOLg was significantly and negatively predicted by Δ PSS ($b = -.714$, $SE = .12$, $p < .001$) and significantly and positively predicted by Δ CSES ($b = .12$, $SE = .02$, $p < .001$). Other direct paths were not significant. Treatment did not predict Δ PSS ($b = 1.12$, $SE = .98$, $p = .18$). Treatment did not directly predict change in Δ QOLg ($b = 1.31$, $SE = 1.51$, $p = .39$).

Indirect Effects. Examination of the bias-corrected bootstrapped confidence intervals revealed that the specific indirect effect of Treatment on Δ QOLg through Δ CSES was statistically significant ($estimate_{a*b} = -0.16$ [-0.28, -0.03]) because the confidence interval does not contain 0. There was not a significant indirect effect of Treatment on Δ QOL through Δ PSS ($estimate_{a*b} = .09$ [-0.04, .022]) because the confidence interval does contain 0. This indicates

that treatment has an effect on ΔQOL by way of changing CSES, such that being in the intervention group is related to higher CSES scores at 3-month follow-up, and higher CSES scores at 3-month follow-up is related to higher scores of QOL at 3-month follow-up. This is not the case for the path from Treatment to $\Delta QOLg$ via ΔPSS .

Standardized estimates of effect size of $\Delta CSES$ on Treatment was in the small range ($\beta = -0.16$). Standardized estimates of effect size of ΔPSS and $\Delta CSES$ on $\Delta QOLg$ were in the medium range ($\Delta PSS: \beta = -0.34$; $\Delta CSES: \beta = 0.41$).

The coefficient R^2 was used to estimate to what extent the model explained variance in outcomes scores. Standard cutoffs for R^2 are .01 (small effect), .09 (medium effect) and .25 (large effect). As a whole, this model explains 40% of the variance in general quality of life ($\Delta QOLg R^2 = 0.40$, $p < .001$). When reviewing the R^2 coefficient, treatment did explain a small amount of variance in the mediators ($\Delta CSES R^2 = 0.03$; $\Delta PSS R^2 = .01$).

The correct interpretation of the slopes for this model is crucial to understanding the way change scores are related. All change scores were calculated by subtracting the 3-month score from the baseline score. As such, for all scores, a positive change scores indicated that raw baseline values were higher than raw 3-month values. And, all negative change scores indicate that raw 3-month values were higher than raw baseline values. A score of 0 indicates no difference in raw scores from baseline to 3-month follow up. To expand, a positive ΔPSS score is in the desired direction because this indicates a perceived stress score at baseline that is higher than a perceived stress score at 3-month follow-up. A negative $\Delta CSES$ scores in in the desired direction, because it indicates coping self-efficacy increased over time. Lastly, a negative ΔQOL score is in the desired direction because in indicates that raw QOL at 3-month follow-up was higher than raw QOL at baseline.

When taking into consideration the slopes of regression of these change scores, it is equally important to understand the meaning of a positive slope compared to a negative slope. For the significant a_2 path from treatment condition to ΔCSES , the negative slope indicates the hypothesized difference. In the data analysis, the control condition was labeled 1, and the intervention condition was labeled 2. The negative slope indicates that positive ΔCSES scores were associated with the Control arm (1) and negative ΔCSES scores were associated with the intervention arm (2). This result demonstrates that negative ΔCSES scores, which indicates raw CSES scores were higher at 3-month follow-up, are associated with the intervention group.

For the significant b_2 path from ΔCSES to ΔQOLg , the positive slope demonstrates the desired result. This is because a positive slope for this path indicates that negative ΔCSES scores were related to negative ΔQOLg scores. Negative ΔCSES and negative ΔQOL are desired because they indicate higher levels of each for the raw 3-month scores. The best way to explain this model is that treatment condition has an indirect effect on change in quality of life through change in coping self-efficacy. While the c' path is not significant, meaning there is no observed direct effect of treatment on ΔQOLg , there is still an observed significant indirect effect (Hayes 2009). The traditional Baron and Kenny model suggests that if the total effect is not significant, then there can be no indirect effect of X to Y, because conceptually a path that does not exist cannot be mediated. However, this is a false interpretation of the data. In reality, the size of the total effect has no impact on the size of the a path, the b path, nor the product of ab . Given this, significant specific indirect effects and indirect effects models do explain the way in which X is able to change Y, and that is through an indirect effect of M.

The above results answer the primary research question about the use of TMSC framework for this data. In this study, ΔCSES did mediate the relation of Treatment to ΔQOLg ,

which supports one hypothesis. However, Δ PSS did not mediate the relation of Treatment to Δ QOLg, the hypothesis that it would was not supported. The final hypothesis regarded the difference in intervention group and outcome variables. Being in the intervention arm was associated with coping self-efficacy change scores that indicate higher CSE at 3-month follow-up, which supported the hypothesis. There was no direct effect of treatment on Δ QOLg, but there was an indirect effect that indicates better QOLg outcomes at 3-month follow-up for those in the intervention group via change in coping self-efficacy. Given these results, there is inconsistent mediation, however given that the effect size of the direct effect was very small and had an insignificant p-value, this was not of major concern.

Exploratory Results

Given the significant results of the indirect effects path model reported above, exploratory research questions were investigated. All exploratory questions were analyzed using Independent Sample T-Test or analysis of variance (ANOVA). Outcomes of these exploratory analyses were reported with a combination of results of the statistical tests, descriptive statistics, and visualizations (See Table 13, and Figure 9-Figure 18).

First, mean differences in the outcome variables (Δ PSS, Δ CSES, Δ QOLg) by Step were assessed. These means are displayed on the bar graphs in Figure 5. The only significant ANOVA test was for the outcome variable Δ CSES, and post-hoc tests revealed that difference was between Step 2 and Step 3 on Δ CSES ($F(3,200)=2.94$, $p=.03$, $\eta^2=.04$, absolute mean difference= 23.78).

Further analysis was done to assess for if treatment step (Step 1, 2, 3, or 4) impacted the effects of the mediators (Figure 6- Figure 8). Given the small number of participants in Step 4

(N=3), that group was collapsed into Step 3. Results from the analysis indicate significant b paths from the mediators (Δ CSES and Δ PSS) to Δ QOLg. For participants in Step 1, there was a significant path from Δ PSS to Δ QOLg ($b=-.71$, $SE=0.19$, $p<.001$, $\beta=-.419$). This indicated that change in PSS impacted change in QOL in the desired direction (increased quality of life at 3-month follow-up). For participants in Step 2, there was a significant path from Δ PSS and Δ CSES to Δ QOLg (Δ PSS: $b=-1.27$, $SE=0.31$, $p<.001$, $\beta=-0.46$; Δ CSES: $b=0.14$, $SE=0.08$, $p<.001$, $\beta=0.380$). This indicated that both change in PSS and change in CSES impacted change in QOL in the desired direction (increased quality of life at 3-month follow-up). For participants in Step 3 (combined with Step 4), there was a significant path from Δ CSES to Δ QOLg ($b=0.13$, $SE=0.03$, $p<.001$, $\beta=0.53$). This indicated that change in CSES impacted change in QOL in the desired direction (increased quality of life at 3-month follow-up).

Second, mean differences in the outcome variables by demographic variables were assessed. The related mean score difference test analyses that indicated significant differences, descriptive statistics and visualizations are reported (Figures 9-Figure 18). Demographic variables included race, ethnicity, sex, age, stage of cancer at diagnosis, cancer treatment type, and hospital site. Outcome mean scores and Cohen's d effect sizes of variables that did not have significant differences are reported in Table 13, outcome mean scores that did have significant differences are reported below. Mean scores were similar for: ethnicity, sex, age, stage of cancer, surgical treatment planned, chemotherapy planned, and biological treatment planned.

A few outcome variables did differ by demographic variables, including differences between racial groups, cancer radiation treatment, and hospital site. Mean scores of Δ QOLg differed significantly between participants were White compared to those who were not White, such that non-White participants had higher mean Δ QOLg scores ($t(202)=2.67$, $p=.008$, Cohen's

$d=.48$, absolute mean difference=6.94). The next significant difference was found in Δ CSES scores for patients who had no plans to receive radiation therapy, compared to those who did, had higher mean scores for Δ CSES ($t=-2.365$, $df=168$, $p=.0219$, Cohen's $d=-0.45$, absolute mean score difference=20.67). Lastly, there were significant differences in the Δ QOLg based on hospital site ($F(4,199)=3.553$, $p=.008$, $\eta^2=.067$, largest absolute mean score difference=9.785) (See Figure 14).

Chapter IV: Discussion

The purpose of this study was to explore if the data collected from LC, HNC, and TC patients involved in a randomized stepped-care CBT treatment study supported the TMSC framework. Important aspects of the TMSC that were analyzed in this study were treatment condition, change in perceived stress, change in coping self-efficacy, and change in QOL. The changes presented in the longitudinal model are from baseline to 3-month follow-up on self-report measures of each outcome. Given that the majority of participants were in Step 1 or Step 2, and few patients received Step 3 and Step 4 interventions, the discussion of treatment effects in the following sections should be interpreted with the understanding that the treatment effects were within the context of many participants self-report from zero distress to mild distress, and the subsequent interventions they received. These implications may be different had more participants indicated moderate and high levels of distress. There are three key findings from this study. Each of these key findings has clinical and research significance.

Three Key Findings

The first key finding is that treatment had a direct and significant impact on change in coping self-efficacy. This indicates that the patients who participated in the CBT stepped-care treatment had higher CSES scores at 3 months than the participants in the control group.

Clinical Implications: CBT interventions tailored to needs of cancer patients work for this patient population, and moreover, the Stepped-care model seemed to appropriately address people's belief in their ability to cope. This finding corroborates and expands on recent findings from Hendriksen, Rivera, Williams, Lee, Sporn, Cases, & Palesh (2019), that experiences of

anxiety and coping methods used by this population translates onto a CBT framework. In addition, this finding fits well with other research which demonstrated that patients find stepped-care approaches tend to meet patient's needs when attempting to cope with and manage the emotional distress associated with a cancer diagnosis (Hauffman, Alfnsson, Igelström & Johansson, 2020). Important to note is that this study adds to the field highly specified findings on a CBT stepped-care intervention for medically underserved LC, HNC, and TC patients, which was previously missing from the literature.

Research Implications: It is important to note that the effect size of this change was relatively small. A small effect size for this relation means that treatment condition had a relatively small impact on change in coping self-efficacy. Possible explanations for this are that the majority of participants were in Step 1 and 2 of the stepped-care model which indicated that they were already high in coping self-efficacy. Regardless, this small effect size was still significant, which could be due to low variability. This finding will allow for continued research with these measures to have a standardized effect score from which to compare. Within meta-analyses, this finding can be used to compare effectiveness of different treatments' impact on change in coping-self efficacy. Seminal research on self-efficacy theory posits that one's belief in their ability to carry out a task, in this case coping adaptively, is an important first step toward taking action (Bandura, 1997). Given this, the construct of coping self-efficacy will continue to be an important aspect of clinical trials aimed at increasing coping, and this effect size can be used to guide development and study of various coping interventions.

The second key take away is that there was a significant indirect effect from treatment to change in quality of life, via changes in participant's coping self-efficacy. This outcome supports

a sequential pathway from treatment condition to changes in coping self-efficacy to changes in quality of life.

Clinical Implications: Although this is not a new finding, it adds to the wealth of literature that mental health clinicians and behavioral health interventionists can utilize which target increasing coping skills and self-efficacy in using those skills. This finding adds an intervention to the literature which can have an impact quality of life for cancer patients who experience highly challenging medical and financial burdens.

Research Implications: This finding adds to literature on change in coping self-efficacy as a mechanism of change in therapeutic outcomes. Kazdin & Nock (2003) presented findings on what makes a construct a mechanism of therapeutic change. These authors define a mechanism as “those processes or events that lead to and cause therapeutic change”. The authors list the following as important to establish in order to indicate a mechanism of change: strong association, specificity, gradient, experiment, temporal relation, consistency, and plausibility and coherence. There was a strong specific indirect effect within this model from treatment to change in quality of life by way of changing coping self-efficacy. Specificity refers to the assurance that the difference in the outcome can actually be attributed to mechanism of change, not an outside construct that was not measured or included in the study. Given the difference in the control arm versus intervention arms, the finding that the intervention group had a change in coping self-efficacy where the control group did not points toward specificity. The gradient refers to a dose-response model, such that those who receive more of the causal mechanism (i.e. more change in coping self-efficacy), should have a greater difference in the outcome variable. In this study there was variability in the change in coping-self efficacy, which was related to changes in quality of life. Given that this was a randomized controlled trial, the experiment

requirement was met. The requirement of temporal relation was not met in this study. Given that baseline scores of all outcome variables were collected at the same time, and 3-month follow-up scores were collected the same time for all variables, the mediator was not measured prior to the outcome of quality of life. However, the treatment that is proposed to change coping self-efficacy was temporally between baseline and 3-month follow up. Not having a clear temporal relation does have a strong impact on being able to determine causal mechanisms and is a place for further investigation to solidify coping self-efficacy as a mechanism of change in quality of life. Consistency refers to the consistent demonstration that this mechanism is significant in multiple studies, samples and conditions. There is a wealth of literature that has used the CSES across various populations, and use of the CSES as it relates to changes in QOL in medically underserved LC, HNC, and TC patients is another check in the mechanisms of change box. Continued use of the CSES and its relation to change in quality of life should be researched, and this study gives an indication that it will continue to perform as a mechanism of change. Lastly, this explanation is plausible and coherent, it makes sense that interventions aimed at teaching coping increased coping self-efficacy and as such had an impact on folks' quality of life.

Lastly, this model explained 40 percent of the variance in change in quality of life.

Clinical Implications: Given the distress and challenges a cancer diagnosis can present, it is valuable information that, given these variables alone, 40% of the variance in quality of life was explained. Many of the patients in this study were experiencing lower levels of depression and anxiety symptoms at baseline. This model shows that by organizing an intervention based on levels of anxiety and depression, and then teaching CBT skills, this approach does lead to changes in quality of life. Given that the treatment was presented at the level needed for the patient, this is also a good indicator that distributing resources at a lower resource intense level

for some and a higher resource intense level is effective. This finding indicates that “meeting patients where they are at” in terms of behavioral health care is mutually beneficial to patient quality of life and hospital resources to conserve and distribute where needed (Krebber 2012; Bower & Gilbody, 2005).

Research Implications: This study further promotes the use of change scores with these variables and promotes the use of the FACT-L and FACT-HN measures with medically underserved cancer patients to measure effects of treatment on Δ QOL (Cella, Tulsky, Gray, et al., 1993)

Other Important Findings

The change in perceived stress variable is an interesting piece of this model that warrants attention. There was no significant path from treatment to change in perceived stress. Some explanations for this may be that perceived stress changed over time for these patients due to changing environmental events appraised as stressful (i.e. beginning cancer treatments, changes in social roles or work ability due to cancer). Although perceived stress did not change with treatment, nor was there an indirect effect on QOL from treatment through change in perceived stress, the TMSC and the CBT intervention presented are more concerned with teaching and changing coping self-efficacy first, rather than focusing on primary appraisal of a stress.

As reported, no direct effect from treatment to QOLg was observed. The explanation for this finding is that any impact treatment had on QOL is conceptualized as moving through change in coping self-efficacy. In addition, it may be understood through the conceptual lens that cancer treatments are very harsh and do have a great impact on QOL.

Exploratory Research Questions Findings

Exploratory research findings indicated that almost all means in outcome variables vary similarly regardless of levels of anxiety and depression (Step) at baseline. This indicator may suggest that the interventions appropriately address the needs of each Step group similarly. Further analysis indicated that mediators of change in perceived stress and change in coping self-efficacy had varying impacts on the QOL outcome by Step 1. Patients in Step 1, lowest level of anxious and depressive symptoms, had a significant path from change in perceived stress to change in QOL. It could be that the treatment was appropriate for these folks to help reduce perceived stress, and there by increase quality of life. In Step 2, both change in CSES and change in PSS had clinically relevant impacts on change in QOL. This could be interpreted to mean that for folks dealing with mild levels of anxiety and depressive symptoms, a change in both PSS and CSES was possible, and did impact their QOL. For the last group, Step 3 and 4, only the path from change in CSES to change in QOL was shown to be significant. This outcome indicates that for the patients with the highest level of anxiety and depressive symptoms, increasing their coping self-efficacy had a large effect on increasing their quality of life at 3-month follow-up.

The finding that nearly all demographic variables had non-significant mean differences indicates that across the participants and varying demographic variables patients generally had similar experiences across individual and community identities. However, a critical difference was with racial identity and hospital site.

Clinical Implications: Awareness and intentionality when treating white patients compared to patients of color is that patients of color may have factors impacting QOL, or different reactions to this intervention. Clinicians should be privy to the unique health disparities and social injustices faced by Black, Asian, American Indian, or other race patients in order to

address client concerns appropriately and mitigate medical racism. The differences in hospital site QOL may also be reflective of the patient population across hospital settings, given that some hospitals were in urban epicenters and others were rural, there may be environmental influences on this finding.

Research Implications: There may be other measures, or additional measures, that better capture QOL for non-White patients compared to White patients. This measure may perform in a way that preferences White experiences and definitions of QOL, which could be explored with further research. It could be that aspects of this intervention did not suit patients of color, and/or there may be other QOL factors to explore and address when developing interventions and measuring results.

Roads Not Traveled

There are multiple ways this data could be organized or tested, especially given the transactional characteristics of the TMSC framework. It could be that a moderated mediation model, in which treatment moderates the effects of change in perceived stress and coping self-efficacy on change in quality of life provides a different picture. While models that vary from this parallel indirect-effects model may be clinically indicated to explore in the future, they were outside the scope of this study.

Limitations

There were enough participants in this study to explore the fit of the data to the TMSC. However, some limitations in the sample collected include low variability in race and ethnicity present. There are limitations in this study of being able to explore how the model varies by different demographic variables given the limitation of diversity in the sample. This study did

not include information about if the patient's primary caregiver was participating in the study, which could be an additional important factor in social QOL. Additionally, the CSES measures only one's ability to use adaptive coping and there may be important aspects of engagement with maladaptive coping that were not considered in this study, which could affect QOL. This aspect of maladaptive coping missing could have had an impact on the model that went unaccounted for given that it was outside the scope of this study.

Future Directions

Moving forward, there are many exciting ways to continue researching and improving outcome for medically underserved LC, HNC, and TC patients. First, different models or configurations of the TMSC could be tested in order to determine coping self-efficacy as a mechanism of change, or to assess for the myriad transactional ways treatment, perceived stress, coping self-efficacy, and quality of life are related. Another way to continue assessing for causal mechanisms would be to collect data at more time points. Lastly, given the bright outlook this study provided, continued utilization, researching and testing of stepped-care behavioral health interventions for cancer patients is recommended. This provision of care will help to ensure patients are getting tailored services as hospitals and behavioral health providers simulations use resources efficiently.

Tables

Table 1
Study Demographic information, n=204

	<i>n</i>	<i>%</i>
Sex		
Male	117	57.4
Female	87	42.6
Age in years		
81+	16	7.8
71-80	52	25.5
61-70	80	39.2
51-60	34	16.7
41-50	13	6.4
31-40	5	2.5
<30	4	2.0
Ethnicity		
Not Hispanic	172	84.3
Hispanic	32	15.7
Race		
White	173	85.6
Black	12	5.3
Asian	2	.5
American Indian/Native Alaskan	4	.5
Hawaiian/Pacific Islander	0	0
Other race	8	3.7
Stage of Cancer at Diagnosis		
Pending	4	2.0
0	2	1.0
1	65	31.9
2	70	34.3
3	0	0.0
4	63	30.9
Primary Cancer Diagnosis		
Lung Cancer	123	60.3
Head and Neck Cancer	65	31.9
Thyroid Cancer	16	7.8
Hospital Site		
Denver Health, Denver	35	17.2
St. Joe's, Denver	31	15.2
St. Mary's Hospital, Grand Junction	103	50.5
National Jewish, Denver	22	10.8
UCCC, Denver	13	6.4

Table 2

Control Participants Descriptive Statistics

		N	Mean	SD	Minimum	Maximum
PSS Baseline	Step 1	41	8.88	5.591	0	21
	Step 2	44	13.25	4.770	4	20
	Step 3	22	19.05	4.786	12	29
	Step 4	1	30.00		30	30
	Total	108	12.93	6.486	0	30
PSS 3-month	Step 1	41	7.86	6.185	0	21
	Step 2	44	14.91	6.144	1	27
	Step 3	22	19.86	6.882	6	35
	Step 4	1	28.00		28	28
	Total	108	13.36	7.878	0	35
CSES Baseline	Step 1	41	232.80	38.860	65	260
	Step 2	44	207.95	48.156	40	260
	Step 3	22	163.64	46.296	90	255
	Step 4	1	130.00		130	130
	Total	108	207.64	51.130	40	260
CSES 3-month	Step 1	41	220.37	42.240	125	260
	Step 2	44	193.64	47.267	100	260
	Step 3	22	166.59	46.481	70	245
	Step 4	1	155.00		155	155
	Total	108	197.92	49.076	70	260
QOLg Baseline	Step 1	41	88.50	12.192	59	107
	Step 2	44	73.11	13.287	47	98
	Step 3	22	60.06	10.117	38	74
	Step 4	1	64.00		64	64
	Total	108	76.21	16.230	38	107
QOLg 3-month	Step 1	41	86.83	14.191	62	108
	Step 2	44	69.63	14.830	36	101
	Step 3	22	57.71	13.384	34	83
	Step 4	1	65.00		65	65
	Total	108	73.69	18.027	34	108

Table 3
Intervention Group Descriptive Statistics

		N	Mean	SD	Minimum	Maximum
PSS Baseline	Step 1	47	7.53	5.237	0	19
	Step 2	27	14.22	4.326	2	20
	Step 3	20	19.40	4.122	9	27
	Step 4	2	27.50	0.707	27	28
	Total	96	12.30	7.041	0	28
PSS 3-month	Step 1	47	7.98	5.979	0	21
	Step 2	27	13.25	6.711	1	25
	Step 3	20	16.20	6.826	2	26
	Step 4	2	24.00	2.828	22	26
	Total	96	11.51	7.347	0	26
CSES Baseline	Step 1	47	232.13	33.956	110	260
	Step 2	27	214.81	38.167	130	260
	Step 3	20	159.00	59.507	45	250
	Step 4	2	87.50	10.607	80	95
	Total	96	209.01	52.704	45	260
CSES 3-month	Step 1	47	235.21	35.201	120	260
	Step 2	27	207.22	43.397	120	260
	Step 3	20	181.50	50.029	115	250
	Step 4	2	107.50	3.536	105	110
	Total	96	213.49	48.090	105	260
QOLg Baseline	Step 1	47	90.08	11.762	60	108
	Step 2	27	74.18	13.479	49	99
	Step 3	20	61.02	13.013	38	79
	Step 4	2	42.83	6.835	38	48
	Total	96	78.57	17.717	38	108
QOLg 3-month	Step 1	47	86.95	16.211	45	108
	Step 2	27	75.50	19.939	36	107
	Step 3	20	61.42	19.012	30	97
	Step 4	2	36.67	5.185	33	40
	Total	96	77.37	21.060	30	108

Table 4

Variable Means, Standard Deviations, and Correlations

Variable	1	2	3	4	5	6	7	8	9	10
1. Tx										
2. ΔPSS	.09									
3. ΔCSES	-.16*	-.43*								
4. ΔQOLg	-.05	-.52*	.55*							
5. ΔQOLp	.82	-.34*	.25*	.66*						
6. ΔQOLs	-.06	-.26*	.34*	.58*	.07					
7. ΔQOLe	-.11	-.45*	.53*	.66*	.28*	.26*				
8. ΔQOLf	-.06	-.37*	.40*	.80*	.39*	.27*	.37*			
9. ΔQOLl	-.05	.01	-.03	-.00	-.10	.11	.00	-.01		
10. ΔQOLhn	.09	.01	.04	.02	.08	-.10	.02	.04	-.92*	
Mean	1.47	0.14	3.09	1.90	0.90	0.72	0.14	0.15	-411.45	-625.90
(SD)	(0.50)	(6.52)	(44.38)	(13.53)	(5.17)	(4.85)	(4.04)	(5.85)	(492.80)	(485.43)

Note: *p<.05

Table 5
Mean differences in QOL General at Baseline by Step

Step at baseline (I)	Step at baseline (J)	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
1	2	15.831*	1.967	0.000	11.95	19.71
	3	28.828*	2.313	0.000	24.27	33.39
	4	39.457*	7.241	0.000	25.18	53.73
2	1	-15.831*	1.967	0.000	-19.71	-11.95
	3	12.997*	2.401	0.000	8.26	17.73
	4	23.626*	7.269	0.001	9.29	37.96
3	1	-28.828*	2.313	0.000	-33.39	-24.27
	2	-12.997*	2.401	0.000	-17.73	-8.26
	4	10.629	7.370	0.151	-3.90	25.16
4	1	-39.457*	7.241	0.000	-53.73	-25.18
	2	-23.626*	7.269	0.001	-37.96	-9.29
	3	-10.629	7.370	0.151	-25.16	3.90

*. The mean difference is significant at the 0.05 level.

Table 6

Parallel Mediation Model for $\Delta QOLg$

Path	<i>b estimates</i>	<i>SE (b)</i>	<i>p-values</i>	<i>LLCI</i>	<i>ULCI</i>	β
a1 (ΔPSS on Tx)	1.23	0.92	0.18	-0.56	2.95	0.09
a2 ($\Delta CSES$ on Tx)	-14.10	5.93	0.02	-25.07	-2.07	-0.16
b1 ($\Delta QOLg$ on ΔPSS)	-0.71	0.12	0.00	-0.98	-0.49	-0.34
b2 ($\Delta QOLg$ on $\Delta CSES$)	0.12	0.02	0.00	0.08	0.16	0.41
c' ($\Delta QOLg$ on Tx)	1.31	1.51	0.39	-1.87	4.12	0.05
a1*b1($\Delta QOLg$ on Tx thru ΔPSS)	-0.88	0.70		-2.35	0.33	
a2*b2 ($\Delta QOLg$ on Tx thru $\Delta CSES$)	-1.75	0.85		-3.55	-0.26	
R-square						
ΔPSS	0.01	0.02	0.55			
$\Delta CSES$	0.03	0.02	0.23			
$\Delta QOLg$	0.40	0.06	0.00			

Note: (N=204) ΔPSS =Change Score on Perceived Stress Scale, $\Delta CSES$ = Change Score on Coping Self-Efficacy Scale, $\Delta QOLg$ =Change Score on FACT-General. LLCI and ULCI are bias-corrected bootstrapped confidence intervals. No variables were controlled for.

Table 7

Parallel Mediation Model for $\Delta QOLp$

Path	<i>b estimates</i>	<i>SE (b)</i>	<i>p-values</i>	<i>LLCI</i>	<i>ULCI</i>	β
a1 (ΔPSS on Tx)	1.23	0.92	0.18	-0.56	2.95	0.09
a2 ($\Delta CSES$ on Tx)	-14.10	5.93	0.02	-25.07	-2.07	-0.16
b1 ($\Delta QOLg$ on ΔPSS)	-0.23	0.06	0.00	-0.34	-0.12	-0.29
b2 ($\Delta QOLg$ on $\Delta CSES$)	0.02	0.01	0.04	0.00	0.03	0.15
c' ($\Delta QOLg$ on Tx)	1.38	0.67	0.04	0.08	2.73	0.13
a1*b1($\Delta QOLg$ on Tx thru ΔPSS)	-0.29	0.23		-0.75	0.12	
a2*b2 ($\Delta QOLg$ on Tx thru $\Delta CSES$)	-0.24	0.17		-0.72	-0.02	
R-square						
ΔPSS	0.01	0.02	0.55			
$\Delta CSES$	0.03	0.02	0.23			
$\Delta QOLp$	0.15	0.05	0.00			

Note: (N=203) ΔPSS =Change Score on Perceived Stress Scale, $\Delta CSES$ = Change Score on Coping Self-Efficacy Scale, $\Delta QOLp$ =Change Score on FACT Physical Subscale. LLCI and ULCI are bias-corrected bootstrapped confidence intervals.

Table 8

Parallel Mediation Model for $\Delta QOLs$

Path	<i>b estimates</i>	<i>SE (b)</i>	<i>p-values</i>	<i>LLCI</i>	<i>ULCI</i>	β
a1 (ΔPSS on Tx)	1.23	0.92	0.18	-0.56	2.95	0.09
a2 ($\Delta CSES$ on Tx)	-14.10	5.93	0.02	-25.07	-2.07	-0.16
b1 ($\Delta QOLg$ on ΔPSS)	-0.10	0.06	0.07	-0.21	0.00	-0.13
b2 ($\Delta QOLg$ on $\Delta CSES$)	0.03	0.01	0.00	0.01	0.05	0.28
c' ($\Delta QOLg$ on Tx)	-0.04	0.67	0.95	-1.39	1.24	0.00
a1*b1($\Delta QOLg$ on Tx thru ΔPSS)	-0.12	0.13		-0.49	0.03	
a2*b2 ($\Delta QOLg$ on Tx thru $\Delta CSES$)	-0.43	0.25		-1.05	-0.06	
R-square						
ΔPSS	0.01	0.02	0.55			
$\Delta CSES$	0.03	0.02	0.23			
$\Delta QOLs$	0.13	0.05	0.02			

Note: (N=203) ΔPSS =Change Score on Perceived Stress Scale, $\Delta CSES$ = Change Score on Coping Self-Efficacy Scale, $\Delta QOLs$ =Change Score on FACT Social Subscale. LLCI and ULCI are bias-corrected bootstrapped confidence intervals.

Table 9

Parallel Mediation Model for $\Delta QOLe$

Path	<i>b estimates</i>	<i>SE (b)</i>	<i>p-value</i>	<i>LLCI</i>	<i>ULCI</i>	β
a1 (ΔPSS on Tx)	1.23	0.92	0.18	-0.56	2.95	0.09
a2 ($\Delta CSES$ on Tx)	-14.10	5.93	0.02	-25.07	-2.07	-0.16
b1 ($\Delta QOLg$ on ΔPSS)	-0.17	0.04	0.00	-0.25	-0.09	-0.27
b2 ($\Delta QOLg$ on $\Delta CSES$)	0.04	0.01	0.00	0.03	0.05	0.41
c' ($\Delta QOLg$ on Tx)	-0.15	0.43	0.73	-0.95	0.70	0.02
a1*b1($\Delta QOLg$ on Tx thru ΔPSS)	-0.21	0.17		-0.59	0.07	
a2*b2 ($\Delta QOLg$ on Tx thru $\Delta CSES$)	-0.52	0.24		-1.09	-0.12	
R-square						
ΔPSS	0.01	0.02	0.55			
$\Delta CSES$	0.03	0.02	0.23			
$\Delta QOLe$	0.34	0.06	0.00			

Note: (N=203) ΔPSS =Change Score on Perceived Stress Scale, $\Delta CSES$ = Change Score on Coping Self-Efficacy Scale, $\Delta QOLe$ =Change Score on FACT Emotional Subscale. LLCI and ULCI are bias-corrected bootstrapped confidence intervals.

Table 10

Parallel Mediation Model for $\Delta QOLf$

Path	<i>b estimates</i>	<i>SE (b)</i>	<i>p-value</i>	<i>LLCI</i>	<i>ULCI</i>	β
a1 (ΔPSS on Tx)	1.23	0.92	0.18	-0.56	2.95	0.09
a2 ($\Delta CSES$ on Tx)	-14.10	5.93	0.02	-25.07	-2.07	-0.16
b1 ($\Delta QOLg$ on ΔPSS)	-0.22	0.06	0.00	-0.34	-0.12	-0.24
b2 ($\Delta QOLg$ on $\Delta CSES$)	0.04	0.01	0.00	0.02	0.06	0.30
c' ($\Delta QOLg$ on Tx)	0.12	0.73	0.87	-1.28	1.49	0.01
a1*b1($\Delta QOLg$ on Tx thru ΔPSS)	-0.27	0.24		-0.83	0.07	
a2*b2 ($\Delta QOLg$ on Tx thru $\Delta CSES$)	-0.55	0.31		-1.30	-0.10	
R-square						
ΔPSS	0.01	0.02	0.55			
$\Delta CSES$	0.03	0.02	0.23			
$\Delta QOLf$	0.21	0.06	0.00			

Note: (N=203) ΔPSS =Change Score on Perceived Stress Scale, $\Delta CSES$ = Change Score on Coping Self-Efficacy Scale, $\Delta QOLf$ =Change Score on FACT Functional Subscale. LLCI and ULCI are bias-corrected bootstrapped confidence intervals.

Table 11

Parallel Mediation Model for ΔQOL

Path	<i>b estimates</i>	<i>SE (b)</i>	<i>p-values</i>	<i>LLCI</i>	<i>ULCI</i>	β
a1 (ΔPSS on Tx)	1.23	0.92	0.18	-0.56	2.95	0.09
a2 ($\Delta CSES$ on Tx)	-14.10	5.93	0.02	-25.07	-2.07	-0.16
b1 ($\Delta QOLg$ on ΔPSS)	-0.13	0.08	0.11	-0.30	0.02	-0.18
b2 ($\Delta QOLg$ on $\Delta CSES$)	0.02	0.01	0.03	0.00	0.05	0.23
c' ($\Delta QOLg$ on Tx)	-0.10	0.80	0.90	-1.66	1.44	-0.01
a1*b1($\Delta QOLg$ on Tx thru ΔPSS)	-0.16	0.18		-0.69	0.04	
a2*b2 ($\Delta QOLg$ on Tx thru $\Delta CSES$)	-1.75	0.23		-0.95	-0.05	
R-square						
ΔPSS	0.01	0.02	0.55			
$\Delta CSES$	0.03	0.02	0.23			
$\Delta QOLg$	0.12	0.06	0.04			

Note: (N=204 for PSS and CSES, N=120 for QOL) ΔPSS =Change Score on Perceived Stress Scale, $\Delta CSES$ = Change Score on Coping Self-Efficacy Scale, ΔQOL =Change Score on FACT Lung Cancer Subscale. LLCI and ULCI are bias-corrected bootstrapped confidence intervals.

Table 12

Parallel Mediation Model for ΔQOL_{hn}

Path	<i>b</i> <i>estimates</i>	<i>SE</i> <i>(b)</i>	<i>p-values</i>	<i>LLCI</i>	<i>ULCI</i>	β
a1 (ΔPSS on Tx)	1.23	0.92	0.18	-0.56	2.95	0.09
a2 ($\Delta CSES$ on Tx)	-14.10	5.93	0.02	-25.07	-2.07	-0.16
b1 (ΔQOL_g on ΔPSS)	-0.39	0.16	0.01	-0.72	-0.08	-0.27
b2 (ΔQOL_g on $\Delta CSES$)	0.01	0.02	0.78	0.05	0.06	0.04
c' (ΔQOL_g on Tx)	-0.89	2.07	0.67	-5.21	2.88	-0.05
a1*b1(ΔQOL_g on Tx thru ΔPSS)	-0.48	0.48		-1.74	0.11	
a2*b2 (ΔQOL_g on Tx thru $\Delta CSES$)	-0.11	0.42		-1.11	0.62	
R-square						
ΔPSS	0.01	0.02	0.55			
$\Delta CSES$	0.03	0.02	0.23			
ΔQOL_g	0.09	0.08	0.25			

Note: (N=204 for PSS and CSES, N=84 for QOL_{hn}) PSS = Note: (N=203) ΔPSS =Change Score on Perceived Stress Scale, $\Delta CSES$ = Change Score on Coping Self-Efficacy Scale, ΔQOL_{hn} =Change Score on FACT Head and Neck Cancer Subscale. LLCI and ULCI are bias-corrected bootstrapped confidence intervals.

Table 13

Mean differences and effect sizes of exploratory variables for outcome variables

Outcome variable	Ethnicity (White/Non-White)		Sex (Male/Female)		Age (≤65, 66+)	
	absolute mean difference	Cohen's d effect size	absolute mean difference	Cohen's d effect size	absolute mean difference	Cohen's d effect size
ΔPSS	2.11	-0.32	0.35	-0.05	0.22	-0.03
ΔCSES	4.22	0.09	0.07	0.00	5.16	0.12
ΔQOLg	1.27	-0.09	3.55	0.26	0.33	0.02

Outcome variable	Surgery (Yes/No)		Chemotherapy (Yes/No)		Biological (Yes/No)	
	absolute mean difference	Cohen's d effect size	absolute mean difference	Cohen's d effect size	absolute mean difference	Cohen's d effect size
ΔPSS	1.03	-0.16	0.26	-0.04	2.33	-0.43
ΔCSES	9.78	0.22	2.91	-0.06	15.75	-0.37
ΔQOLg	1.81	0.13	1.03	0.07	-3.04	-0.26

Note: There were no significant differences between these groups. Absolute mean differences and Cohen's d effect sizes that were significantly different are reported and discussed within the body of text.

Figures

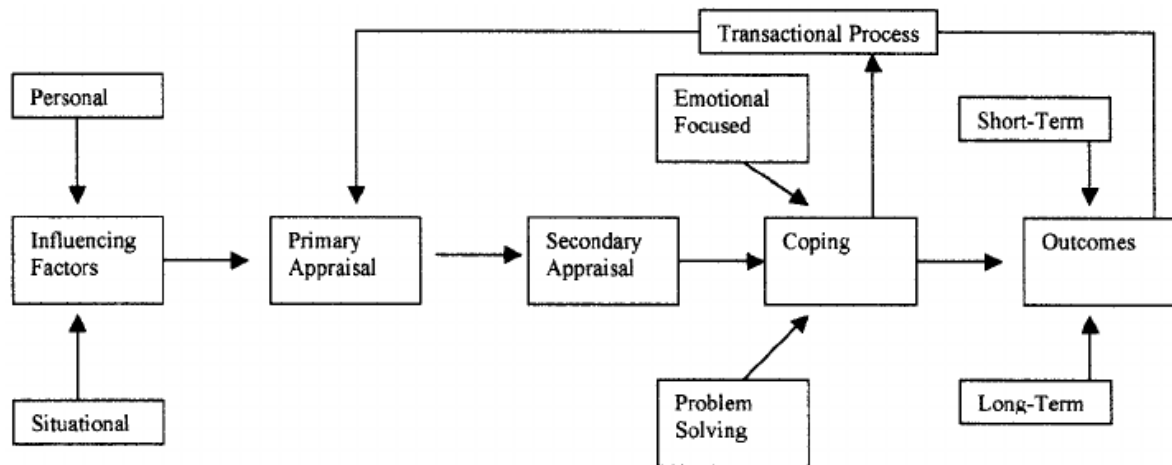


Figure 1. Model based on the Transactional Model of Stress and Coping.

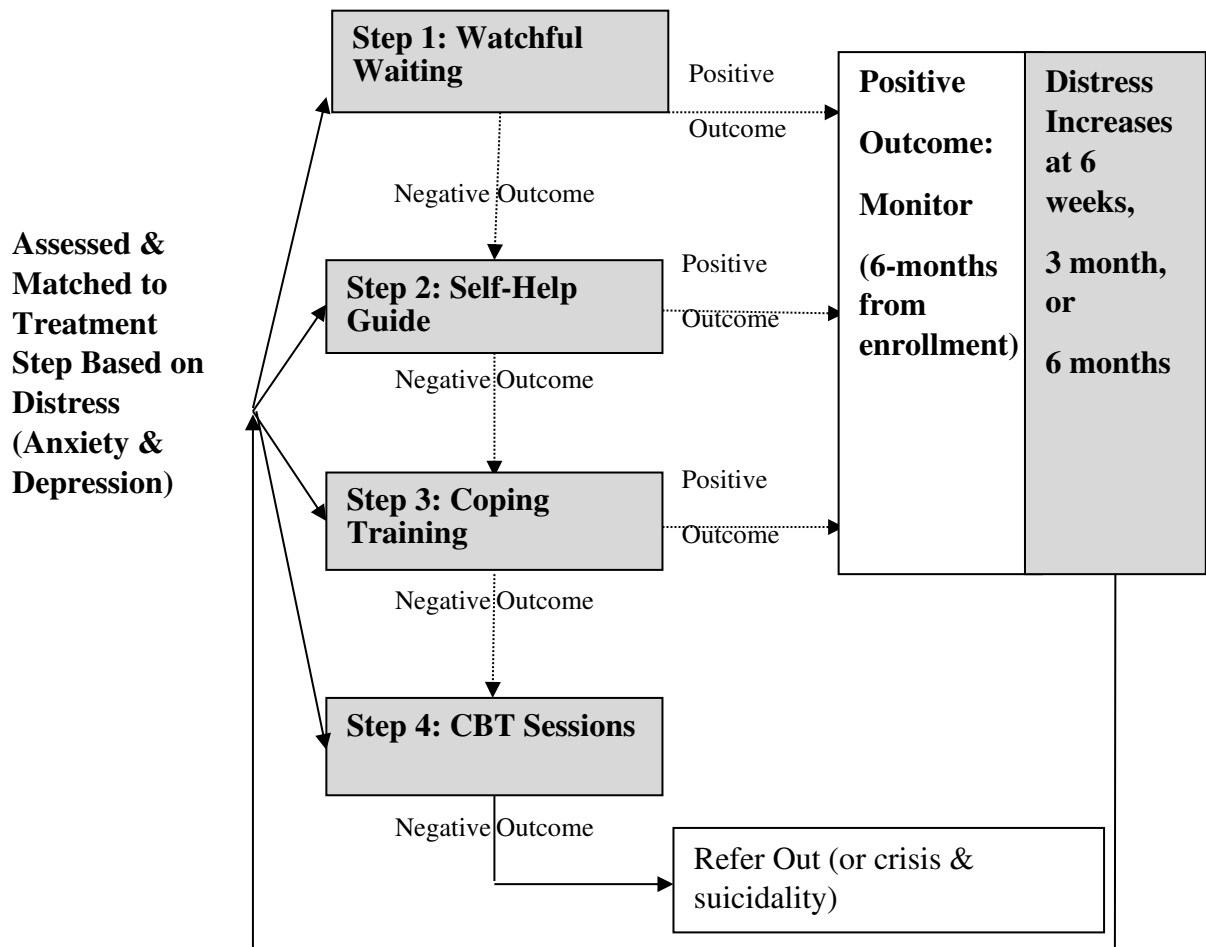


Figure 2. Stepped-Care Intervention Conceptual Framework to Assign Participants to a Step.

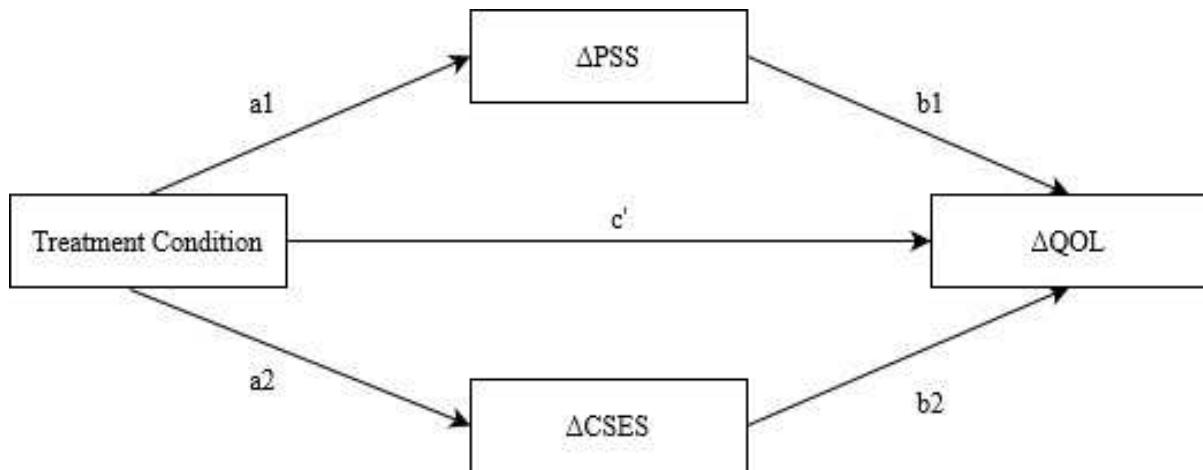


Figure 3. Parallel mediation model of indirect effects of Treatment Conditions on ΔQOL with $\Delta CSES$ and ΔPSS as mediators.

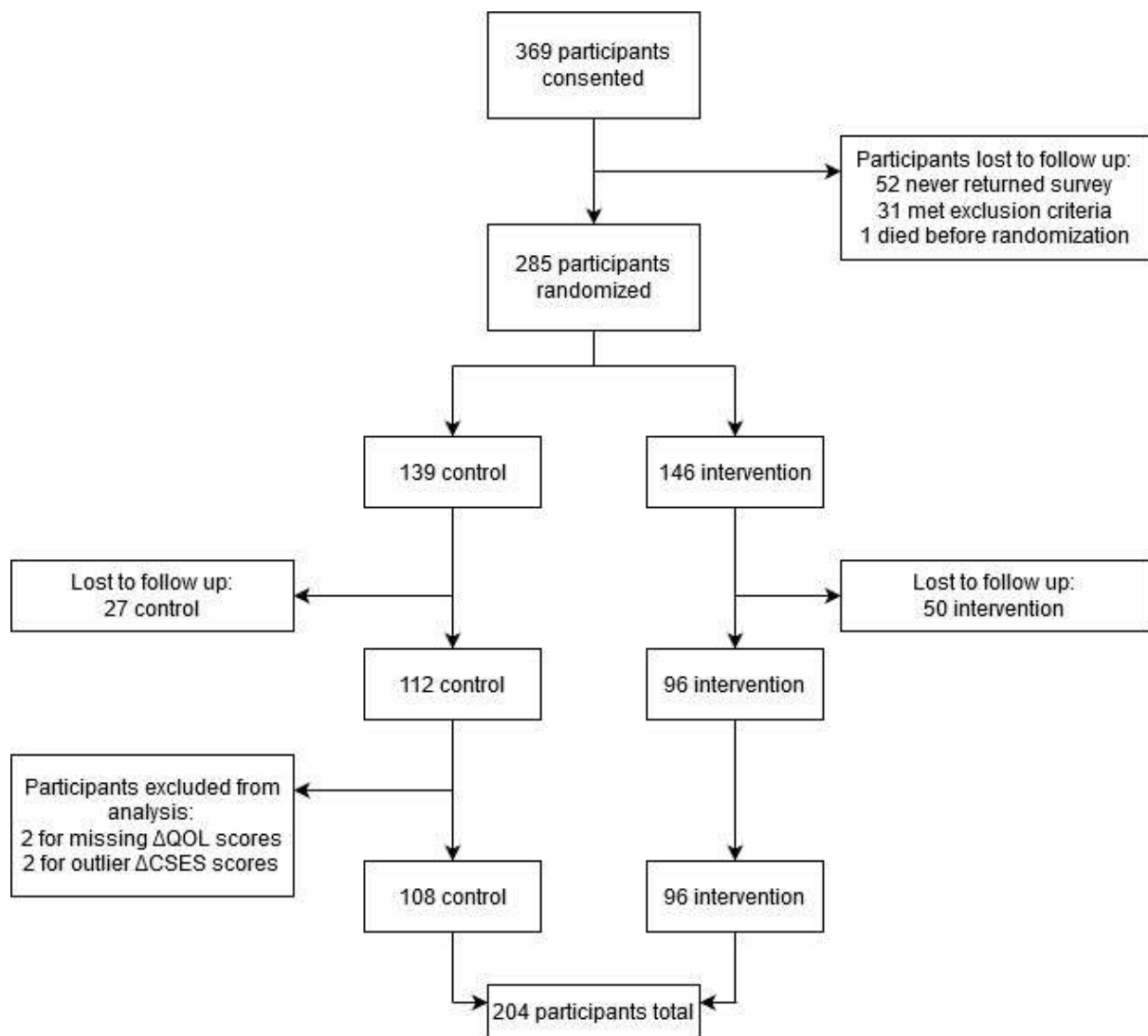


Figure 4. CONSORT diagram of participants in this study.

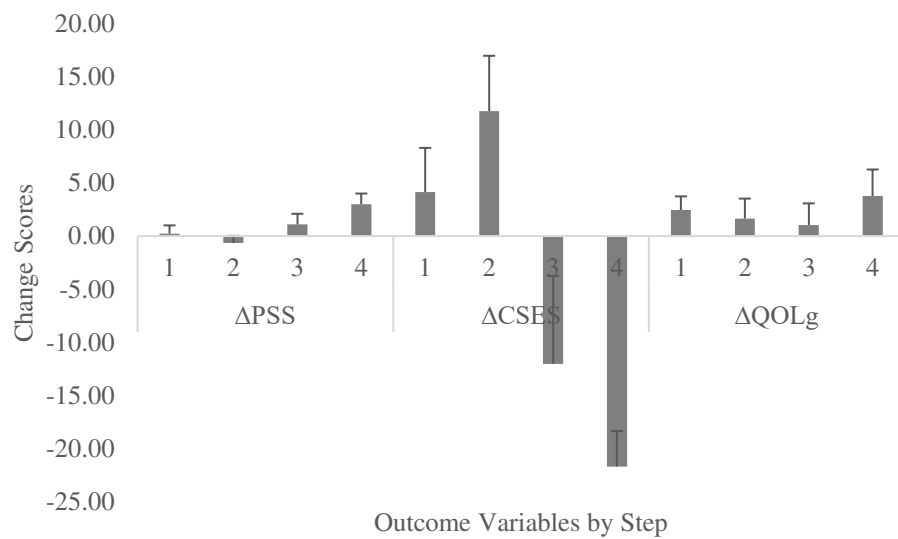


Figure 5. Mean changes score differences of different outcome variables by Step with standard error bars.

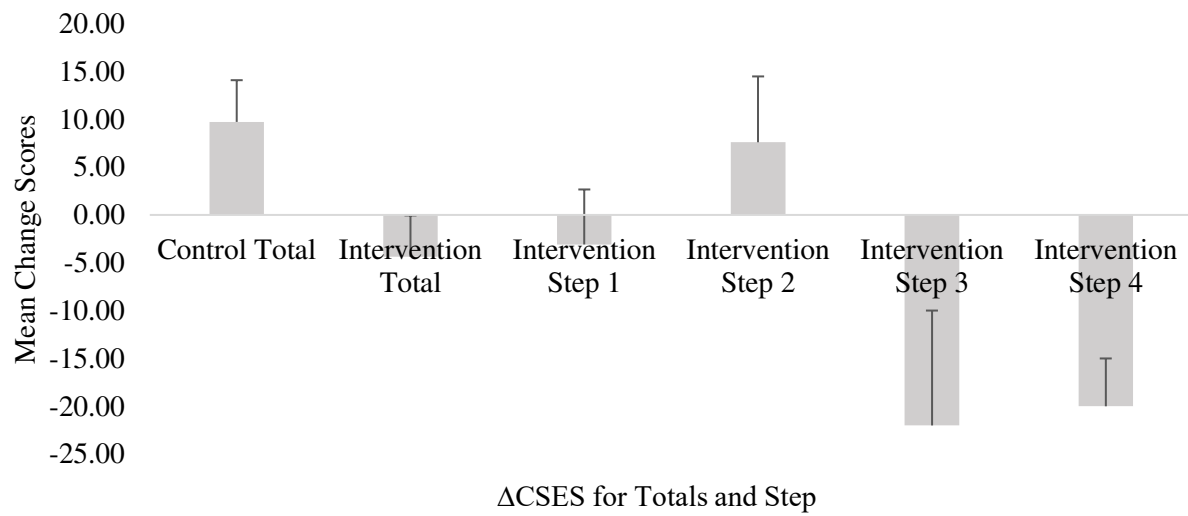


Figure 6. Mean change scores for Δ CSES for Totals and Step with standard error bars.

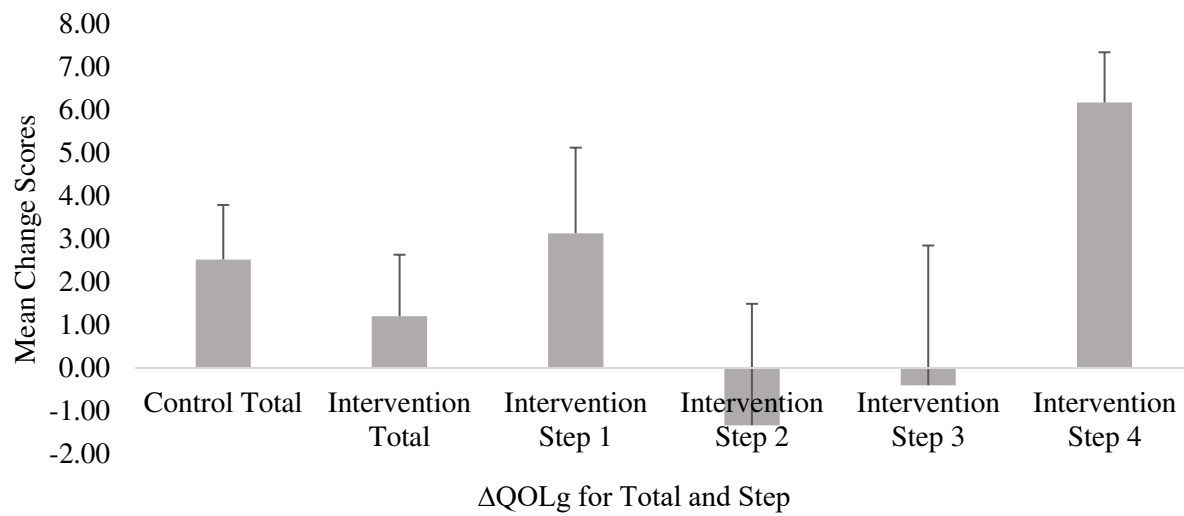


Figure 7. Mean changes scores for $\Delta QOLg$ for Total and Step with standard error bars.

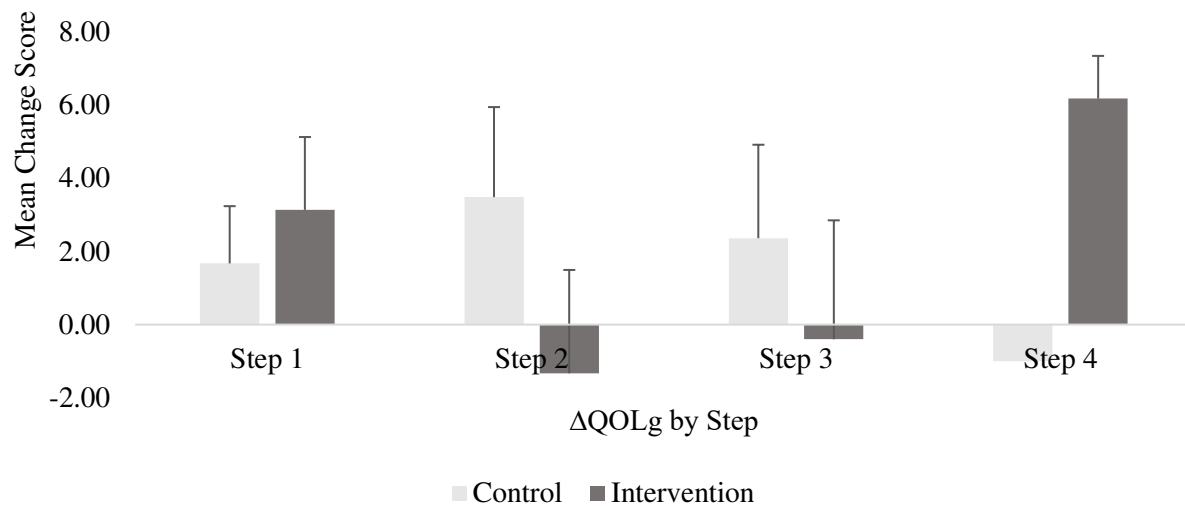


Figure 8. Mean changes Scores for $\Delta QOLg$ by Step with standard error bars.

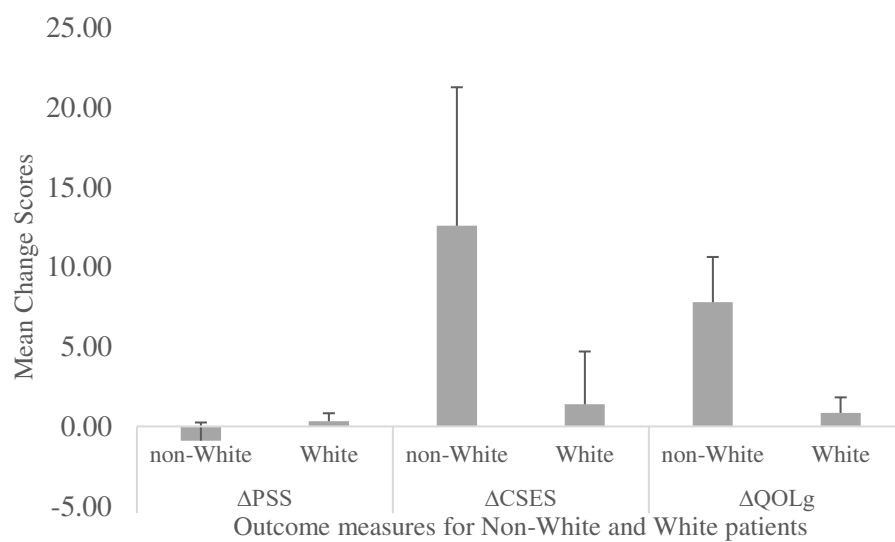


Figure 9. Change scores differences in all outcomes by race with standard error bars.

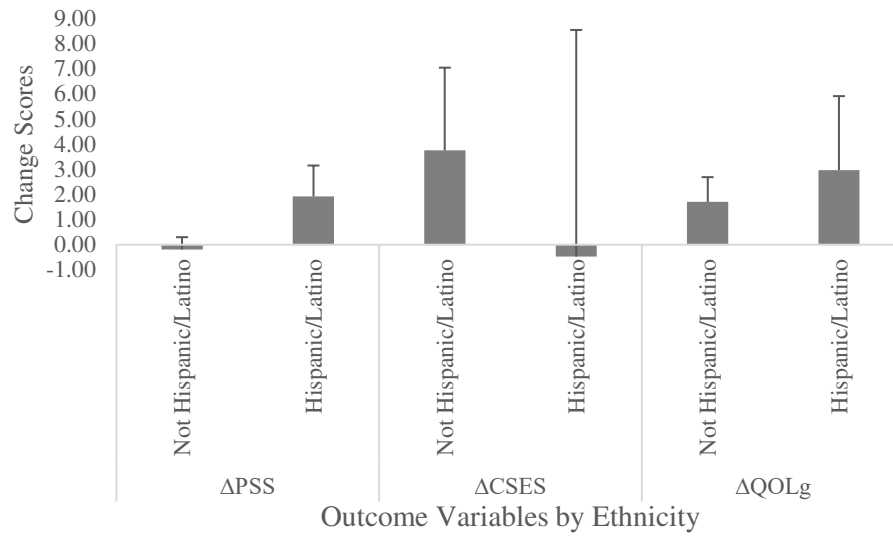


Figure 10. Mean change score differences in outcome variables by ethnicity with standard error bars.

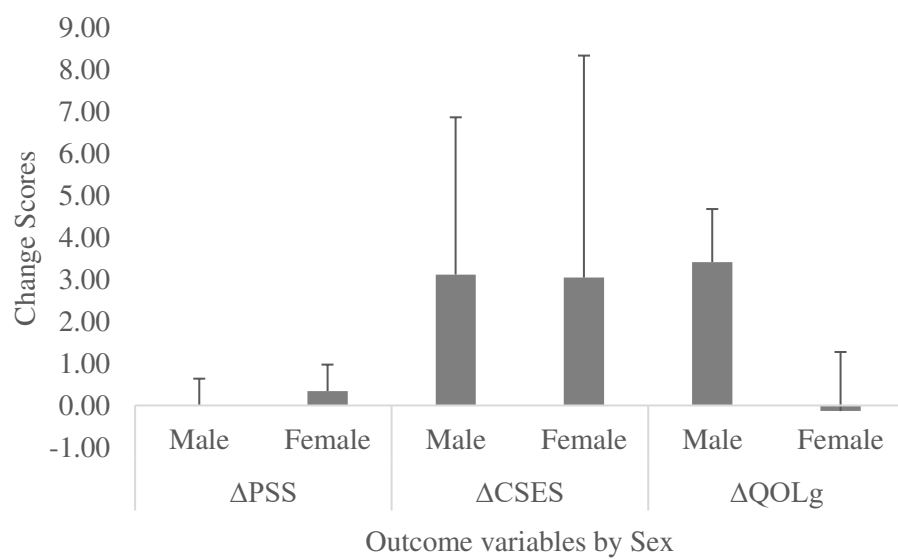


Figure 11. Mean change score differences in outcome variables by sex with standard error bars.

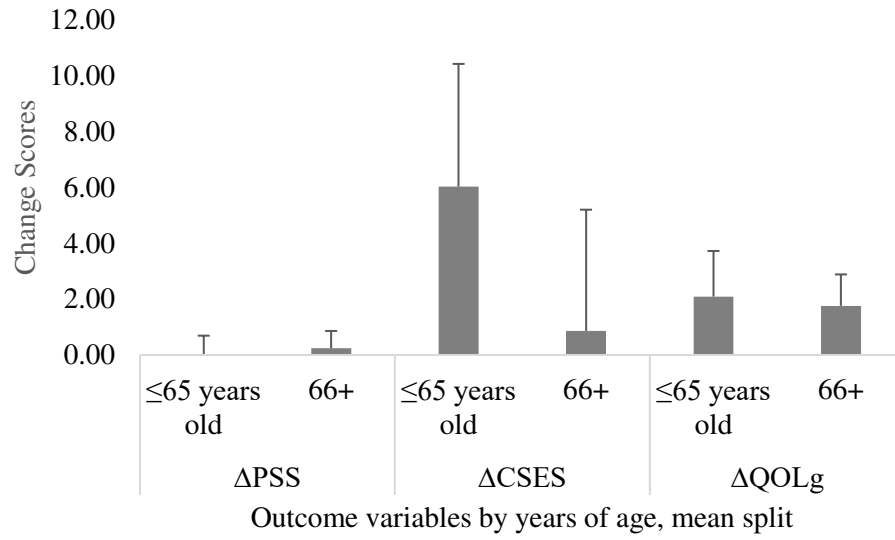


Figure 12. Mean change score differences in outcome variables by age with standard error bars.

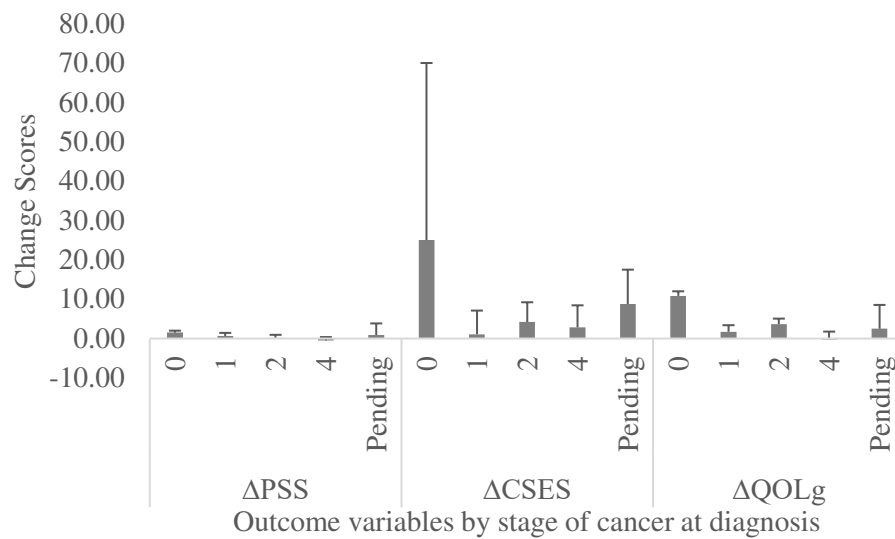


Figure 13. Mean change score differences in outcome variables by stage of cancer at diagnosis (0-4 and Pending) with standard error bars.

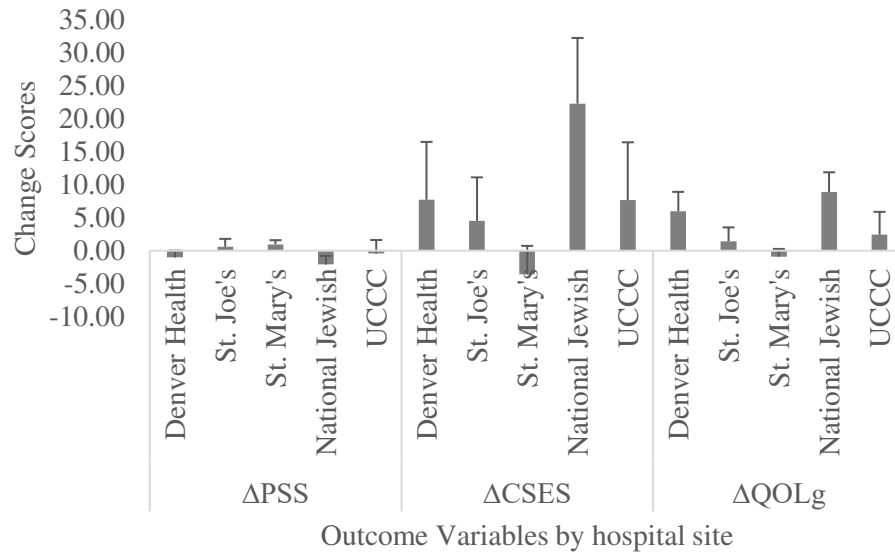


Figure 14. Mean change score differences in outcome variables by hospital site with standard error bars.

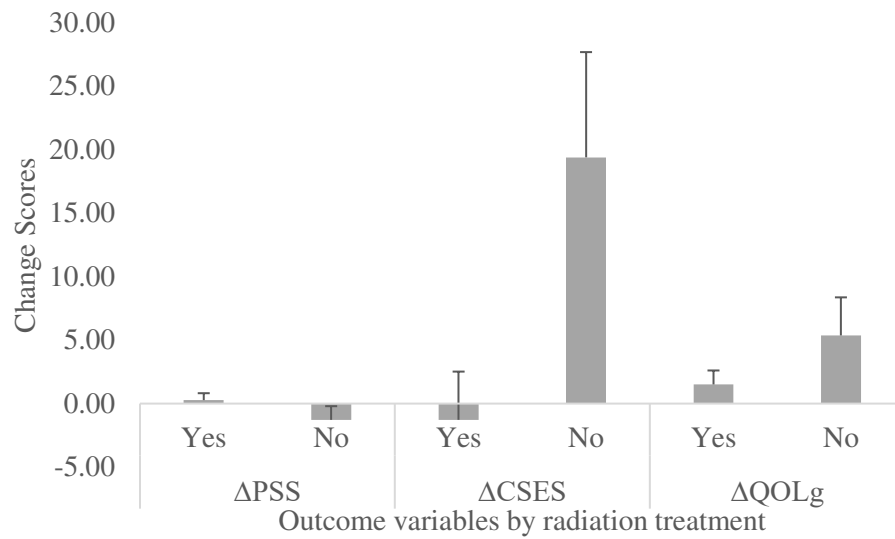


Figure 15. Mean change score differences in outcome variables by radiation treatment for cancer planned with standard error bars.

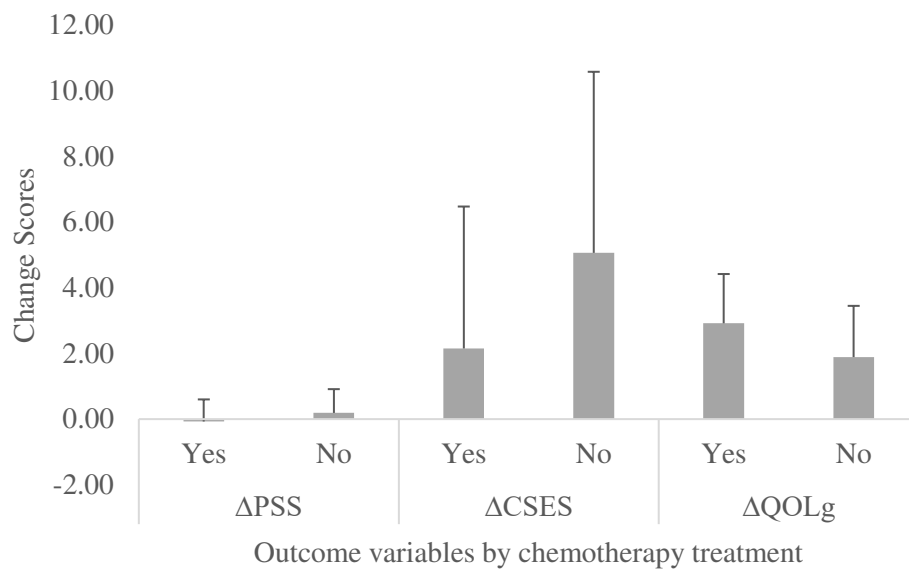


Figure 16. Mean change score differences in outcome variables by chemotherapy treatment for cancer planned with standard error bars.

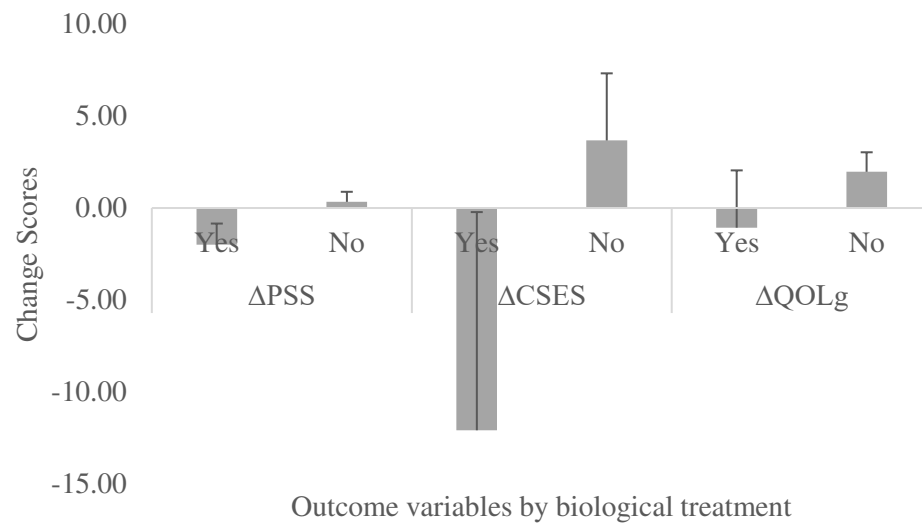


Figure 17. Mean change score differences in outcome variables by biological treatment for cancer planned with standard error bars.

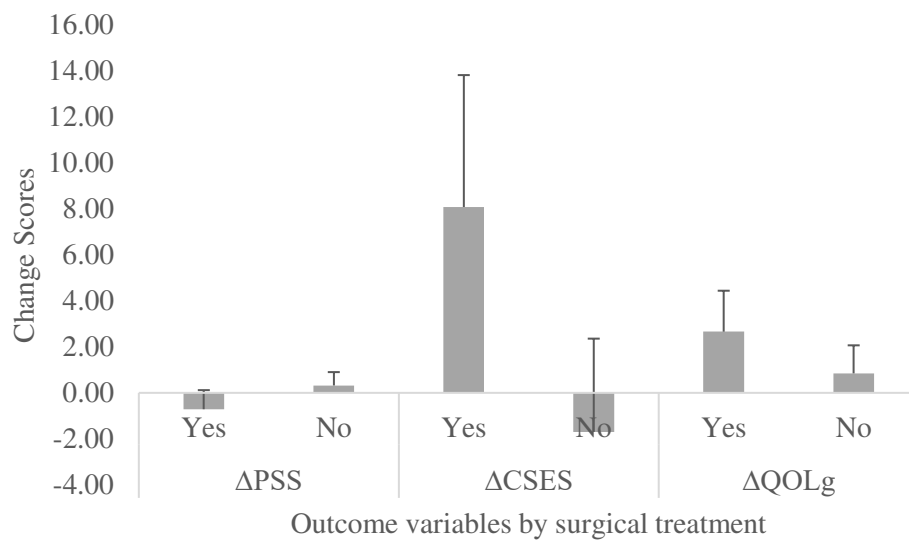


Figure 18. Mean change score differences in outcome variables by surgical treatment for cancer planned with standard error bars.

References

- Akin, S., Can, G., Aydinler, A., Ozdilli, K., & Durna, Z. (2010). Quality of life, symptom experience and distress of lung cancer patients undergoing chemotherapy. *European Journal of Oncology Nursing*, 14(5), 400–409. <https://doi-org.ezproxy2.library.colostate.edu/10.1016/j.ejon.2010.01.003>
- Alcoholism. (2018). *Funk & Wagnalls New World Encyclopedia*, 1; Retrieved from <http://search.ebscohost.com.ezproxy2.library.colostate.edu/login.aspx?direct=true&AuthType=cookie,ip,url,cpid&custid=s4640792&db=funk&AN=al058300&site=ehost-live>
- Allison, P. D. (1990). Change Scores as Dependent Variables in Regression Analysis. *Sociological Methodology*, 20, 92-114.
- American Cancer Society (ACS) (2015). Cancer Staging. Retrieved from: <https://www.cancer.org/treatment/understanding-your-diagnosis/staging.html>
- American Cancer Society (ACS) (2016). How chemotherapy drugs work. Retrieved from: <https://www.cancer.org/treatment/treatments-and-side-effects/treatment-types/chemotherapy/how-chemotherapy-drugs-work.html>
- Andrykowski, M. & Kangas, M. (2010). Posttraumatic stress disorder associated with cancer diagnosis and treatment. In J. C. Holland, W. S. Breitbart, P. B. Jacobsen, M. S. Lederberg, M. J. Loscalzo, & R. McCorkle (Eds.), *Psycho-oncology* (2nd ed.; pp. 348–357). New York, NY: Oxford University Press.
- Bandura A. Self-efficacy: The exercise of control. New York: W. H. Freeman; 1997.
- Baron, R. M., & Kenny, D. A. (1986). The moderator-mediator variable distinction in social psychological research: Conceptual, strategic, and statistical considerations. *Journal of Personality and Social Psychology*, 51, 1173-1182.
- Beck, A. T. (1979). *Cognitive therapy and the emotional disorders*. Penguin.
- Beck, A. T. (1993). Cognitive therapy: Past, present, and future. *Journal of Consulting and Clinical Psychology*, 61(2), 194–198. <https://doi-org.ezproxy2.library.colostate.edu/10.1037/0022-006X.61.2.194>
- Bower, P., & Gilbody, S. (2005). Stepped care in psychological therapies: Access, effectiveness and efficiency. Narrative literature review. *The British Journal of Psychiatry*, 186(1), 11-17. <http://dx.doi.org/10.1192/bjp.186.1.11>
- Cella DF, Tulsky DS, Gray G, et al. (1993) The Functional Assessment of Cancer Therapy Scale: development and validation of the general measure. *J Clin Oncol*; 11:570-79.
- Center for Disease Control and Prevention (CDC) (2018). Health Disparities. Retrieved from: <https://www.cdc.gov/healthyyouth/disparities/index.htm>

- Center for Disease Control and Prevention (CDC). (2018) HRQOL Concepts. Retrieved from <https://www.cdc.gov/hrqol/concept.htm>.
- Chesney, M. A., Neilands, T. B., Chambers, D. B., Taylor, J. M., & Folkman, S. (2006). A validity and reliability study of the coping self-efficacy scale. *British journal of health psychology*, 11(Pt 3), 421–437. <https://doi.org/10.1348/135910705X53155>
- Cumming, G., & Calin-Jageman, R. (2016). *Introduction to the new statistics: Estimation, open science, and beyond*. Routledge.
- DiGiovanni, J., Popovic, M., Chow, E., Cella, D., Beaumont, J. L., Nguyen, J., ... & Lam, H. (2015). Comparison of the EORTC QLQ-LC13 and the FACT-L for assessment of quality of life in patients with lung cancer. *Journal of Pain Management*, 8(2), 103.
- Fagundes, C., Jones, D., Vichaya, E., Lu, C., & Cleeland, C. S. (2014). Socioeconomic status is associated with depressive severity among patients with advanced non-small-cell lung cancer: treatment setting and minority status do not make a difference. *Journal Of Thoracic Oncology: Official Publication Of The International Association For The Study Of Lung Cancer*, 9(10), 1459–1463. <https://doi-org.ezproxy2.library.colostate.edu/10.1097/JTO.0000000000000284>
- Fernández-Rodríguez, C., Villoria-Fernández, E., Fernández-García, P., González-Fernández, S., & Pérez-Álvarez, M. (2019). Effects of behavioral activation on the quality of life and emotional state of lung cancer and breast cancer patients during chemotherapy treatment. *Behavior Modification*, 43(2), 151–180. <https://doi-org.ezproxy2.library.colostate.edu/10.1177/0145445517746915>
- Greer, J. A., Park, E. R., Prigerson, H. G., & Safren, S. A. (2010). Tailoring cognitive-behavioral therapy to treat anxiety comorbid with advanced cancer. *Journal of Cognitive Psychotherapy*, 24(4), 294–313. <https://doi-org.ezproxy2.library.colostate.edu/10.1891/0889-8391.24.4.294>
- Ha, D., Ries, A. L., Mazzone, P. J., Lippman, S. M., & Fuster, M. M. (2018). Exercise capacity and cancer-specific quality of life following curative intent treatment of stage I-IIIa lung cancer. *Supportive Care In Cancer: Official Journal Of The Multinational Association Of Supportive Care In Cancer*, 26(7), 2459–2469. <https://doi-org.ezproxy2.library.colostate.edu/10.1007/s00520-018-4078-4>
- Hauffman, A., Alfnsson, S., Igelström, H., & Johansson, B. (2020). Experiences of Internet-Based Stepped Care in Individuals With Cancer and Concurrent Symptoms of Anxiety and Depression: Qualitative Exploration Conducted Alongside the U-CARE AdultCan Randomized Controlled Trial. *Journal of Medical Internet Research*, 22(3), N.PAG. <https://doi-org.ezproxy2.library.colostate.edu/10.2196/16547>
- Hayes, A. F. (2009). Beyond Baron and Kenny: Statistical mediation analysis in the new millennium. *Communication monographs*, 76(4), 408–420.
- Hendriksen, E., Rivera, A., Williams, E., Lee, E., Sporn, N., Cases, M. G., & Palesh, O. (2019). Manifestations of anxiety and coping strategies in patients with metastatic lung cancer and their family caregivers: a qualitative study. *Psychology & Health*, 34(7), 886–899.

- Heroiu Cataloiu, A. D., Danciu, C. E., & Popescu, C. R. (2013). Multiple cancers of the head and neck. *Maedica*, 8(1), 80–85.
- Hinz, A., Friedrich, M., Kuhnt, S., Zenger, M., & Schulte, T. (2019). The influence of self-efficacy and resilient coping on cancer patients' quality of life. *European Journal of Cancer Care*, 28(1), 1–8. <https://doi-org.ezproxy2.library.colostate.edu/10.1111/ecc.12952>
- Hsieh, C. C., & Hsiao, F. H. (2017). The effects of supportive care interventions on depressive symptoms among patients with lung cancer: A metaanalysis of randomized controlled studies. *Palliative & supportive care*, 15(6), 710-723.
- IBM Corp. Released 2019. IBM SPSS Statistics for Windows, Version 26.0. Armonk, NY: IBM Corp.
- Karnofsky, D., & Burchenal, J. H. (1949). Evaluation of Chemotherapeutic Agents. *New York, NY, Columbia University*, 19.
- Krebber, A. M. H., Leemans, C. R., de Bree, R., van Straten, A., Smit, F., Smit, E. F., ... & Verdonck-de Leeuw, I. M. (2012). Stepped care targeting psychological distress in head and neck and lung cancer patients: a randomized clinical trial. *BMC cancer*, 12(1), 173.
- MacKinnon, D. P., Warsi, G., & Dwyer, J. H. (1995). A simulation study of mediated effect measures. *Multivariate behavioral research*, 30(1), 41-62.
- Mattsson, S., Alfnsson, S., Carlsson, M., Nygren, P., Olsson, E., & Johansson, B. (2013). U-CARE: Internet-based stepped care with interactive support and cognitive behavioral therapy for reduction of anxiety and depressive symptoms in cancer--a clinical trial protocol. *BMC Cancer*, 13, 414. <https://doi-org.ezproxy2.library.colostate.edu/10.1186/1471-2407-13-414>
- Miranda, J., Duan, N., Sherbourne, C., Schoenbaum, M., Lagomasino, I., Jackson-Triche, M., & Wells, K. B. (2003). Improving care for minorities: can quality improvement interventions improve care and outcomes for depressed minorities? Results of a randomized, controlled trial. *Health Services Research*, 38, 613–630. <https://doi.org/10.1111/1475-6773.00136>.
- Muthén, L.K. and Muthén, B.O. (1998-2012). Mplus User's Guide. Seventh Edition.
- National Cancer's Institute (2017). Head and neck cancers. Retrieved from: <https://www.cancer.gov/types/head-and-neck/head-neck-fact-sheet#what-are-cancers-of-the-head-and-neck>
- Pearl, J. (2016). Lord's Paradox Revisited – (Oh Lord! Kumbaya!). Technical Report.
- Preacher, K. J., Rucker, D. D., & Hayes, A. F. (2007). Addressing moderated mediation hypotheses: Theory, methods, and prescriptions. *Multivariate behavioral research*, 42(1), 185-227.
- REDCap. (n.d.). Retrieved April 20, 2020, from <https://www.project-redcap.org/>

- Tallman, B. A. (2013). Anticipated posttraumatic growth from cancer: The roles of adaptive and maladaptive coping strategies. *Counselling Psychology Quarterly*, 26(1), 72–88.
<https://doi-org.ezproxy2.library.colostate.edu/10.1080/09515070.2012.728762>
- World Health Organization (2014). WHOQOL: Measuring Quality of Life. Retrieved from <https://www.who.int/healthinfo/survey/whoqol-qualityoflife/en/>.
- Zeng C, Wen W, Morgans AK, Pao W, Shu XO, Zheng WD. Disparities by Race, Age, and Sex in the Improvement of Survival for Major Cancers: Results From the National Cancer Institute Surveillance, Epidemiology, and End Results (SEER) Program in the United States, 1990 to 2010. *JAMA Oncol.* 2015;1: 88-96.

Appendix A: Measures

Perceived Stress Scale

The questions in this scale ask you about your feelings and thoughts during the last month. In each case, you will be asked to indicate by circling *how often* you felt or thought a certain way.

0 = Never 1 = Almost Never 2 = Sometimes 3 = Fairly Often 4 = Very Often

1. In the last month, how often have you been upset because of something that happened unexpectedly?	0	1	2	3	4
2. In the last month, how often have you felt that you were unable to control the important things in your life?	0	1	2	3	4
3. In the last month, how often have you felt nervous and “stressed”?	0	1	2	3	4
4. In the last month, how often have you felt confident about your ability to handle your personal problems?	0	1	2	3	4
5. In the last month, how often have you felt that things were going your way?	0	1	2	3	4
6. In the last month, how often have you found that you could not cope with all the things that you had to do?	0	1	2	3	4
7. In the last month, how often have you been able to control irritations in your life?	0	1	2	3	4
8. In the last month, how often have you felt that you were on top of things?	0	1	2	3	4
9. In the last month, how often have you been angered because of things that were outside of your control?	0	1	2	3	4
10. In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?	0	1	2	3	4

Coping Self-Efficacy Scale (CSES)
(Chesney et al., 2006)
Modified Scale

When things aren't going well for you, or when you're having problems, how confident or certain are you that you can do the following:

Activity		Scale		
1.	Keep from getting down in the dumps	Cannot do	Maybe can do	Certain can do
2.	Talk positively to yourself	Cannot do	Maybe can do	Certain can do
3.	Sort out what can be changed, and what cannot be changed	Cannot do	Maybe can do	Certain can do
4.	Get emotional support from friends and family	Cannot do	Maybe can do	Certain can do
5.	Find solutions to your most difficult problems	Cannot do	Maybe can do	Certain can do
6.	Break an upsetting problem down into smaller parts	Cannot do	Maybe can do	Certain can do
7.	Leave options open when things get stressful	Cannot do	Maybe can do	Certain can do
8.	Make a plan of action and follow it when confronted with a problem	Cannot do	Maybe can do	Certain can do
9.	Develop new hobbies or recreations	Cannot do	Maybe can do	Certain can do
10.	Take your mind off unpleasant thoughts	Cannot do	Maybe can do	Certain can do
11.	Look for something good in a negative situation	Cannot do	Maybe can do	Certain can do
12.	Keep from feeling sad	Cannot do	Maybe can do	Certain can do
13.	See things from the other person's point of view during a heated argument	Cannot do	Maybe can do	Certain can do
14.	Try other solutions to your problems if your first solutions don't work	Cannot do	Maybe can do	Certain can do
15.	Stop yourself from being upset by unpleasant thoughts	Cannot do	Maybe can do	Certain can do
16.	Make new friends	Cannot do	Maybe can do	Certain can do
17.	Get friends to help you with the things you need	Cannot do	Maybe can do	Certain can do

18.	Do something positive for yourself when you are feeling discouraged	Cannot do	Maybe can do	Certain can do
19.	Make unpleasant thoughts go away	Cannot do	Maybe can do	Certain can do
20.	Think about one part of the problem at a time	Cannot do	Maybe can do	Certain can do
21.	Visualize a pleasant activity or place	Cannot do	Maybe can do	Certain can do
22.	Keep yourself from feeling lonely	Cannot do	Maybe can do	Certain can do
23.	Pray or meditate	Cannot do	Maybe can do	Certain can do
24.	Get emotional support from community organizations or resources	Cannot do	Maybe can do	Certain can do
25.	Stand your ground and fight for what you want	Cannot do	Maybe can do	Certain can do
26.	Resist the impulse to act hastily when under pressure	Cannot do	Maybe can do	Certain can do

FACT-L (Version 4)

Below is a list of statements that other people with your illness have said are important. Please circle or mark one number per line to indicate your response as it applies to the past 7 days.

	<u>PHYSICAL WELL-BEING</u>	Not at all	A little bit	Some- what	Quite a bit	Very much
GP1	I have a lack of energy	0	1	2	3	4
GP2	I have nausea	0	1	2	3	4
GP3	Because of my physical condition, I have trouble meeting the needs of my family	0	1	2	3	4
GP4	I have pain	0	1	2	3	4
GP5	I am bothered by side effects of treatment	0	1	2	3	4
GP6	I feel ill	0	1	2	3	4
GP7	I am forced to spend time in bed	0	1	2	3	4
	<u>SOCIAL/FAMILY WELL-BEING</u>	Not at all	A little bit	Some- what	Quite a bit	Very much
GS1	I feel close to my friends	0	1	2	3	4
GS2	I get emotional support from my family	0	1	2	3	4
GS3	I get support from my friends	0	1	2	3	4

GS4	My family has accepted my illness	0	1	2	3	4
GS5	I am satisfied with family communication about my illness	0	1	2	3	4
GS6	I feel close to my partner (or the person who is my main support)	0	1	2	3	4
Q1	<i>Regardless of your current level of sexual activity, please answer the following question. If you prefer not to answer it,</i>					
GS7	I am satisfied with my sex life	0	1	2	3	4
	<u>EMOTIONAL WELL-BEING</u>	Not at all	A little bit	Some-what	Quite a bit	Very much
GE1	I feel sad	0	1	2	3	4
GE2	I am satisfied with how I am coping with my illness	0	1	2	3	4
GE3	I am losing hope in the fight against my illness	0	1	2	3	4
GE4	I feel nervous	0	1	2	3	4
GE5	I worry about dying	0	1	2	3	4
GE6	I worry that my condition will get worse	0	1	2	3	4

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

	<u>ADDITIONAL CONCERNS</u>	Not at all	A little bit	Some-what	Quite a bit	Very much
B1	I have been short of breath	0	1	2	3	4
C2	I am losing weight	0	1	2	3	4
L1	My thinking is clear	0	1	2	3	4
L2	I have been coughing	0	1	2	3	4

B5	I am bothered by hair loss	0	1	2	3	4
C6	I have a good appetite	0	1	2	3	4
L3	I feel tightness in my chest	0	1	2	3	4
L4	Breathing is easy for me	0	1	2	3	4
Q3	Have you ever smoked? No ____ Yes ____ If yes:					
L5	I regret my smoking	0	1	2	3	4

FACT-H&N (Version 4)

Below is a list of statements that other people with your illness have said are important. Please circle or mark one number per line to indicate your response as it applies to the past 7 days.

	<u>PHYSICAL WELL-BEING</u>	Not at all	A little bit	Some-what	Quite a bit	Very much
GP1	I have a lack of energy	0	1	2	3	4
GP2	I have nausea	0	1	2	3	4
GP3	Because of my physical condition, I have trouble meeting the needs of my family	0	1	2	3	4
GP4	I have pain	0	1	2	3	4
GP5	I am bothered by side effects of treatment	0	1	2	3	4
GP6	I feel ill	0	1	2	3	4
GP7	I am forced to spend time in bed	0	1	2	3	4
	<u>SOCIAL/FAMILY WELL-BEING</u>	Not at all	A little bit	Some-what	Quite a bit	Very much
GS1	I feel close to my friends	0	1	2	3	4
GS2	I get emotional support from my family	0	1	2	3	4
GS3	I get support from my friends	0	1	2	3	4

GS4	My family has accepted my illness	0	1	2	3	4
GS5	I am satisfied with family communication about my illness	0	1	2	3	4
GS6	I feel close to my partner (or the person who is my main support)	0	1	2	3	4
Q1	<i>Regardless of your current level of sexual activity, please answer the following question.</i>					
GS7	I am satisfied with my sex life	0	1	2	3	4

EMOTIONAL WELL-BEING

Not at all A little bit Some-what Quite a bit Very much

GE1 GE2 GE3 GE4 GE5 GE6	I feel sad	0	1	2	3	4
	I am satisfied with how I am coping with my illness	0	1	2	3	4
	I am losing hope in the fight against my illness	0	1	2	3	4
	I feel nervous	0	1	2	3	4
	I worry about dying	0	1	2	3	4
	I worry that my condition will get worse	0	1	2	3	4

	<u>FUNCTIONAL WELL-BEING</u>	Not at all	A little bit	Some-what	Quite a bit	Very much
GF1	I am able to work (include work at home)	0	1	2	3	4
GF2	My work (include work at home) is fulfilling	0	1	2	3	4
GF3	I am able to enjoy life	0	1	2	3	4
GF4	I have accepted my illness	0	1	2	3	4
GF5	I am sleeping well	0	1	2	3	4
GF6	I am enjoying the things I usually do for fun	0	1	2	3	4
GF7	I am content with the quality of my life right now	0	1	2	3	4
	<u>ADDITIONAL CONCERNS</u>	Not at all	A little bit	Some-what	Quite a bit	Very much
H&N 1	I am able to eat the foods that I like	0	1	2	3	4
H&N 2	My mouth is dry	0	1	2	3	4
H&N 3	I have trouble breathing	0	1	2	3	4

H&N 4	My voice has its usual quality and strength	0	1	2	3	4
H&N 5	I am able to eat as much food as I want	0	1	2	3	4
H&N 6	I am unhappy with how my face and neck look	0	1	2	3	4
H&N 7	I can swallow naturally and easily	0	1	2	3	4
H&N 8	I smoke cigarettes or other tobacco products	0	1	2	3	4
H&N 9	I drink alcohol (e.g. beer, wine, etc.)	0	1	2	3	4
H&N 10	I am able to communicate with others	0	1	2	3	4
H&N	I can eat solid foods	0	1	2	3	4
H&N 12	I have pain in my mouth, throat or neck	0	1	2	3	4